Protocol ID: PERL001
Study Name: PERL
Site: _____

Study Subject ID:_____
Study Subject DOB:_____

	Source Documents	Visit 1	Visit 1a	Eligibility Run-In	Visit 2	Visit 3	Visit 4	Visit 4a	Eligibility Randomization	Visit 5 - V6	Visit 5 Call - V7	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17	Unscheduled Visit	Final Status	Unmasking	Initial Complications and Screening eGFR	AE, Con Med, Compliance, BP Med, and Deviation Logs	SAE	Pilot Unscheduled Visit	ESRD
PERL_000_Source Document Uploads - V1.0	X																													
PERL_000-022_Source Document Uploads - V1.0	X																													
PERL_000_Additional Source Document Uploads - V1.0	X																													
PERL_002_Demographics - V3.0		X	X																											
PERL_003_Medical History - V2.0		X			X		X																							
PERL_006_Blood Pressure and Measurements - P1.1																													X	
PERL_006_Blood Pressure and Measurements - V1.0		X	X		X	X	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X							
PERL_008_Local Laboratory Results - V5.0		X	X			X	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X						X	
PERL_009_ECG Report - V1.0		X			X		X	X					X				X					X		X						
PERL_010 Central Lab Specimen Collection - V4.0		X	X			X	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X						
PERL_016_ACR/AER Screening - V4.0		X	X																											
PERL_001S_Eligibility_RunIn - V3.0				X																										
PERL_001RS_Eligibility Re Screen - V1.0				X																										
PERL_015_Exemption Request - V2.0				X					X																					
PERL_007_Physical Examination - V1.0					X		X	X					X				X					X		X						
PERL_010A_Central Lab Specimen Collection - V5.0						X	X	X																						
PERL_019_iGFR Procedures Form - V3.0							X	X					X				X					X	X	X						
PERL_019_iGFR Procedures Form - P2.1																													X	
PERL_014_Family History - V1.0							X	X		X																				
PERL_011_Skin Assessment - V3.0							X					X	X	X	X	X	X	X	X	X	X	X	X						X	
PERL_011_Skin Assessment - V2.0										X																				
PERL_001R_Eligibility_Randomization - V3.0									X																					
PERL_021_Telephone_Visit - V1.0											X																			
PERL_022_Study Drug Compliance and Exposure - V3.0												X	X	X	X	X	X	X	X	X	X								X	
PERL_023F_Follow Up_Complication Questionnaire - 1.0																						X								
PERL_025 Unscheduled Visit Reason - V1.0																							X							
PERL_035_Final Status Form - 2.0																								X						
PERL_041_Unmasking Report - V1.0																									X					
PERL_023I_Initial_Complication Questionnaire - 1.0																										X				
PERL_026_Historical eGFR Slope - 2.0																										X				
PERL_012_RAS and BP Medication Log - V3.0																											X			
PERL_013_Concomitant Medication Log - V2.0																											X			
PERL_013_pg2 Concomitant Medications Contd - 1.0																											X			
PERL_020_Adverse Event Log - V1.0																											X			
PERL_040_Protocol Deviation Log - V1.0																											X			
PERL_045_Serious Adverse Event - V5.0																												X		
PERL_028_ESRD - 1.0																														X

Source Documents:

PERL_000_Source Document Uploads - V1.0
PERL_000-022_Source Document Uploads - V1.0
PERL_000_Additional Source Document Uploads - V1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Source Documents
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_000_Source Document Uploads - V1.0

Section Title: Source Documents Uploads
A1. Visit 1: Please upload original source documents associated with: Form 006, Form 008, Form 009, Form 016 and Slope Worksheet if required
A2. Visit 2: Please upload original source documents associated with: Form 006, Form 007, Form 008, and Form 009
A3. Visit 3: Please upload original source documents associated with: Form 006, Form 008
A4. Visit 4/4a: Please upload original source documents associated with: Form 006, Form 007, Form 008, Form 009, Form 019
A6. Visit 6: Please upload original source documents associated with: Form 006, Form 008
A7. Visit 7: Please upload original source documents associated with: Form 006, Form 007, Form 008, Form 009, Form 019
A8. Visit 8: Please upload original source documents associated with: Form 006, Form 008
A9. Visit 9: Please upload original source documents associated with: Form 006, Form 008
A10. Visit 10: Please upload original source documents associated with: Form 006, Form 008
A11. Visit 11: Please upload original source documents associated with: Form 006, Form 007, Form 008, Form 009, Form 019
A12. Visit 12: Please upload original source documents associated with: Form 006, Form 008
A13. Visit 13: Please upload original source documents associated with: Form 006, Form 008
A14. Visit 14: Please upload original source documents associated with: Form 006, Form 008
A15. Visit 15: Please upload original source documents associated with: Form 006, Form 008
A16. Visit 16: Please upload original source documents associated with: Form 006, Form 007, Form 008, Form 009, Form 019
A17. Visit 17: Please upload original source documents associated with: Form 006, Form 008, Form 019

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Source Documents
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_000-022_Source Document Uploads - V1.0

Section Title: Source Documents Uploads
A6. Visit 6: Please upload original source documents associated with Form 022
A7. Visit 7: Please upload original source documents associated with Form 022
A8. Visit 8: Please upload original source documents associated with Form 022
A9. Visit 9: Please upload original source documents associated with Form 022
A10. Visit 10: Please upload original source documents associated with Form 022
A11. Visit 11: Please upload original source documents associated with Form 022
A12. Visit 12: Please upload original source documents associated with Form 022
A13. Visit 13: Please upload original source documents associated with Form 022
A14. Visit 14: Please upload original source documents associated with Form 022
A15. Visit 15: Please upload original source documents associated with Form 022
A16. Visit 16: Please upload original source documents associated with Form 022
A17. Visit 17: Please upload original source documents associated with Form 022

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Source Documents
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_000_Additional Source Document Uploads - V1.0

Section Title: Source Documents Uploads

1. Additional Source Document Upload

Please include a description of upload file:

2. Additional Source Document Upload

Please include a description of upload file:

3. Additional Source Document Upload

Please include a description of upload file:

4. Additional Source Document Upload

Please include a description of upload file:

5. Additional Source Document Upload

Please include a description of upload file:

6. Additional Source Document Upload

Please include a description of upload file:

7. Additional Source Document Upload

Please include a description of upload file:

8. Additional Source Document Upload

Please include a description of upload file:

9. Additional Source Document Upload

Please include a description of upload file:

10. Additional Source Document Upload

Please include a description of upload file:

Visit 1:

PERL_002_Demographics - V3.0
PERL_003_Medical History - V2.0
PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_009_ECG Report - V1.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_016_ACR/AER Screening - V4.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_002_Demographics - V3.0

Section Title: Demographics
Instructions:

Date of Consent:
A1. Date of Consent:

Date of Birth:
A2. Date of Birth:

Age:
A3. (yrs)

Gender:
A4. Gender: *
- ○ Male
- ○ Female of childbearing potential
- ○ Female not of childbearing potential
- ○ Female

A4a. Reason: (Please select all that apply)
- ☐ Hysterectomy
- ☐ Tubal Ligation
- ☐ Post-menopausal
- ☐ Other If Other, Specify:

Ethnicity:
A5. Ethnitic:
- ○ Hispanic or Latino
- ○ Non-Hispanic or Non-Latino
- ○ Unknown/Undisclosed

Race:
A6. Please select all that apply:
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ African-American or Black
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Unknown or not reported
- ☐ Prefer not to answer

Marital Status:
A7. Marital Status:
- ○ Single
- ○ Married
- ○ Divorced/Separated
- ○ Widowed
- ○ Unknown

History of Smoking:
A8. Does the participant have a history of smoking?
- ○ Yes
- ○ No

A8a. Smoking status:
- ○ Current
- ○ Past
- ○ Not in Last 30 Days
- ○ In Last 30 Days

A8b. Quit Date:

A8c. How many years has the participant smoked? years

A8d. On average, during that time, how many cigarettes per day did the participant smoke? cigarettes/day

Alcohol Consumption:
A9. Does the participant consume alcohol?
- ○ Yes
- ○ No

A9a. Average number of drinks/week: drinks/week

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_003_Medical History - V2.0

Section Title: Diabetes/GI

Subtitle:

Instructions:

Complete each section A-H.
Check all conditions that the participant has had in the past five years.
If a condition is marked present, indicate if it is ongoing at the time of consent.

A1. Year of Type I Diabetes Diagnosis: * (YYYY)

Gastrointestinal Problems

☐A2. GERD

Ongoing? ○Yes ○No

☐A3. Hemorrhoids

Ongoing? ○Yes ○No

☐A4. Appendicitis

Ongoing? ○Yes ○No

☐A5. Celiac Disease

Ongoing? ○Yes ○No

☐A6. Colitis

Ongoing? ○Yes ○No

☐A7. Colon Polyps

Ongoing? ○Yes ○No

☐A8. Constipation

Ongoing? ○Yes ○No

☐A9. Crohns Disease

Ongoing? ○Yes ○No

☐A10. Diarrhea

Ongoing? ○Yes ○No

☐A11. Diverticulitis

Ongoing? ○Yes ○No

☐A12. Ulcers

Ongoing? ○Yes ○No

☐A13. Dysphagia

Ongoing? ○Yes ○No

☐A14. Gallstones

Ongoing? ○Yes ○No

☐A15. Gastrointestinal Bleeding

Ongoing? ○Yes ○No

☐A16. Hernia

Ongoing? ○Yes ○No

☐A17. IBS

Ongoing? ○Yes ○No

☐A18. Peptic Ulcers

Ongoing? ○Yes ○No

☐A19. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐A20. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Brain/Nervous System
Subtitle:

Brain & Nervous System

☐B1. Alzheimer's Disease

Ongoing? ○Yes ○No

☐B2. Tremors

Ongoing? ○Yes ○No

☐B3. Bells Palsy

Ongoing? ○Yes ○No

☐B4. Embolism

Ongoing? ○Yes ○No

☐B5. Stroke

Ongoing? ○Yes ○No

☐B6. Dementia

Ongoing? ○Yes ○No

☐B7. Epilepsy

Ongoing? ○Yes ○No

☐B8. Guillain-Barre Syndrome

Ongoing? ○Yes ○No

☐B9. Migraines

Ongoing? ○Yes ○No

☐B10. Meningitis

Ongoing? ○Yes ○No

☐B11. Neuropathy

Ongoing? ○Yes ○No

☐B12. TIA

Ongoing? ○Yes ○No

☐B13. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐B14. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Skin/Musculoskeletal
Subtitle:

Skin

☐C1. Rash

Ongoing? ○Yes ○No

☐C2. Skin Cancer

Ongoing? ○Yes ○No

☐C3. Psoriasis

Ongoing? ○Yes ○No

☐C4. Rosacea

Ongoing? ○Yes ○No

☐C5. Eczema

Ongoing? ○Yes ○No

☐C6. Ulcers

Ongoing? ○Yes ○No

☐C7. Hives

Ongoing? ○Yes ○No

☐C8. Cellulitis

Ongoing? ○Yes ○No

☐C9. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐C10. None

Musculoskeletal/Joints

☐C11. Spondylitis

Ongoing? ○Yes ○No

☐C12. Back Pain

Ongoing? ○Yes ○No

☐C13. Carpal Tunnel Syndrome

Ongoing? ○Yes ○No

☐C14. Fibromyalgia

Ongoing? ○Yes ○No

☐C15. Joint Pain or Swelling

Ongoing? ○Yes ○No

☐C16. Arthritis

Ongoing? ○Yes ○No

☐C17. Gout

Ongoing? ○Yes ○No

☐C18. Osteoarthritis

Ongoing? ○Yes ○No

☐C19. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐C20. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Cardiovascular/Pulmonary
Subtitle:

Cardiovascular System

☐D1. Coronary artery disease

Ongoing? ○Yes ○No

☐D2. Percutaneous coronary intervention

Ongoing? ○Yes ○No

☐D3. Peripheral artery disease

Ongoing? ○Yes ○No

☐D4. Congestive heart failure

Ongoing? ○Yes ○No

☐D5. Arrhythmia

Ongoing? ○Yes ○No

☐D6. MI

Ongoing? ○Yes ○No

☐D7. Congenital heart failure

Ongoing? ○Yes ○No

☐D8. Cardiomyopathy

Ongoing? ○Yes ○No

☐D9. Vascular Disease

Ongoing? ○Yes ○No

☐D10. Angina

Ongoing? ○Yes ○No

☐D11. Hypertension

Ongoing? ○Yes ○No

☐D12. Hypotension

Ongoing? ○Yes ○No

☐D13. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐D14. None

Pulmonary System

☐D15. COPD

Ongoing? ○Yes ○No

☐D16. Asthma

Ongoing? ○Yes ○No

☐D17. Pulmonary Embolism

Ongoing? ○Yes ○No

☐D18. Pneumonia

Ongoing? ○Yes ○No

☐D19. Pulmonary Edema

Ongoing? ○Yes ○No

☐D20. Emphysema

Ongoing? ○Yes ○No

☐D21. Shortness of Breath

Ongoing? ○Yes ○No

☐D22. Seasonal/Environmental Allergies

Ongoing? ○Yes ○No

☐D23. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐D24. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Autoimmune/Urinary
Subtitle:

Autoimmune Disease

☐E1. Hashimoto thyroiditis

Ongoing? ○Yes ○No

☐E2. Rheumatoid Arthritis

Ongoing? ○Yes ○No

☐E3. Lupus

Ongoing? ○Yes ○No

☐E4. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐E5. None

Urinary System

☐E6. Kidney Stones

Ongoing? ○Yes ○No

☐E7. Cystitis

Ongoing? ○Yes ○No

☐E8. Dysuria

Ongoing? ○Yes ○No

☐E9. Incontinence

Ongoing? ○Yes ○No

☐E10. Urethritis

Ongoing? ○Yes ○No

☐E11. UTI

Ongoing? ○Yes ○No

☐E12. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐E13. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Endocrine/Mental Health
Subtitle:

Endocrine System

☐F1. Adrenal Insufficiency

Ongoing? ○Yes ○No

☐F2. Growth Disorder

Ongoing? ○Yes ○No

☐F3. Hyperthyroidism

Ongoing? ○Yes ○No

☐F4. Hypothyroidism

Ongoing? ○Yes ○No

☐F5. Polycystic Ovary Syndrome

Ongoing? ○Yes ○No

☐F6. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐F7. None

Mental Health

☐F8. Depression

Ongoing? ○Yes ○No

☐F9. Bipolar

Ongoing? ○Yes ○No

☐F10. Anxiety

Ongoing? ○Yes ○No

☐F11. Schizophrenia

Ongoing? ○Yes ○No

☐F12. Obsessive Compulsive Disorder

Ongoing? ○Yes ○No

☐F13. Eating disorder

Ongoing? ○Yes ○No

☐F14. Post-traumatic stress syndrome

Ongoing? ○Yes ○No

☐F15. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐F16. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Hepatic/Cancer/Eye
Subtitle:

Hepatic

☐G1. Jaundice

Ongoing? ○Yes ○No

☐G2. Cirrhosis

Ongoing? ○Yes ○No

☐G3. Fatty Liver Disease

Ongoing? ○Yes ○No

☐G4. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐G5. None

Cancer

☐G6. Head/Neck Cancer

Ongoing? ○Yes ○No

☐G7. Renal/Urinary Tract Cancer

Ongoing? ○Yes ○No

☐G8. Leukemia/Lymphoma

Ongoing? ○Yes ○No

☐G9. Solid Tumor

Ongoing? ○Yes ○No

☐G10. Other

Ongoing? ○Yes ○No

☐G11. None

Eye

☐G12. Conjunctivitis

Ongoing? ○Yes ○No

☐G13. Cataract

Ongoing? ○Yes ○No

☐G14. Cataract Removal

Ongoing? ○Yes ○No

☐G15. Vitrectomy

Ongoing? ○Yes ○No

☐G16. Retinopathy

Ongoing? ○Yes ○No

☐G17. Laser Therapy

Ongoing? ○Yes ○No

☐G18. Blindness

Ongoing? ○Yes ○No

☐G19. Glaucoma

Ongoing? ○Yes ○No

☐G20. Myopia

Ongoing? ○Yes ○No

☐G21. Hyperopia

Ongoing? ○Yes ○No

☐G22. Macular Degeneration

Ongoing? ○Yes ○No

☐G23. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐G24. None

Date of Last Eye Exam:

☐Never Examined

☐Eye Exam Date Unknown

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Hospitalizations/Allergies/Pregnancies

Allergies

H1. Do you have any food, drug or environmental allergies?
- ○ Yes
- ○ No
- ○ Unknown

List allergens:

Pregnancies

H2. Has participant ever been pregnant?
- ○ Yes
- ○ No
- ○ NA

Number of pregnancies:

Number of live births:

Hospitalizations

H3. Has the participant had any Hospitalizations in the last 5 years requiring overnight stay?
- ○ Yes
- ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Hospitalizations Log

Reason:	If Other or non-elective surgery, specify:	Month:	Year:	Length of Stay (days):
○ Elective Surgery		○ January		
○ Cardiovascular		○ February		
○ Diabetes		○ March		
○ Renal		○ April		
○ Accident		○ May		
○ Non-Elective Surgery		○ June		
○ Pulmonary		○ July		
○ Psychiatric		○ August		
○ Other		○ September		
		○ October		
		○ November		
		○ December		

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading
B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading
B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading
B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: **Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.**

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR

Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_009_ECG Report - V1.0

Section Title: ECG Report

ECG Completed? *
- ○ Completed
- ○ Not Completed

Upload Source Document:

A1. Date of ECG:

A2. Heart Rate: (bpm)

A3. ECG Findings:
- ○ Normal
- ○ Abnormal

A3a. If abnormal (select all that apply):
- ☐ ST Elevation
- ☐ Atrial Fib
- ☐ T Inversion
- ☐ Q Wave
- ☐ AV Block
- ☐ MI Changes
- ☐ Tachycardia
- ☐ Bradycardia
- ☐ Other

If Other, Specify:

A3b. Is this abnormality clinically significant?
- ○ Yes **** If yes, report on AE Log**
- ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_016_ACR/AER Screening - V4.0

Section Title: ACR/AER Screening

Which of the criteria was used to document microalbuminuria or moderate macroalbuminuria at screening? (Check all that apply)

A1a. ☐ Urinary albumin excretion rates

Select RASB status:
○ Not on RASB 30-5000 mg/24hr or 20-3333 g/min or 30-5000 mg/g
○ On RASB 18-5000 mg/24hr or 12-3333 g/min or 18-5000 mg/g

☐ Albumin creatinine ratios

Select RASB status:
○ Not on RASB 30-5000 mg/24hr or 20-3333 g/min or 30-5000 mg/g
○ On RASB 18-5000 mg/24hr or 12-3333 g/min or 18-5000 mg/g

If A1c checkbox is selected, provide Slope Calculation Result:

Enter results for qualifying values.

Date of Test:	ACR Result:	AER Result:	ACR/AER Units:	GFR: Enter values for the last 3-5 years (ml/min/1.73 m^2)
			○ Mg/24 hr ○ Mcg/min	
			○ Mg/24 hr ○ Mcg/min	
			○ Mg/24 hr ○ Mcg/min	

Visit 1a:

PERL_016_ACR/AER Screening - V4.0
PERL_002_Demographics - V3.0
PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_016_ACR/AER Screening - V4.0

Section Title: ACR/AER Screening

Which of the criteria was used to document microalbuminuria or moderate macroalbuminuria at screening? (Check all that apply)

A1a. ☐ Urinary albumin excretion rates

Select RASB status: ○ Not on RASB 30-5000 mg/24hr or 20-3333 g/min or 30-5000 mg/g
○ On RASB 18-5000 mg/24hr or 12-3333 g/min or 18-5000 mg/g

☐ Albumin creatinine ratios

Select RASB status: ○ Not on RASB 30-5000 mg/24hr or 20-3333 g/min or 30-5000 mg/g
○ On RASB 18-5000 mg/24hr or 12-3333 g/min or 18-5000 mg/g

If A1c checkbox is selected, provide Slope Calculation Result:

Enter results for qualifying values.

Date of Test:	ACR Result:	AER Result:	ACR/AER Units:	GFR: Enter values for the last 3-5 years (ml/min/1.73 m^2)
			○ Mg/24 hr ○ Mcg/min	
			○ Mg/24 hr ○ Mcg/min	
			○ Mg/24 hr ○ Mcg/min	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_002_Demographics - V3.0

Section Title: Demographics

Instructions:

Date of Consent:

A1. Date of Consent:

Date of Birth:

A2. Date of Birth:

Age:

A3. (yrs)

Gender:

A4. Gender: *
- ○ Male
- ○ Female of childbearing potential
- ○ Female not of childbearing potential
- ○ Female

A4a. Reason: (Please select all that apply)
- ☐ Hysterectomy
- ☐ Tubal Ligation
- ☐ Post-menopausal
- ☐ Other If Other, Specify:

Ethnicity:

A5. Ethnitic:
- ○ Hispanic or Latino
- ○ Non-Hispanic or Non-Latino
- ○ Unknown/Undisclosed

Race:

A6. Please select all that apply:
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ African-American or Black
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Unknown or not reported
- ☐ Prefer not to answer

Marital Status:

A7. Marital Status:
- ○ Single
- ○ Married
- ○ Divorced/Separated
- ○ Widowed
- ○ Unknown

History of Smoking:

A8. Does the participant have a history of smoking?
- ○ Yes
- ○ No

A8a. Smoking status:
- ○ Current
- ○ Past
- ○ Not in Last 30 Days
- ○ In Last 30 Days

A8b. Quit Date:

A8c. How many years has the participant smoked? years

A8d. On average, during that time, how many cigarettes per day did the participant smoke? cigarettes/day

Alcohol Consumption:

A9. Does the participant consume alcohol?
- ○ Yes
- ○ No

A9a. Average number of drinks/week: drinks/week

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading
B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading
B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading
B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate

Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure

Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: **Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.**

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR

Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 1a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Eligibility Run-In:

PERL_001S_Eligibility_RunIn - V3.0
PERL_001RS_Eligibility Re Screen - V1.0
PERL_015_Exemption Request - V2.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Eligibility Run-In
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_001S_Eligibility_RunIn - V3.0

Section Title: PERL Pilot

Is this participant active in the PERL Pilot Study?
* ○ Yes ○ No

Enter Pilot Subject ID
If Pilot Study Participant, Skip to Eligibility Status.

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Eligibility Run-In
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Inclusion Criteria

A1. Between 18 and 70 years of age, inclusive.
○Yes ○ No ○ Not Done

A3. Continuously treated with insulin within one year of T1D diagnosis.
○Yes ○ No ○ Not Done

A5. Duration of T1D ≥ 8 years
○Yes ○ No

A6. History or presence of microalbuminuria, moderate macroalbuminuria or evidence of declining kidney function according to the specific protocol requirements.
○Yes ○ No ○ Not Done

A7. Estimated GFR based on serum creatinine between 40 and 99.9 ml/min/1.73 m^2 at screening according to the specific protocol requirements.
○Yes ○ No

A8. Serum UA ≥ 4.5 mg/dl at the screening visit.
○Yes ○ No ○ Not Done

A9. Willing to comply with schedule of events and protocol requirements.
○Yes ○ No ○ Not Done

A10. Participant signed informed consent.
○Yes ○ No ○ Not Done

A11. Male or female T1D patient.
○Yes ○ No

A12. Was T1D diagnosis after age 35?
○Yes ○ No ○ NA

A12a. If yes, please indicate which additional criteria was met:
□Documentation of the presence of circulating T1D-associated autoantibodies at diagnosis or any other time □History of hospitalization for DKA □Plasma C-peptide below the limit of detection with Standard assay (durrent blood glucose >100mg/dl

A13. Participant eligible to skip to Visit 4.
○Yes ○ Not Applicable

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Eligibility Run-In
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Exclusion Criteria

B1. History of gout requiring allopurinol therapy or xanthinuria or other indications for uric acid lowering therapy such as cancer chemotherapy or extremely high serum uric acid values (>12 mg/dl).
○Yes ○No ○Not Done

B2. Recurrent renal calculi (history of more than 1 episode).
○Yes ○No ○Not Done

B3. Use of urate-lowering agents within 3 months prior to screening.
○Yes ○No ○Not Done

B4. Current use of drugs known to interact with allopurinol.
○Yes ○No ○Not Done

B5. Known allergy to xanthine-oxidase inhibitors or iodine containing substances.
○Yes ○No ○Not Done

B7. Renal transplant
○Yes ○No ○Not Done

B8. Non-diabetic kidney disease as indicated by medical history and/or laboratory findings.
○Yes ○No ○Not Done

B9. SBP>160 or DBP>100 mmHg at screening.
○Yes ○No ○Not Done

B11. Cancer treatment (excluding non-melanoma skin cancer treated by excision) within two years before screening.
○Yes ○No ○Not Done

B12. History of clinically significant hepatic disease including hepatitis B or C and/or ALT >2.50 ULN at screening and/or history of HBV/HCV antibody positivity.
○Yes ○No ○Not Done

B13. History of acquired immune deficiency syndrome or human immunodeficiency virus (HIV) infection
○Yes ○No ○Not Done

B14. Hemoglobin concentration <11 g/dL (males), <10 g/dL (females) at screening.
○Yes ○No ○Not Done

B15. Platelet count <100,000/mm^3 at screening.
○Yes ○No ○Not Done

B16. Ongoing alcohol or drug abuse or history of treatment for these conditions in the past 6 months.
○Yes ○No ○Not Done

B17. Blood donation in the 3 months before screening.
○Yes ○No ○Not Done

B18. Breastfeeding or pregnancy or unwillingness to be on contraception if fertile.
○Yes ○No ○Not Done

B19. Poor mental function or any other reason to expect patient difficulty in complying with the requirements of the study.
○Yes ○No ○Not Done

B20. Serious pre-existing medical problems (except T1D).
○Yes ○No ○Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Eligibility Run-In
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Eligibility Status

If any Inclusion Criteria are 'No' or if any Exclusion Criteria are 'Yes', the participant is not eligible.

Participant Is:

- ○ Eligible for Run-In
- ○ Eligible (Pilot Participant)
- ○ Ineligible for Run-In
- ○ Eligible for Run-In by Exemption

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Eligibility Run-In
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_001RS_Eligibility Re Screen - V1.0

Section Title: Eligibility ReScreen

A1. Date participant considered for re-screening assessments
*

A2. Which eligibility criteria was not met at Visit 1 Screening?
Please refer to the Inclusion and Exclusion Criteria sections of Form 001S Eligibility RunIn CRF and select the appropriate question number(s) that the subject did not meet at Visit 1 Screening.

- ☐A6
- ☐A7
- ☐A8
- ☐B3
- ☐B4
- ☐B9
- ☐B11
- ☐B12
- ☐B14
- ☐B15
- ☐B16
- ☐B17

A3. Projected date of re-screen visit

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Eligibility Run-In
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_015_Exemption Request - V2.0

Section Title: Exemption Request

Instructions:
Completion of items A1-A3 will send an email to the Exemption Review Committee.
Please enter relevant details into A3 below. This is required in order to send the alert and for the Exemption Committee to make a decision.

A1. Select Inclusion criteria not met:

Select criteria for review:
- ○ Male or female between 18 and 70 years of age
- ○ T1D diagnosed after age 35 and additional criteria not met
- ○ Continuously treated with insulin within one year of T1D diagnosis
- ○ Duration of T1D ≥ 8 years
- ○ History or presence of microalbuminuria or moderate macroalbuminuria or evidence of declining kidney function according to the specific protocol requirements
- ○ Estimated GFR between 40 and 99.9 ml/min/1.73 m2. The upper limit should be decreased by 1 ml/min/1.73 m2 for each year over age 60
- ○ Serum UA ≥ 4.5 mg/dl at the screening visit

A2. Select Exclusion criteria violated:

Select criteria for review:
- ○ History of gout requiring allopurinol therapy or xanthinuria or other indications for uric acid lowering therapy such as cancer chemotherapy or extremely high serum uric acid values (>12 mg/dl)
- ○ Recurrent renal calculi (history of more than 1 episode)
- ○ Use of urate-lowering agents within 3 months prior to screening
- ○ Current use of drugs known to interact with allopurinol
- ○ Known allergy to xanthine-oxidase inhibitors or iodine containing substances
- ○ Non-diabetic kidney disease as indicated by medical history and/or laboratory findings
- ○ SBP>160 or DBP >100mmHg at screening
- ○ SBP>150 or DBP >95mmHg at the end of the run-in period
- ○ Cancer treatment within two years before screening
- ○ Hemoglobin concentration <11 _tmpItem="755" g/dL (males) or <10 g/dL (females) at screening
- ○ Platelet count <100000/mm3
- ○ Ongoing alcohol or drug abuse or history of treatment for these conditions in the past 6 months
- ○ Blood donation in the 3 months before screening
- ○ Serious pre-existing medical problems (except T1D)
- ○ Other

If Other, Specify:

A3. Reason this participant should be considered for the study:

Please Provide: *

A4. Exemption Granted?

Please Select One:
- ○ Yes
- ○ No

A4a. If No, Reason:

A5. Date of Decision

Date:

Visit 2:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_007_Physical Examination - V1.0
PERL_003_Medical History - V2.0
PERL_009_ECG Report - V1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading
B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading
B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading
B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_007_Physical Examination - V1.0

Section Title: Body System

A0. Was a physical exam performed at this visit?
- ○ Yes
- ○ No

Upload source documents:

A1. Eyes:

Eyes (including fundoscopy):
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Retinopathy
- ☐ Macular Degeneration
- ☐ Other

If other, specify:

A2. Cardiovascular:

Cardiovascular:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Arrhythmia
- ☐ Murmur
- ☐ Other

If other, specify:

A3. Extremities:

Extremities:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Amputation

Amputation, specify:
- ☐ Tenderness
- ☐ Edema
- ☐ Pulses

Pulses:
- ○ 0+
- ○ 1+
- ○ 2+
- ○ 3+
- ○ 4+
- ☐ Other

If other, specify:

A4. Lymph Nodes:

Lymph Nodes:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Swelling
- ☐ Other

If other, specify:

A5. Pulmonary:

Pulmonary:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Reduced breath sounds
- ☐ Other

If other, specify:

A6. Skin:

Skin:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Red or purple painful rash
- ☐ Scar
- ☐ Eczema
- ☐ Psoriasis
- ☐ Ulcers
- ☐ Excessive Bruising
- ☐ Other

If other, specify:

A7. Gastrointestinal:

Gastrointestinal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Ascites
- ☐ Abdominal Mass
- ☐ Organomegaly

Organomegaly, specify:
- ☐ Stoma
- ☐ Other

If other, specify:

A8. Musculoskeletal

Musculoskeletal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Stiffness

☐ Tenderness

☐ Injury

Injury, specify:

☐ Reduced strength

☐ Reduced range of motion

☐ Other

If other, specify:

A9. Genitourinary:

Genitourinary: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Specify:

A10. Neurological:

Neurological: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Abnormal Reflex Response

Abnormal reflex response, specify: ○ Hyperflexia
○ Hypoflexia

☐ Diminished sensation

☐ Cranial Nerves

Abnormal, specify:

☐ Other

If other, specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Other Body System

Other Body System

A11. Other Body System:	Describe

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_003_Medical History - V2.0

Section Title: Diabetes/GI

Subtitle:

Instructions:

Complete each section A-H.
Check all conditions that the participant has had in the past five years.
If a condition is marked present, indicate if it is ongoing at the time of consent.

A1. Year of Type I Diabetes Diagnosis: * (YYYY)

Gastrointestinal Problems

☐A2. GERD

Ongoing? ○Yes ○No

☐A3. Hemorrhoids

Ongoing? ○Yes ○No

☐A4. Appendicitis

Ongoing? ○Yes ○No

☐A5. Celiac Disease

Ongoing? ○Yes ○No

☐A6. Colitis

Ongoing? ○Yes ○No

☐A7. Colon Polyps

Ongoing? ○Yes ○No

☐A8. Constipation

Ongoing? ○Yes ○No

☐A9. Crohns Disease

Ongoing? ○Yes ○No

☐A10. Diarrhea

Ongoing? ○Yes ○No

☐A11. Diverticulitis

Ongoing? ○Yes ○No

☐A12. Ulcers

Ongoing? ○Yes ○No

☐A13. Dysphagia

Ongoing? ○Yes ○No

☐A14. Gallstones

Ongoing? ○Yes ○No

☐A15. Gastrointestinal Bleeding

Ongoing? ○Yes ○No

☐A16. Hernia

Ongoing? ○Yes ○No

☐A17. IBS

Ongoing? ○Yes ○No

☐A18. Peptic Ulcers

Ongoing? ○Yes ○No

☐A19. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐A20. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Brain/Nervous System
Subtitle:

Brain & Nervous System

☐B1. Alzheimer's Disease

Ongoing? ○Yes ○No

☐B2. Tremors

Ongoing? ○Yes ○No

☐B3. Bells Palsy

Ongoing? ○Yes ○No

☐B4. Embolism

Ongoing? ○Yes ○No

☐B5. Stroke

Ongoing? ○Yes ○No

☐B6. Dementia

Ongoing? ○Yes ○No

☐B7. Epilepsy

Ongoing? ○Yes ○No

☐B8. Guillain-Barre Syndrome

Ongoing? ○Yes ○No

☐B9. Migraines

Ongoing? ○Yes ○No

☐B10. Meningitis

Ongoing? ○Yes ○No

☐B11. Neuropathy

Ongoing? ○Yes ○No

☐B12. TIA

Ongoing? ○Yes ○No

☐B13. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐B14. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Skin/Musculoskeletal
Subtitle:

Skin

☐C1. Rash

Ongoing? ○Yes ○No

☐C2. Skin Cancer

Ongoing? ○Yes ○No

☐C3. Psoriasis

Ongoing? ○Yes ○No

☐C4. Rosacea

Ongoing? ○Yes ○No

☐C5. Eczema

Ongoing? ○Yes ○No

☐C6. Ulcers

Ongoing? ○Yes ○No

☐C7. Hives

Ongoing? ○Yes ○No

☐C8. Cellulitis

Ongoing? ○Yes ○No

☐C9. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐C10. None

Musculoskeletal/Joints

☐C11. Spondylitis

Ongoing? ○Yes ○No

☐C12. Back Pain

Ongoing? ○Yes ○No

☐C13. Carpal Tunnel Syndrome

Ongoing? ○Yes ○No

☐C14. Fibromyalgia

Ongoing? ○Yes ○No

☐C15. Joint Pain or Swelling

Ongoing? ○Yes ○No

☐C16. Arthritis

Ongoing? ○Yes ○No

☐C17. Gout

Ongoing? ○Yes ○No

☐C18. Osteoarthritis

Ongoing? ○Yes ○No

☐C19. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐C20. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Cardiovascular/Pulmonary
Subtitle:

Cardiovascular System

☐D1. Coronary artery disease

Ongoing? ○Yes ○No

☐D2. Percutaneous coronary intervention

Ongoing? ○Yes ○No

☐D3. Peripheral artery disease

Ongoing? ○Yes ○No

☐D4. Congestive heart failure

Ongoing? ○Yes ○No

☐D5. Arrhythmia

Ongoing? ○Yes ○No

☐D6. MI

Ongoing? ○Yes ○No

☐D7. Congenital heart failure

Ongoing? ○Yes ○No

☐D8. Cardiomyopathy

Ongoing? ○Yes ○No

☐D9. Vascular Disease

Ongoing? ○Yes ○No

☐D10. Angina

Ongoing? ○Yes ○No

☐D11. Hypertension

Ongoing? ○Yes ○No

☐D12. Hypotension

Ongoing? ○Yes ○No

☐D13. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐D14. None

Pulmonary System

☐D15. COPD

Ongoing? ○Yes ○No

☐D16. Asthma

Ongoing? ○Yes ○No

☐D17. Pulmonary Embolism

Ongoing? ○Yes ○No

☐D18. Pneumonia

Ongoing? ○Yes ○No

☐D19. Pulmonary Edema

Ongoing? ○Yes ○No

☐D20. Emphysema

Ongoing? ○Yes ○No

☐D21. Shortness of Breath

Ongoing? ○Yes ○No

☐D22. Seasonal/Environmental Allergies

Ongoing? ○Yes ○No

☐D23. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐D24. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Autoimmune/Urinary
Subtitle:

Autoimmune Disease

☐E1. Hashimoto thyroiditis

Ongoing? ○Yes ○No

☐E2. Rheumatoid Arthritis

Ongoing? ○Yes ○No

☐E3. Lupus

Ongoing? ○Yes ○No

☐E4. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐E5. None

Urinary System

☐E6. Kidney Stones

Ongoing? ○Yes ○No

☐E7. Cystitis

Ongoing? ○Yes ○No

☐E8. Dysuria

Ongoing? ○Yes ○No

☐E9. Incontinence

Ongoing? ○Yes ○No

☐E10. Urethritis

Ongoing? ○Yes ○No

☐E11. UTI

Ongoing? ○Yes ○No

☐E12. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐E13. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Endocrine/Mental Health
Subtitle:

Endocrine System

☐F1. Adrenal Insufficiency

Ongoing? ○Yes ○No

☐F2. Growth Disorder

Ongoing? ○Yes ○No

☐F3. Hyperthyroidism

Ongoing? ○Yes ○No

☐F4. Hypothyroidism

Ongoing? ○Yes ○No

☐F5. Polycystic Ovary Syndrome

Ongoing? ○Yes ○No

☐F6. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐F7. None

Mental Health

☐F8. Depression

Ongoing? ○Yes ○No

☐F9. Bipolar

Ongoing? ○Yes ○No

☐F10. Anxiety

Ongoing? ○Yes ○No

☐F11. Schizophrenia

Ongoing? ○Yes ○No

☐F12. Obsessive Compulsive Disorder

Ongoing? ○Yes ○No

☐F13. Eating disorder

Ongoing? ○Yes ○No

☐F14. Post-traumatic stress syndrome

Ongoing? ○Yes ○No

☐F15. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐F16. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Hepatic/Cancer/Eye
Subtitle:

Hepatic

☐G1. Jaundice

Ongoing? ○Yes ○No

☐G2. Cirrhosis

Ongoing? ○Yes ○No

☐G3. Fatty Liver Disease

Ongoing? ○Yes ○No

☐G4. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐G5. None

Cancer

☐G6. Head/Neck Cancer

Ongoing? ○Yes ○No

☐G7. Renal/Urinary Tract Cancer

Ongoing? ○Yes ○No

☐G8. Leukemia/Lymphoma

Ongoing? ○Yes ○No

☐G9. Solid Tumor

Ongoing? ○Yes ○No

☐G10. Other

Ongoing? ○Yes ○No

☐G11. None

Eye

☐G12. Conjunctivitis

Ongoing? ○Yes ○No

☐G13. Cataract

Ongoing? ○Yes ○No

☐G14. Cataract Removal

Ongoing? ○Yes ○No

☐G15. Vitrectomy

Ongoing? ○Yes ○No

☐G16. Retinopathy

Ongoing? ○Yes ○No

☐G17. Laser Therapy

Ongoing? ○Yes ○No

☐G18. Blindness

Ongoing? ○Yes ○No

☐G19. Glaucoma

Ongoing? ○Yes ○No

☐G20. Myopia

Ongoing? ○Yes ○No

☐G21. Hyperopia

Ongoing? ○Yes ○No

☐G22. Macular Degeneration

Ongoing? ○Yes ○No

☐G23. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐G24. None

Date of Last Eye Exam:

☐Never Examined

☐Eye Exam Date Unknown

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Hospitalizations/Allergies/Pregnancies

Allergies

H1. Do you have any food, drug or environmental allergies?
- ○ Yes
- ○ No
- ○ Unknown

List allergens:

Pregnancies

H2. Has participant ever been pregnant?
- ○ Yes
- ○ No
- ○ NA

Number of pregnancies:

Number of live births:

Hospitalizations

H3. Has the participant had any Hospitalizations in the last 5 years requiring overnight stay?
- ○ Yes
- ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Hospitalizations Log

Reason:	If Other or non-elective surgery, specify:	Month:	Year:	Length of Stay (days):
○ Elective Surgery		○ January		
○ Cardiovascular		○ February		
○ Diabetes		○ March		
○ Renal		○ April		
○ Accident		○ May		
○ Non-Elective Surgery		○ June		
○ Pulmonary		○ July		
○ Psychiatric		○ August		
○ Other		○ September		
		○ October		
		○ November		
		○ December		

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 2
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_009_ECG Report - V1.0

Section Title: ECG Report

ECG Completed? *
○ Completed
○ Not Completed

Upload Source Document:

A1. Date of ECG:

A2. Heart Rate: (bpm)

A3. ECG Findings:
○ Normal
○ Abnormal

A3a. If abnormal (select all that apply):
☐ ST Elevation
☐ Atrial Fib
☐ T Inversion
☐ Q Wave
☐ AV Block
☐ MI Changes
☐ Tachycardia
☐ Bradycardia
☐ Other

If Other, Specify:

A3b. Is this abnormality clinically significant?
○ Yes **** If yes, report on AE Log**
○ No

Visit 3:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_010A_Central Lab Specimen Collection - V5.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading
B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading
B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading
B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure

Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: **Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.**

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR

Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010A_Central Lab Specimen Collection - V5.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum for Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A3. HLA B*5810 Collected	○ Yes ○ No	Date Collected
A4. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 3
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected ○ Yes ○ No

Overnight ○ Yes ○ No Date Ended Collection

First Morning ○ Yes ○ No Date Collected

Spot Urine ○ Yes ○ No Date Collected

B2. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Visit 4:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_009_ECG Report - V1.0
PERL_010A_Central Lab Specimen Collection - V5.0
PERL_019_iGFR Procedures Form - V3.0
PERL_007_Physical Examination - V1.0
PERL_014_Family History - V1.0
PERL_011_Skin Assessment - V3.0
PERL_003_Medical History - V2.0
PERL_010 Central Lab Specimen Collection - V4.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading
B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading
B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading
B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure

Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: **Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.**

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR

Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_009_ECG Report - V1.0

Section Title: ECG Report

ECG Completed? *
- ○ Completed
- ○ Not Completed

Upload Source Document:

A1. Date of ECG:

A2. Heart Rate: (bpm)

A3. ECG Findings:
- ○ Normal
- ○ Abnormal

A3a. If abnormal (select all that apply):
- ☐ ST Elevation
- ☐ Atrial Fib
- ☐ T Inversion
- ☐ Q Wave
- ☐ AV Block
- ☐ MI Changes
- ☐ Tachycardia
- ☐ Bradycardia
- ☐ Other

If Other, Specify:

A3b. Is this abnormality clinically significant?
- ○ Yes **** If yes, report on AE Log**
- ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010A_Central Lab Specimen Collection - V5.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum for Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A3. HLA B*5810 Collected	○ Yes ○ No	Date Collected
A4. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected ○ Yes ○ No

Overnight ○ Yes ○ No Date Ended Collection

First Morning ○ Yes ○ No Date Collected

Spot Urine ○ Yes ○ No Date Collected

B2. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_019_iGFR Procedures Form - V3.0

Section Title: I. iGFR Procedure

Upload source documents:

A1. Was the iGFR Performed?

Please Select:
- ○ Yes
- ○ No

If No, Reason:
(check all that apply)
- ☐ UTI
- ☐ BP too high
- ☐ Positive pregnancy test
- ☐ Hyperglycemia
- ☐ Hypoglycemia
- ☐ Vomiting
- ☐ Febrile
- ☐ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: II. iGFR Draw Times

A2. Date of iGFR:
Date of iGFR:

A3. iGFR Collections:
Start clock at end of Omnipaque injection* (No Sample) "0" time 00:00

A4. 120 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A5. 150 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A6. 180 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A7. 210 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A8. 240 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A9. Samples shipped to central lab?

Please Select: ☐ Yes ☐ No Date Samples Shipped:

A10. Backup samples shipped to central lab?

Please Select: ☐ Yes ☐ No ☐ NA Date Backup Samples Shipped:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_007_Physical Examination - V1.0

Section Title: Body System

A0. Was a physical exam performed at this visit?
- ○ Yes
- ○ No

Upload source documents:

A1. Eyes:

Eyes (including fundoscopy):
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Retinopathy
- ☐ Macular Degeneration
- ☐ Other

If other, specify:

A2. Cardiovascular:

Cardiovascular:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Arrhythmia
- ☐ Murmur
- ☐ Other

If other, specify:

A3. Extremities:

Extremities:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Amputation

Amputation, specify:
- ☐ Tenderness
- ☐ Edema
- ☐ Pulses

Pulses:
- ○ 0+
- ○ 1+
- ○ 2+
- ○ 3+
- ○ 4+
- ☐ Other

If other, specify:

A4. Lymph Nodes:

Lymph Nodes:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Swelling
- ☐ Other

If other, specify:

A5. Pulmonary:

Pulmonary:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Reduced breath sounds
- ☐ Other

If other, specify:

A6. Skin:

Skin:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Red or purple painful rash
- ☐ Scar
- ☐ Eczema
- ☐ Psoriasis
- ☐ Ulcers
- ☐ Excessive Bruising
- ☐ Other

If other, specify:

A7. Gastrointestinal:

Gastrointestinal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Ascites
- ☐ Abdominal Mass
- ☐ Organomegaly

Organomegaly, specify:
- ☐ Stoma
- ☐ Other

If other, specify:

A8. Musculoskeletal

Musculoskeletal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Stiffness

☐ Tenderness

☐ Injury

Injury, specify:

☐ Reduced strength

☐ Reduced range of motion

☐ Other

If other, specify:

A9. Genitourinary:

Genitourinary: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Specify:

A10. Neurological:

Neurological: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Abnormal Reflex Response

Abnormal reflex response, specify: ○ Hyperflexia
○ Hypoflexia

☐ Diminished sensation

☐ Cranial Nerves

Abnormal, specify:

☐ Other

If other, specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Other Body System

Other Body System

A11. Other Body System:	Describe

Protocol ID: PERL001
Study Name: PERL
Site: ____________________
Event Name: Visit 4
Event Date: ____________________

Study Subject ID:___________
Study Subject DOB:___________

PERL_014_Family History - V1.0

Section Title: Section A. Mother/Father/Grandparents

Please complete the chart for Mother, Father, Maternal Grandmother and Grandfather and Paternal Grandmother and Grandfather.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Brothers

Please complete the chart for all full biological brothers.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Brother1	○ Alive	○ Cardiovascular		□ No History	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	
○ Brother2	○ Deceased	○ Cancer			○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	
○ Brother3	○ Unknown	○ Accident			○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	
○ Brother4		○ Other												
○ Brother5		○ Unknown												
○ Brother6														
○ Brother7														
○ Brother8														
○ Brother9														
○ Brother10														
○ Brother11														
○ Brother12														
○ Brother13														
○ Brother14														
○ Brother15														

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Sisters

Please complete the chart for all full biological sisters.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Sister1	○ Alive	○ Cardiovascular		☐ No History	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	
○ Sister2	○ Deceased	○ Cancer			○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	
○ Sister3	○ Unknown	○ Accident			○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	
○ Sister4		○ Other												
○ Sister5		○ Unknown												
○ Sister6														
○ Sister7														
○ Sister8														
○ Sister9														
○ Sister10														
○ Sister11														
○ Sister12														
○ Sister13														
○ Sister14														
○ Sister15														

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Children

Please complete the chart for all full biological children.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Son 1	○ Alive	○ Cardiovascular		☐ No History	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	
○ Son 2	○ Deceased	○ Cancer			○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	
○ Son 3	○ Unknown	○ Accident			○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	
○ Son 4		○ Other												
○ Son 5		○ Unknown												
○ Son 6														
○ Son 7														
○ Son 8														
○ Son 9														
○ Son 10														
○ Daughter 1														
○ Daughter 2														
○ Daughter 3														
○ Daughter 4														
○ Daughter 5														
○ Daughter 6														
○ Daughter 7														
○ Daughter 8														
○ Daughter 9														
○ Daughter 10														

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit: ○ ºC ○ ºF ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_003_Medical History - V2.0

Section Title: Diabetes/GI
Subtitle:
Instructions:

Complete each section A-H.
Check all conditions that the participant has had in the past five years.
If a condition is marked present, indicate if it is ongoing at the time of consent.

A1. Year of Type I Diabetes Diagnosis: * (YYYY)

Gastrointestinal Problems

☐A2. GERD

Ongoing? ○Yes ○No

☐A3. Hemorrhoids

Ongoing? ○Yes ○No

☐A4. Appendicitis

Ongoing? ○Yes ○No

☐A5. Celiac Disease

Ongoing? ○Yes ○No

☐A6. Colitis

Ongoing? ○Yes ○No

☐A7. Colon Polyps

Ongoing? ○Yes ○No

☐A8. Constipation

Ongoing? ○Yes ○No

☐A9. Crohns Disease

Ongoing? ○Yes ○No

☐A10. Diarrhea

Ongoing? ○Yes ○No

☐A11. Diverticulitis

Ongoing? ○Yes ○No

☐A12. Ulcers

Ongoing? ○Yes ○No

☐A13. Dysphagia

Ongoing? ○Yes ○No

☐A14. Gallstones

Ongoing? ○Yes ○No

☐A15. Gastrointestinal Bleeding

Ongoing? ○Yes ○No

☐A16. Hernia

Ongoing? ○Yes ○No

☐A17. IBS

Ongoing? ○Yes ○No

☐A18. Peptic Ulcers

Ongoing? ○Yes ○No

☐A19. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐A20. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Brain/Nervous System
Subtitle:

Brain & Nervous System

☐B1. Alzheimer's Disease

Ongoing? ○Yes ○No

☐B2. Tremors

Ongoing? ○Yes ○No

☐B3. Bells Palsy

Ongoing? ○Yes ○No

☐B4. Embolism

Ongoing? ○Yes ○No

☐B5. Stroke

Ongoing? ○Yes ○No

☐B6. Dementia

Ongoing? ○Yes ○No

☐B7. Epilepsy

Ongoing? ○Yes ○No

☐B8. Guillain-Barre Syndrome

Ongoing? ○Yes ○No

☐B9. Migraines

Ongoing? ○Yes ○No

☐B10. Meningitis

Ongoing? ○Yes ○No

☐B11. Neuropathy

Ongoing? ○Yes ○No

☐B12. TIA

Ongoing? ○Yes ○No

☐B13. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐B14. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Skin/Musculoskeletal
Subtitle:

Skin

☐C1. Rash

Ongoing? ○Yes ○No

☐C2. Skin Cancer

Ongoing? ○Yes ○No

☐C3. Psoriasis

Ongoing? ○Yes ○No

☐C4. Rosacea

Ongoing? ○Yes ○No

☐C5. Eczema

Ongoing? ○Yes ○No

☐C6. Ulcers

Ongoing? ○Yes ○No

☐C7. Hives

Ongoing? ○Yes ○No

☐C8. Cellulitis

Ongoing? ○Yes ○No

☐C9. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐C10. None

Musculoskeletal/Joints

☐C11. Spondylitis

Ongoing? ○Yes ○No

☐C12. Back Pain

Ongoing? ○Yes ○No

☐C13. Carpal Tunnel Syndrome

Ongoing? ○Yes ○No

☐C14. Fibromyalgia

Ongoing? ○Yes ○No

☐C15. Joint Pain or Swelling

Ongoing? ○Yes ○No

☐C16. Arthritis

Ongoing? ○Yes ○No

☐C17. Gout

Ongoing? ○Yes ○No

☐C18. Osteoarthritis

Ongoing? ○Yes ○No

☐C19. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐C20. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Cardiovascular/Pulmonary
Subtitle:

Cardiovascular System

☐D1. Coronary artery disease

Ongoing? ○Yes ○No

☐D2. Percutaneous coronary intervention

Ongoing? ○Yes ○No

☐D3. Peripheral artery disease

Ongoing? ○Yes ○No

☐D4. Congestive heart failure

Ongoing? ○Yes ○No

☐D5. Arrhythmia

Ongoing? ○Yes ○No

☐D6. MI

Ongoing? ○Yes ○No

☐D7. Congenital heart failure

Ongoing? ○Yes ○No

☐D8. Cardiomyopathy

Ongoing? ○Yes ○No

☐D9. Vascular Disease

Ongoing? ○Yes ○No

☐D10. Angina

Ongoing? ○Yes ○No

☐D11. Hypertension

Ongoing? ○Yes ○No

☐D12. Hypotension

Ongoing? ○Yes ○No

☐D13. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐D14. None

Pulmonary System

☐D15. COPD

Ongoing? ○Yes ○No

☐D16. Asthma

Ongoing? ○Yes ○No

☐D17. Pulmonary Embolism

Ongoing? ○Yes ○No

☐D18. Pneumonia

Ongoing? ○Yes ○No

☐D19. Pulmonary Edema

Ongoing? ○Yes ○No

☐D20. Emphysema

Ongoing? ○Yes ○No

☐D21. Shortness of Breath

Ongoing? ○Yes ○No

☐D22. Seasonal/Environmental Allergies

Ongoing? ○Yes ○No

☐D23. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐D24. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Autoimmune/Urinary
Subtitle:

Autoimmune Disease

☐E1. Hashimoto thyroiditis

Ongoing? ○Yes ○No

☐E2. Rheumatoid Arthritis

Ongoing? ○Yes ○No

☐E3. Lupus

Ongoing? ○Yes ○No

☐E4. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐E5. None

Urinary System

☐E6. Kidney Stones

Ongoing? ○Yes ○No

☐E7. Cystitis

Ongoing? ○Yes ○No

☐E8. Dysuria

Ongoing? ○Yes ○No

☐E9. Incontinence

Ongoing? ○Yes ○No

☐E10. Urethritis

Ongoing? ○Yes ○No

☐E11. UTI

Ongoing? ○Yes ○No

☐E12. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐E13. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Endocrine/Mental Health
Subtitle:

Endocrine System

☐F1. Adrenal Insufficiency

Ongoing? ○Yes ○No

☐F2. Growth Disorder

Ongoing? ○Yes ○No

☐F3. Hyperthyroidism

Ongoing? ○Yes ○No

☐F4. Hypothyroidism

Ongoing? ○Yes ○No

☐F5. Polycystic Ovary Syndrome

Ongoing? ○Yes ○No

☐F6. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐F7. None

Mental Health

☐F8. Depression

Ongoing? ○Yes ○No

☐F9. Bipolar

Ongoing? ○Yes ○No

☐F10. Anxiety

Ongoing? ○Yes ○No

☐F11. Schizophrenia

Ongoing? ○Yes ○No

☐F12. Obsessive Compulsive Disorder

Ongoing? ○Yes ○No

☐F13. Eating disorder

Ongoing? ○Yes ○No

☐F14. Post-traumatic stress syndrome

Ongoing? ○Yes ○No

☐F15. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐F16. None

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Hepatic/Cancer/Eye
Subtitle:

Hepatic

☐G1. Jaundice

Ongoing? ○Yes ○No

☐G2. Cirrhosis

Ongoing? ○Yes ○No

☐G3. Fatty Liver Disease

Ongoing? ○Yes ○No

☐G4. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐G5. None

Cancer

☐G6. Head/Neck Cancer

Ongoing? ○Yes ○No

☐G7. Renal/Urinary Tract Cancer

Ongoing? ○Yes ○No

☐G8. Leukemia/Lymphoma

Ongoing? ○Yes ○No

☐G9. Solid Tumor

Ongoing? ○Yes ○No

☐G10. Other

Ongoing? ○Yes ○No

☐G11. None

Eye

☐G12. Conjunctivitis

Ongoing? ○Yes ○No

☐G13. Cataract

Ongoing? ○Yes ○No

☐G14. Cataract Removal

Ongoing? ○Yes ○No

☐G15. Vitrectomy

Ongoing? ○Yes ○No

☐G16. Retinopathy

Ongoing? ○Yes ○No

☐G17. Laser Therapy

Ongoing? ○Yes ○No

☐G18. Blindness

Ongoing? ○Yes ○No

☐G19. Glaucoma

Ongoing? ○Yes ○No

☐G20. Myopia

Ongoing? ○Yes ○No

☐G21. Hyperopia

Ongoing? ○Yes ○No

☐G22. Macular Degeneration

Ongoing? ○Yes ○No

☐G23. Other

If Other, Specify:

Ongoing? ○Yes ○No

☐G24. None

Date of Last Eye Exam:

☐Never Examined

☐Eye Exam Date Unknown

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Hospitalizations/Allergies/Pregnancies

Allergies

H1. Do you have any food, drug or environmental allergies?
- ○ Yes
- ○ No
- ○ Unknown

List allergens:

Pregnancies

H2. Has participant ever been pregnant?
- ○ Yes
- ○ No
- ○ NA

Number of pregnancies:

Number of live births:

Hospitalizations

H3. Has the participant had any Hospitalizations in the last 5 years requiring overnight stay?
- ○ Yes
- ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Hospitalizations Log

Reason:	If Other or non-elective surgery, specify:	Month:	Year:	Length of Stay (days):
○ Elective Surgery		○ January		
○ Cardiovascular		○ February		
○ Diabetes		○ March		
○ Renal		○ April		
○ Accident		○ May		
○ Non-Elective Surgery		○ June		
○ Pulmonary		○ July		
○ Psychiatric		○ August		
○ Other		○ September		
		○ October		
		○ November		
		○ December		

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○Yes ○No

C1. Serum Collected ○Yes ○No Date Collected

C2. Plasma Collected ○Yes ○No Date Collected

C3. Urine Collected ○Yes ○No Date Collected

C3a. Protease Inhibitor Added ○Yes ○No

C4. *Shipped to ARDL* ○Yes ○No Date Shipped

Visit 4a:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_007_Physical Examination - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_009_ECG Report - V1.0
PERL_010A_Central Lab Specimen Collection - V5.0
PERL_019_iGFR Procedures Form - V3.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_014_Family History - V1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_007_Physical Examination - V1.0

Section Title: Body System

A0. Was a physical exam performed at this visit?
- ○ Yes
- ○ No

Upload source documents:

A1. Eyes:
Eyes (including fundoscopy):
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Retinopathy
- ☐ Macular Degeneration
- ☐ Other

If other, specify:

A2. Cardiovascular:
Cardiovascular:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Arrhythmia
- ☐ Murmur
- ☐ Other

If other, specify:

A3. Extremities:
Extremities:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Amputation

Amputation, specify:
- ☐ Tenderness
- ☐ Edema
- ☐ Pulses

Pulses:
- ○ 0+
- ○ 1+
- ○ 2+
- ○ 3+
- ○ 4+
- ☐ Other

If other, specify:

A4. Lymph Nodes:
Lymph Nodes:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Swelling
- ☐ Other

If other, specify:

A5. Pulmonary:
Pulmonary:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Reduced breath sounds
- ☐ Other

If other, specify:

A6. Skin:
Skin:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Red or purple painful rash
- ☐ Scar
- ☐ Eczema
- ☐ Psoriasis
- ☐ Ulcers
- ☐ Excessive Bruising
- ☐ Other

If other, specify:

A7. Gastrointestinal:
Gastrointestinal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Ascites
- ☐ Abdominal Mass
- ☐ Organomegaly

Organomegaly, specify:
- ☐ Stoma
- ☐ Other

If other, specify:

A8. Musculoskeletal
Musculoskeletal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Stiffness

☐ Tenderness

☐ Injury

Injury, specify:

☐ Reduced strength

☐ Reduced range of motion

☐ Other

If other, specify:

A9. Genitourinary:

Genitourinary: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Specify:

A10. Neurological:

Neurological: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Abnormal Reflex Response

Abnormal reflex response, specify: ○ Hyperflexia
○ Hypoflexia

☐ Diminished sensation

☐ Cranial Nerves

Abnormal, specify:

☐ Other

If other, specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Other Body System

Other Body System

A11. Other Body System:	Describe

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_009_ECG Report - V1.0

Section Title: ECG Report

ECG Completed? *
- ○ Completed
- ○ Not Completed

Upload Source Document:

A1. Date of ECG:

A2. Heart Rate: (bpm)

A3. ECG Findings:
- ○ Normal
- ○ Abnormal

A3a. If abnormal (select all that apply):
- ☐ ST Elevation
- ☐ Atrial Fib
- ☐ T Inversion
- ☐ Q Wave
- ☐ AV Block
- ☐ MI Changes
- ☐ Tachycardia
- ☐ Bradycardia
- ☐ Other

If Other, Specify:

A3b. Is this abnormality clinically significant?
- ○ Yes **** If yes, report on AE Log**
- ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010A_Central Lab Specimen Collection - V5.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum for Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A3. HLA B*5810 Collected	○ Yes ○ No	Date Collected
A4. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected ○ Yes ○ No

Overnight ○ Yes ○ No Date Ended Collection

First Morning ○ Yes ○ No Date Collected

Spot Urine ○ Yes ○ No Date Collected

B2. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_019_iGFR Procedures Form - V3.0

Section Title: I. iGFR Procedure

Upload source documents:

A1. Was the iGFR Performed?

Please Select:
- ○ Yes
- ○ No

If No, Reason:
(check all that apply)
- ☐ UTI
- ☐ BP too high
- ☐ Positive pregnancy test
- ☐ Hyperglycemia
- ☐ Hypoglycemia
- ☐ Vomiting
- ☐ Febrile
- ☐ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: II. iGFR Draw Times

A2. Date of iGFR:
Date of iGFR:

A3. iGFR Collections:
Start clock at end of Omnipaque injection* (No Sample) "0" time 00:00

A4. 120 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A5. 150 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A6. 180 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A7. 210 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A8. 240 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A9. Samples shipped to central lab?

Please Select: ☐ Yes ☐ No Date Samples Shipped:

A10. Backup samples shipped to central lab?

Please Select: ☐ Yes ☐ No ☐ NA Date Backup Samples Shipped:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: ____________________
Event Name: Visit 4a
Event Date: ____________________

Study Subject ID:___________
Study Subject DOB:___________

PERL_014_Family History - V1.0

Section Title: Section A. Mother/Father/Grandparents

Please complete the chart for Mother, Father, Maternal Grandmother and Grandfather and Paternal Grandmother and Grandfather.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Brothers

Please complete the chart for all full biological brothers.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Brother1	○ Alive	○ Cardiovascular		□ No History	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	
○ Brother2	○ Deceased	○ Cancer			○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	
○ Brother3	○ Unknown	○ Accident			○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	
○ Brother4		○ Other												
○ Brother5		○ Unknown												
○ Brother6														
○ Brother7														
○ Brother8														
○ Brother9														
○ Brother10														
○ Brother11														
○ Brother12														
○ Brother13														
○ Brother14														
○ Brother15														

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Sisters

Please complete the chart for all full biological sisters.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Sister1	○ Alive	○ Cardiovascular		☐ No History	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	
○ Sister2	○ Deceased	○ Cancer			○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	
○ Sister3	○ Unknown	○ Accident			○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	
○ Sister4		○ Other												
○ Sister5		○ Unknown												
○ Sister6														
○ Sister7														
○ Sister8														
○ Sister9														
○ Sister10														
○ Sister11														
○ Sister12														
○ Sister13														
○ Sister14														
○ Sister15														

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 4a
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Children

Please complete the chart for all full biological children.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Son 1	○ Alive	○ Cardiovascular		☐ No History	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	
○ Son 2	○ Deceased	○ Cancer			○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	
○ Son 3	○ Unknown	○ Accident			○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	
○ Son 4		○ Other												
○ Son 5		○ Unknown												
○ Son 6														
○ Son 7														
○ Son 8														
○ Son 9														
○ Son 10														
○ Daughter 1														
○ Daughter 2														
○ Daughter 3														
○ Daughter 4														
○ Daughter 5														
○ Daughter 6														
○ Daughter 7														
○ Daughter 8														
○ Daughter 9														
○ Daughter 10														

Eligibility Randomization:

PERL_001R_Eligibility_Randomization - V3.0
PERL_015_Exemption Request - V2.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Eligibility Randomization
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_001R_Eligibility_Randomization - V3.0

Section Title: Inclusion

A2. Valid baseline (Visit 4) iGFR measurement.
* ○ Yes ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Eligibility Randomization
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Exclusion

B6. HLA B*58:01 genotype indicating increased risk of Stevens-Johnson syndrome in response to allopurinol.
* ○ Yes ○ No ○ Not Done

B10. SBP>150 or DBP>95mmHg at the end of the Run-In period.
* ○ Yes ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Eligibility Randomization
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Eligibility

If any Inclusion Criteria are 'No' or if any Exclusion Criteria are 'Yes', the participant is not eligible.

C1. Subject is: *
- ○ Eligible for Randomization
- ○ Ineligible for Randomization
- ○ Eligible for Randomization by Exemption

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Eligibility Randomization
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_015_Exemption Request - V2.0

Section Title: Exemption Request

Instructions:
Completion of items A1-A3 will send an email to the Exemption Review Committee.
Please enter relevant details into A3 below. This is required in order to send the alert and for the Exemption Committee to make a decision.

A1. Select Inclusion criteria not met:

Select criteria for review:
- ○ Male or female between 18 and 70 years of age
- ○ T1D diagnosed after age 35 and additional criteria not met
- ○ Continuously treated with insulin within one year of T1D diagnosis
- ○ Duration of T1D ≥ 8 years
- ○ History or presence of microalbuminuria or moderate macroalbuminuria or evidence of declining kidney function according to the specific protocol requirements
- ○ Estimated GFR between 40 and 99.9 ml/min/1.73 m2. The upper limit should be decreased by 1 ml/min/1.73 m2 for each year over age 60
- ○ Serum UA ≥ 4.5 mg/dl at the screening visit

A2. Select Exclusion criteria violated:

Select criteria for review:
- ○ History of gout requiring allopurinol therapy or xanthinuria or other indications for uric acid lowering therapy such as cancer chemotherapy or extremely high serum uric acid values (>12 mg/dl)
- ○ Recurrent renal calculi (history of more than 1 episode)
- ○ Use of urate-lowering agents within 3 months prior to screening
- ○ Current use of drugs known to interact with allopurinol
- ○ Known allergy to xanthine-oxidase inhibitors or iodine containing substances
- ○ Non-diabetic kidney disease as indicated by medical history and/or laboratory findings
- ○ SBP>160 or DBP >100mmHg at screening
- ○ SBP>150 or DBP >95mmHg at the end of the run-in period
- ○ Cancer treatment within two years before screening
- ○ Hemoglobin concentration <11 _tmpItem="2513" g/dL (males) or <10 g/dL (females) at screening
- ○ Platelet count <100000/mm3
- ○ Ongoing alcohol or drug abuse or history of treatment for these conditions in the past 6 months
- ○ Blood donation in the 3 months before screening
- ○ Serious pre-existing medical problems (except T1D)
- ○ Other

If Other, Specify:

A3. Reason this participant should be considered for the study:

Please Provide: *

A4. Exemption Granted?

Please Select One:
- ○ Yes
- ○ No

A4a. If No, Reason:

A5. Date of Decision

Date:

Visit 5 - V6:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V2.0
PERL_014_Family History - V1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

☐ Visit 1
☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V2.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit: ○ ºC ○ ºF ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles

A3. During assessment was any mucous membrane involvement noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: ____________________
Event Name: Visit 5 - V6
Event Date: ____________________

Study Subject ID:___________
Study Subject DOB:___________

PERL_014_Family History - V1.0

Section Title: Section A. Mother/Father/Grandparents

Please complete the chart for Mother, Father, Maternal Grandmother and Grandfather and Paternal Grandmother and Grandfather.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	
○ Mother ○ Maternal Grandmother ○ Maternal Grandfather ○ Father ○ Paternal Grandmother ○ Paternal Grandfather	○ Alive ○ Deceased ○ Unknown	○ Cardiovascular ○ Cancer ○ Accident ○ Other ○ Unknown		☐ No History	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	○ Yes ○ No ○ Unknown	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Brothers

Please complete the chart for all full biological brothers.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Brother1	○ Alive	○ Cardiovascular		□ No History	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	
○ Brother2	○ Deceased	○ Cancer			○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	
○ Brother3	○ Unknown	○ Accident			○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	
○ Brother4		○ Other												
○ Brother5		○ Unknown												
○ Brother6														
○ Brother7														
○ Brother8														
○ Brother9														
○ Brother10														
○ Brother11														
○ Brother12														
○ Brother13														
○ Brother14														
○ Brother15														

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Sisters

Please complete the chart for all full biological sisters.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Sister1	○ Alive	○ Cardiovascular		☐ No History	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	
○ Sister2	○ Deceased	○ Cancer			○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	
○ Sister3	○ Unknown	○ Accident			○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	
○ Sister4		○ Other												
○ Sister5		○ Unknown												
○ Sister6														
○ Sister7														
○ Sister8														
○ Sister9														
○ Sister10														
○ Sister11														
○ Sister12														
○ Sister13														
○ Sister14														
○ Sister15														

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 - V6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Children

Please complete the chart for all full biological children.

Relative:	Alive/Deceased:	If Deceased, cause of death:	If Other, Specify:	No History:	Hypertension:	Heart Attack:	Stroke:	Type II Diabetes:	Type I Diabetes:	Obesity:	Hyperlipidemia:	Kidney Disease:	End Stage Renal Disease	Other:
○ Son 1	○ Alive	○ Cardiovascular		☐ No History	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	○ Yes	
○ Son 2	○ Deceased	○ Cancer			○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	○ No	
○ Son 3	○ Unknown	○ Accident			○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	○ Unknown	
○ Son 4		○ Other												
○ Son 5		○ Unknown												
○ Son 6														
○ Son 7														
○ Son 8														
○ Son 9														
○ Son 10														
○ Daughter 1														
○ Daughter 2														
○ Daughter 3														
○ Daughter 4														
○ Daughter 5														
○ Daughter 6														
○ Daughter 7														
○ Daughter 8														
○ Daughter 9														
○ Daughter 10														

Visit 5 Call - V7:

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 5 Call - V7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_021_Telephone_Visit - V1.0

Section Title: Telephone Visit

A0. Was contact made with the participant via telephone?
* ○ Yes ○ No

A1. If No, reason for no contact:
☐ Phone number no longer valid
☐ No response from participant after multiple contact attempts
☐ Participant no longer interested in participating in the study
☐ Participant moved
☐ Other If Other, Specify

A2. Date of Contact

A3. Is subject eligible to continue in the study?
○ Yes
○ No

A4. Were any AE's identified when speaking with subject?
○ Yes
○ No

A5. Was participant randomized immediately after the telephone visit?
○ Yes
○ No

A6. Was study medication prescription sent to the Study Pharmacy?
○ Yes
○ No

Visit 6:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit:
- ○ ºC
- ○ ºF
- ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes ○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:
*
- ○ Yes
- ○ No
- ○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:
*
- ○ Subject did not return pills
- ○ Pills were thrown away
- ○ Pills were lost
- ○ Start date and/or Stop date unknown
- ○ Not applicable
- ○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 6
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Visit 7:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_007_Physical Examination - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_009_ECG Report - V1.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_019_iGFR Procedures Form - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_007_Physical Examination - V1.0

Section Title: Body System

A0. Was a physical exam performed at this visit?
- ○ Yes
- ○ No

Upload source documents:

A1. Eyes:
Eyes (including fundoscopy):
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Retinopathy
- ☐ Macular Degeneration
- ☐ Other

If other, specify:

A2. Cardiovascular:
Cardiovascular:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Arrhythmia
- ☐ Murmur
- ☐ Other

If other, specify:

A3. Extremities:
Extremities:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Amputation

Amputation, specify:
- ☐ Tenderness
- ☐ Edema
- ☐ Pulses

Pulses:
- ○ 0+
- ○ 1+
- ○ 2+
- ○ 3+
- ○ 4+
- ☐ Other

If other, specify:

A4. Lymph Nodes:
Lymph Nodes:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Swelling
- ☐ Other

If other, specify:

A5. Pulmonary:
Pulmonary:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Reduced breath sounds
- ☐ Other

If other, specify:

A6. Skin:
Skin:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Red or purple painful rash
- ☐ Scar
- ☐ Eczema
- ☐ Psoriasis
- ☐ Ulcers
- ☐ Excessive Bruising
- ☐ Other

If other, specify:

A7. Gastrointestinal:
Gastrointestinal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Ascites
- ☐ Abdominal Mass
- ☐ Organomegaly

Organomegaly, specify:
- ☐ Stoma
- ☐ Other

If other, specify:

A8. Musculoskeletal
Musculoskeletal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Stiffness

☐ Tenderness

☐ Injury

Injury, specify:

☐ Reduced strength

☐ Reduced range of motion

☐ Other

If other, specify:

A9. Genitourinary:

Genitourinary: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Specify:

A10. Neurological:

Neurological: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Abnormal Reflex Response

Abnormal reflex response, specify: ○ Hyperflexia
○ Hypoflexia

☐ Diminished sensation

☐ Cranial Nerves

Abnormal, specify:

☐ Other

If other, specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Other Body System

Other Body System

A11. Other Body System:	Describe

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_009_ECG Report - V1.0

Section Title: ECG Report

ECG Completed? *
- ○ Completed
- ○ Not Completed

Upload Source Document:

A1. Date of ECG:

A2. Heart Rate: (bpm)

A3. ECG Findings:
- ○ Normal
- ○ Abnormal

A3a. If abnormal (select all that apply):
- ☐ ST Elevation
- ☐ Atrial Fib
- ☐ T Inversion
- ☐ Q Wave
- ☐ AV Block
- ☐ MI Changes
- ☐ Tachycardia
- ☐ Bradycardia
- ☐ Other

If Other, Specify:

A3b. Is this abnormality clinically significant?
- ○ Yes **** If yes, report on AE Log**
- ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit:
- ○ ºC
- ○ ºF
- ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_019_iGFR Procedures Form - V3.0

Section Title: I. iGFR Procedure

Upload source documents:

A1. Was the iGFR Performed?

Please Select:
- ○ Yes
- ○ No

If No, Reason:
(check all that apply)
- ☐ UTI
- ☐ BP too high
- ☐ Positive pregnancy test
- ☐ Hyperglycemia
- ☐ Hypoglycemia
- ☐ Vomiting
- ☐ Febrile
- ☐ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: II. iGFR Draw Times

A2. Date of iGFR:
Date of iGFR:

A3. iGFR Collections:
Start clock at end of Omnipaque injection* (No Sample) "0" time 00:00

A4. 120 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A5. 150 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A6. 180 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A7. 210 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A8. 240 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A9. Samples shipped to central lab?

Please Select: ○ Yes ○ No | Date Samples Shipped:

A10. Backup samples shipped to central lab?

Please Select: ○ Yes ○ No ○ NA | Date Backup Samples Shipped:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes
○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:
*
- ○ Yes
- ○ No
- ○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:
*
- ○ Subject did not return pills
- ○ Pills were thrown away
- ○ Pills were lost
- ○ Start date and/or Stop date unknown
- ○ Not applicable
- ○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 7
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Visit 8:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

☐ Visit 1
☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit:
- ○ ºC
- ○ ºF
- ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes
○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:
*
- ○ Yes
- ○ No
- ○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:
*
- ○ Subject did not return pills
- ○ Pills were thrown away
- ○ Pills were lost
- ○ Start date and/or Stop date unknown
- ○ Not applicable
- ○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 8
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Visit 9:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

☐ Visit 1
☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: * ○ Participant Self-Assessment ○ Clinician Assessment

Was any rash present during the assessment?
* ○ Yes ○ No ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select: ○ Yes ○ No ○ Not Assessed

Select all that apply:

Fever
☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit: ○ ºC ○ ºF ☐ Unknown temperature

Skin tenderness
☐ Skin tenderness

Sore throat
☐ Sore throat

Photophobia
☐ Photophobia

Burning eyes
☐ Burning eyes

Itching eyes
☐ Itching eyes

Cough productive of thick and purulent sputum
☐ Cough

Headache
☐ Headache

Malaise
☐ Malaise

Arthralgia
☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select: ○ Yes ○ No ○ Not Assessed

Select all that apply:

Burning rash
☐ Burning rash

Skin pain
☐ Skin pain

Facial swelling
☐ Facial swelling

Tongue swelling
☐ Tongue swelling

Red or purple skin rash
☐ Red or purple skin rash

Area of rash (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Target lesions surrounded by macular erythema
☐ Target lesions

Hives
☐ Hives

Area of hives (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Blisters
☐ Blisters

Area of blisters (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Genitals ☐ Anal
☐ Back

Shedding
☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Denuded skin areas
☐ Denuded skin areas

Area of denudation (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes
○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)

Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)

Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)

Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:

* ○ Yes
○ No
○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)

Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)

Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:

* ○ Subject did not return pills
○ Pills were thrown away
○ Pills were lost
○ Start date and/or Stop date unknown
○ Not applicable
○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 9
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Visit 10:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit:
- ○ ºC
- ○ ºF
- ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes
○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:
*
- ○ Yes
- ○ No
- ○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:
*
- ○ Subject did not return pills
- ○ Pills were thrown away
- ○ Pills were lost
- ○ Start date and/or Stop date unknown
- ○ Not applicable
- ○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 10
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Visit 11:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_007_Physical Examination - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_009_ECG Report - V1.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_019_iGFR Procedures Form - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_007_Physical Examination - V1.0

Section Title: Body System

A0. Was a physical exam performed at this visit?
- ○ Yes
- ○ No

Upload source documents:

A1. Eyes:

Eyes (including fundoscopy):
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Retinopathy
- ☐ Macular Degeneration
- ☐ Other

If other, specify:

A2. Cardiovascular:

Cardiovascular:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Arrhythmia
- ☐ Murmur
- ☐ Other

If other, specify:

A3. Extremities:

Extremities:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Amputation

Amputation, specify:
- ☐ Tenderness
- ☐ Edema
- ☐ Pulses

Pulses:
- ○ 0+
- ○ 1+
- ○ 2+
- ○ 3+
- ○ 4+
- ☐ Other

If other, specify:

A4. Lymph Nodes:

Lymph Nodes:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Swelling
- ☐ Other

If other, specify:

A5. Pulmonary:

Pulmonary:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Reduced breath sounds
- ☐ Other

If other, specify:

A6. Skin:

Skin:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Red or purple painful rash
- ☐ Scar
- ☐ Eczema
- ☐ Psoriasis
- ☐ Ulcers
- ☐ Excessive Bruising
- ☐ Other

If other, specify:

A7. Gastrointestinal:

Gastrointestinal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply:
- ☐ Ascites
- ☐ Abdominal Mass
- ☐ Organomegaly

Organomegaly, specify:
- ☐ Stoma
- ☐ Other

If other, specify:

A8. Musculoskeletal

Musculoskeletal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Stiffness

☐ Tenderness

☐ Injury

Injury, specify:

☐ Reduced strength

☐ Reduced range of motion

☐ Other

If other, specify:

A9. Genitourinary:

Genitourinary: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Specify:

A10. Neurological:

Neurological: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Abnormal Reflex Response

Abnormal reflex response, specify: ○ Hyperflexia
○ Hypoflexia

☐ Diminished sensation

☐ Cranial Nerves

Abnormal, specify:

☐ Other

If other, specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Other Body System

Other Body System

A11. Other Body System:	Describe

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_009_ECG Report - V1.0

Section Title: ECG Report

ECG Completed? *
- ○ Completed
- ○ Not Completed

Upload Source Document:

A1. Date of ECG:

A2. Heart Rate: (bpm)

A3. ECG Findings:
- ○ Normal
- ○ Abnormal

A3a. If abnormal (select all that apply):
- ☐ ST Elevation
- ☐ Atrial Fib
- ☐ T Inversion
- ☐ Q Wave
- ☐ AV Block
- ☐ MI Changes
- ☐ Tachycardia
- ☐ Bradycardia
- ☐ Other

If Other, Specify:

A3b. Is this abnormality clinically significant?
- ○ Yes **** If yes, report on AE Log**
- ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: * ○ Participant Self-Assessment ○ Clinician Assessment

Was any rash present during the assessment?
* ○ Yes ○ No ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select: ○ Yes ○ No ○ Not Assessed

Select all that apply:

Fever
☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit: ○ ºC ○ ºF ☐ Unknown temperature

Skin tenderness
☐ Skin tenderness

Sore throat
☐ Sore throat

Photophobia
☐ Photophobia

Burning eyes
☐ Burning eyes

Itching eyes
☐ Itching eyes

Cough productive of thick and purulent sputum
☐ Cough

Headache
☐ Headache

Malaise
☐ Malaise

Arthralgia
☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select: ○ Yes ○ No ○ Not Assessed

Select all that apply:

Burning rash
☐ Burning rash

Skin pain
☐ Skin pain

Facial swelling
☐ Facial swelling

Tongue swelling
☐ Tongue swelling

Red or purple skin rash
☐ Red or purple skin rash

Area of rash (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Target lesions surrounded by macular erythema
☐ Target lesions

Hives
☐ Hives

Area of hives (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Blisters
☐ Blisters

Area of blisters (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Genitals ☐ Anal
☐ Back

Shedding
☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Denuded skin areas
☐ Denuded skin areas

Area of denudation (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_019_iGFR Procedures Form - V3.0

Section Title: I. iGFR Procedure

Upload source documents:

A1. Was the iGFR Performed?

Please Select:
- ○ Yes
- ○ No

If No, Reason:
(check all that apply)
- ☐ UTI
- ☐ BP too high
- ☐ Positive pregnancy test
- ☐ Hyperglycemia
- ☐ Hypoglycemia
- ☐ Vomiting
- ☐ Febrile
- ☐ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: II. iGFR Draw Times

A2. Date of iGFR:
Date of iGFR:

A3. iGFR Collections:
Start clock at end of Omnipaque injection* (No Sample) "0" time 00:00

A4. 120 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A5. 150 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A6. 180 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A7. 210 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A8. 240 minutes

Projected draw time for sample: Actual draw time of sample (24 hour clock): (00:00) Glucose value (mg/dl) ☐ Not Done

A9. Samples shipped to central lab?

Please Select: ☐ Yes ☐ No Date Samples Shipped:

A10. Backup samples shipped to central lab?

Please Select: ☐ Yes ☐ No ☐ NA Date Backup Samples Shipped:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes
○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:
*
- ○ Yes
- ○ No
- ○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:
*
- ○ Subject did not return pills
- ○ Pills were thrown away
- ○ Pills were lost
- ○ Start date and/or Stop date unknown
- ○ Not applicable
- ○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 11
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Visit 12:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit:
- ○ ºC
- ○ ºF
- ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes ○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:
*
- ○ Yes
- ○ No
- ○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:
*
- ○ Subject did not return pills
- ○ Pills were thrown away
- ○ Pills were lost
- ○ Start date and/or Stop date unknown
- ○ Not applicable
- ○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 12
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Visit 13:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: * ○ Participant Self-Assessment ○ Clinician Assessment

Was any rash present during the assessment?
* ○ Yes ○ No ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select: ○ Yes ○ No ○ Not Assessed

Select all that apply:

Fever
☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit: ○ ºC ○ ºF ☐ Unknown temperature

Skin tenderness
☐ Skin tenderness

Sore throat
☐ Sore throat

Photophobia
☐ Photophobia

Burning eyes
☐ Burning eyes

Itching eyes
☐ Itching eyes

Cough productive of thick and purulent sputum
☐ Cough

Headache
☐ Headache

Malaise
☐ Malaise

Arthralgia
☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select: ○ Yes ○ No ○ Not Assessed

Select all that apply:

Burning rash
☐ Burning rash

Skin pain
☐ Skin pain

Facial swelling
☐ Facial swelling

Tongue swelling
☐ Tongue swelling

Red or purple skin rash
☐ Red or purple skin rash

Area of rash (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Target lesions surrounded by macular erythema
☐ Target lesions

Hives
☐ Hives

Area of hives (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Blisters
☐ Blisters

Area of blisters (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Genitals ☐ Anal
☐ Back

Shedding
☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Denuded skin areas
☐ Denuded skin areas

Area of denudation (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes
○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:
*
- ○ Yes
- ○ No
- ○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:
*
- ○ Subject did not return pills
- ○ Pills were thrown away
- ○ Pills were lost
- ○ Start date and/or Stop date unknown
- ○ Not applicable
- ○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 13
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Visit 14:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

☐ Visit 1
☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit:
- ○ ºC
- ○ ºF
- ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes
○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:
*
- ○ Yes
- ○ No
- ○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:
*
- ○ Subject did not return pills
- ○ Pills were thrown away
- ○ Pills were lost
- ○ Start date and/or Stop date unknown
- ○ Not applicable
- ○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 14
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Visit 15:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

- ☐ Visit 1
- ☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit:
- ○ ºC
- ○ ºF
- ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes ○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:
*
- ○ Yes
- ○ No
- ○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:
*
- ○ Subject did not return pills
- ○ Pills were thrown away
- ○ Pills were lost
- ○ Start date and/or Stop date unknown
- ○ Not applicable
- ○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 15
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

*

☐Confirm form is complete and source document uploaded.

Visit 16:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_007_Physical Examination - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_009_ECG Report - V1.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_019_iGFR Procedures Form - V3.0
PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_007_Physical Examination - V1.0

Section Title: Body System

A0. Was a physical exam performed at this visit?
- ○ Yes
- ○ No

Upload source documents:

A1. Eyes:
Eyes (including fundoscopy):
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Retinopathy
- ☐ Macular Degeneration
- ☐ Other

If other, specify:

A2. Cardiovascular:
Cardiovascular:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Arrhythmia
- ☐ Murmur
- ☐ Other

If other, specify:

A3. Extremities:
Extremities:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Amputation

Amputation, specify:
- ☐ Tenderness
- ☐ Edema
- ☐ Pulses

Pulses:
- ○ 0+
- ○ 1+
- ○ 2+
- ○ 3+
- ○ 4+
- ☐ Other

If other, specify:

A4. Lymph Nodes:
Lymph Nodes:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Swelling
- ☐ Other

If other, specify:

A5. Pulmonary:
Pulmonary:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Reduced breath sounds
- ☐ Other

If other, specify:

A6. Skin:
Skin:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Red or purple painful rash
- ☐ Scar
- ☐ Eczema
- ☐ Psoriasis
- ☐ Ulcers
- ☐ Excessive Bruising
- ☐ Other

If other, specify:

A7. Gastrointestinal:
Gastrointestinal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Ascites
- ☐ Abdominal Mass
- ☐ Organomegaly

Organomegaly, specify:
- ☐ Stoma
- ☐ Other

If other, specify:

A8. Musculoskeletal
Musculoskeletal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Stiffness

☐ Tenderness

☐ Injury

Injury, specify:

☐ Reduced strength

☐ Reduced range of motion

☐ Other

If other, specify:

A9. Genitourinary:

Genitourinary: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Specify:

A10. Neurological:

Neurological: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Abnormal Reflex Response

Abnormal reflex response, specify: ○ Hyperflexia
○ Hypoflexia

☐ Diminished sensation

☐ Cranial Nerves

Abnormal, specify:

☐ Other

If other, specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Other Body System

Other Body System

A11. Other Body System:	Describe

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

☐ Visit 1
☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_009_ECG Report - V1.0

Section Title: ECG Report

ECG Completed? *
- ○ Completed
- ○ Not Completed

Upload Source Document:

A1. Date of ECG:

A2. Heart Rate: (bpm)

A3. ECG Findings:
- ○ Normal
- ○ Abnormal

A3a. If abnormal (select all that apply):
- ☐ ST Elevation
- ☐ Atrial Fib
- ☐ T Inversion
- ☐ Q Wave
- ☐ AV Block
- ☐ MI Changes
- ☐ Tachycardia
- ☐ Bradycardia
- ☐ Other

If Other, Specify:

A3b. Is this abnormality clinically significant?
- ○ Yes **** If yes, report on AE Log**
- ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○Yes ○No

C1. Serum Collected ○Yes ○No Date Collected

C2. Plasma Collected ○Yes ○No Date Collected

C3. Urine Collected ○Yes ○No Date Collected

C3a. Protease Inhibitor Added ○Yes ○No

C4. *Shipped to ARDL* ○Yes ○No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit:
- ○ ºC
- ○ ºF
- ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_019_iGFR Procedures Form - V3.0

Section Title: I. iGFR Procedure

Upload source documents:

A1. Was the iGFR Performed?

Please Select:
- ○ Yes
- ○ No

If No, Reason:
(check all that apply)
- ☐ UTI
- ☐ BP too high
- ☐ Positive pregnancy test
- ☐ Hyperglycemia
- ☐ Hypoglycemia
- ☐ Vomiting
- ☐ Febrile
- ☐ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: II. iGFR Draw Times

A2. Date of iGFR:
Date of iGFR:

A3. iGFR Collections:
Start clock at end of Omnipaque injection* (No Sample) "0" time 00:00

A4. 120 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A5. 150 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A6. 180 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A7. 210 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A8. 240 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A9. Samples shipped to central lab?

Please Select: ○ Yes ○ No | Date Samples Shipped:

A10. Backup samples shipped to central lab?

Please Select: ○ Yes ○ No ○ NA | Date Backup Samples Shipped:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes
○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)

Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)

Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)

Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:

* ○ Yes
○ No
○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)

Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)

Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:

* ○ Subject did not return pills
○ Pills were thrown away
○ Pills were lost
○ Start date and/or Stop date unknown
○ Not applicable
○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 16
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Visit 17:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_019_iGFR Procedures Form - V3.0
PERL_023F_Follow Up_Complication Questionnaire - 1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done
B5a. Neutrophils:	(%)	☐ Not Done	
B5b. Lymphocytes:	(%)	☐ Not Done	
B5c. Monocytes:	(%)	☐ Not Done	
B5d. Eosinophils:	(%)	☐ Not Done	
B5e. Basophils:	(%)	☐ Not Done	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

☐ Visit 1
☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit:
- ○ ºC
- ○ ºF
- ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_019_iGFR Procedures Form - V3.0

Section Title: I. iGFR Procedure

Upload source documents:

A1. Was the iGFR Performed?

Please Select:
- ○ Yes
- ○ No

If No, Reason:
(check all that apply)
- ☐ UTI
- ☐ BP too high
- ☐ Positive pregnancy test
- ☐ Hyperglycemia
- ☐ Hypoglycemia
- ☐ Vomiting
- ☐ Febrile
- ☐ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: II. iGFR Draw Times

A2. Date of iGFR:
Date of iGFR:

A3. iGFR Collections:
Start clock at end of Omnipaque injection* (No Sample) "0" time 00:00

A4. 120 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A5. 150 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A6. 180 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A7. 210 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A8. 240 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A9. Samples shipped to central lab?

Please Select: ○ Yes ○ No | Date Samples Shipped:

A10. Backup samples shipped to central lab?

Please Select: ○ Yes ○ No ○ NA | Date Backup Samples Shipped:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_023F_Follow Up_Complication Questionnaire - 1.0

Section Title: Initial

Instructions: The PERL_023_Initial Complications Questionnaire should be completed prior to completing the PERL_023_Follow Up Complications Questionnaire. If the subject has progressed to visit 17 prior to implementation of this form, complete only the PERL_023_Initial Complications Questionnaire.

A1. Was the PERL_023_Initial Complications Questionnaire completed?

* ○ Yes
○ No-Complete the Initial form prior to completion of the follow up form

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: CHF

B1. Select one of the following that best reflects your current health status:

*

- ○ I have no limitation of my physical activity. Ordinary physical activity does not cause me undue fatigue, palpitation (irregular or strong heart beat sensations), or shortness of breath.
- ○ I have slight limitation of physical activity. I am comfortable at rest, however ordinary physical activity causes me fatigue, palpitation (irregular or strong heart beat sensations), or shortness of breath.
- ○ I have marked limitation of physical activity. I am comfortable at rest, however less than ordinary activity causes fatigue, palpitation (irregular or strong heart beat sensations), or shortness of breath.
- ○ I am unable to carry on any physical activity without discomfort. I have symptoms of symptoms of heart failure at rest. If any physical activity is undertaken, my discomfort increases.

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Visit 17
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Neuropathy

Peripheral Neuropathy Symptoms
In the questions below, please select the best answer that reflects your current health status.
D3. Are your feet and/or legs numb?
*
○ Yes
○ No

D4. Do you ever have any burning pain in your legs and/or feet?
*
○ Yes
○ No

D5. Are your symptoms worse at night?
*
○ Yes
○ No

D6. Does it hurt when the bed covers touch your skin?
*
○ Yes
○ No

Autonomic neuropathy (SAS)
In the questions below, please select the best answer that reflects your current health status.
D7. Do you have light headedness?
*
○ Yes
○ No

D8. Do you have a dry mouth or dry eyes?
*
○ Yes
○ No

D9. Are your feet pale or blue?
*
○ Yes
○ No

D10. Are your feet colder than the rest of your body?
*
○ Yes
○ No

D11. Is sweating in your feet decreased or absent (for example, after exercise or during hot weather)?
*
○ Yes
○ No

D12. Is sweating in your hands increased compared to the rest of your body?
*
○ Yes
○ No

D13. Do you have nausea, vomiting or bloating after eating a small meal?
*
○ Yes
○ No

D14. Do you have persistent diarrhea (more than 3 loose bowel movements per day)?
*
○ Yes
○ No

D15. Do you have persistent constipation (less than 1 bowel movement every other day)?
*
○ Yes
○ No

D16. Do you have leaking of urine?
*
○ Yes
○ No

D17. Do you have difficulty obtaining an erection?
*
○ Yes
○ No
○ Female

Unscheduled Visit:

PERL_006_Blood Pressure and Measurements - V1.0
PERL_007_Physical Examination - V1.0
PERL_008_Local Laboratory Results - V5.0
PERL_009_ECG Report - V1.0
PERL_010 Central Lab Specimen Collection - V4.0
PERL_011_Skin Assessment - V3.0
PERL_019_iGFR Procedures Form - V3.0
PERL_025 Unscheduled Visit Reason - V1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - V1.0

Section Title: Blood Pressure and Heart Rate
Subtitle:

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading

B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading

B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading

B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_007_Physical Examination - V1.0

Section Title: Body System

A0. Was a physical exam performed at this visit?
- ○ Yes
- ○ No

Upload source documents:

A1. Eyes:
Eyes (including fundoscopy):
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Retinopathy
- ☐ Macular Degeneration
- ☐ Other

If other, specify:

A2. Cardiovascular:
Cardiovascular:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Arrhythmia
- ☐ Murmur
- ☐ Other

If other, specify:

A3. Extremities:
Extremities:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Amputation

Amputation, specify:
- ☐ Tenderness
- ☐ Edema
- ☐ Pulses

Pulses:
- ○ 0+
- ○ 1+
- ○ 2+
- ○ 3+
- ○ 4+
- ☐ Other

If other, specify:

A4. Lymph Nodes:
Lymph Nodes:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Swelling
- ☐ Other

If other, specify:

A5. Pulmonary:
Pulmonary:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Reduced breath sounds
- ☐ Other

If other, specify:

A6. Skin:
Skin:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Red or purple painful rash
- ☐ Scar
- ☐ Eczema
- ☐ Psoriasis
- ☐ Ulcers
- ☐ Excessive Bruising
- ☐ Other

If other, specify:

A7. Gastrointestinal:
Gastrointestinal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:
Select all that apply:
- ☐ Ascites
- ☐ Abdominal Mass
- ☐ Organomegaly

Organomegaly, specify:
- ☐ Stoma
- ☐ Other

If other, specify:

A8. Musculoskeletal
Musculoskeletal:
- ○ Normal
- ○ Abnormal
- ○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Stiffness

☐ Tenderness

☐ Injury

Injury, specify:

☐ Reduced strength

☐ Reduced range of motion

☐ Other

If other, specify:

A9. Genitourinary:

Genitourinary: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Specify:

A10. Neurological:

Neurological: ○ Normal
○ Abnormal
○ Not Done

If abnormal, describe findings:

Select all that apply: ☐ Abnormal Reflex Response

Abnormal reflex response, specify: ○ Hyperflexia
○ Hypoflexia

☐ Diminished sensation

☐ Cranial Nerves

Abnormal, specify:

☐ Other

If other, specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Other Body System

Other Body System

A11. Other Body System:	Describe

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

☐ Visit 1
☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_009_ECG Report - V1.0

Section Title: ECG Report

ECG Completed? *
- ○ Completed
- ○ Not Completed

Upload Source Document:

A1. Date of ECG:

A2. Heart Rate: (bpm)

A3. ECG Findings:
- ○ Normal
- ○ Abnormal

A3a. If abnormal (select all that apply):
- ☐ ST Elevation
- ☐ Atrial Fib
- ☐ T Inversion
- ☐ Q Wave
- ☐ AV Block
- ☐ MI Changes
- ☐ Tachycardia
- ☐ Bradycardia
- ☐ Other

If Other, Specify:

A3b. Is this abnormality clinically significant?
- ○ Yes **** If yes, report on AE Log**
- ○ No

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_010 Central Lab Specimen Collection - V4.0

Section Title: Section A. Blood Specimens

Instructions:
Please indicate the collected specimens and provide the date of collection.

A1. Serum Uric Acid, Creatinine, Cystatin C Collected	○ Yes ○ No	Date Collected
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected
A3. *Shipped to ARDL*	○ Yes ○ No	Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. Urine Specimens

B1. ACR/AER Collected
- ○ Yes
- ○ No
- ○ NA-if visit 6_8_10_12 or 14

Overnight
- ○ Yes
- ○ No

Date Ended Collection

First Morning
- ○ Yes
- ○ No

Date Collected

Spot Urine
- ○ Yes
- ○ No

Date Collected | Additional Date Collected *If necessary* | Additional Date Collected *If necessary*

B2. *Shipped to ARDL*
- ○ Yes
- ○ No

Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Biospecimens for Repository

Is this Visit 4, 11, 16 or 17 ○ Yes ○ No

C1. Serum Collected ○ Yes ○ No Date Collected

C2. Plasma Collected ○ Yes ○ No Date Collected

C3. Urine Collected ○ Yes ○ No Date Collected

C3a. Protease Inhibitor Added ○ Yes ○ No

C4. *Shipped to ARDL* ○ Yes ○ No Date Shipped

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: * ○ Participant Self-Assessment ○ Clinician Assessment

Was any rash present during the assessment?
* ○ Yes ○ No ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select: ○ Yes ○ No ○ Not Assessed

Select all that apply:

Fever
☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit: ○ ºC ○ ºF ☐ Unknown temperature

Skin tenderness
☐ Skin tenderness

Sore throat
☐ Sore throat

Photophobia
☐ Photophobia

Burning eyes
☐ Burning eyes

Itching eyes
☐ Itching eyes

Cough productive of thick and purulent sputum
☐ Cough

Headache
☐ Headache

Malaise
☐ Malaise

Arthralgia
☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select: ○ Yes ○ No ○ Not Assessed

Select all that apply:

Burning rash
☐ Burning rash

Skin pain
☐ Skin pain

Facial swelling
☐ Facial swelling

Tongue swelling
☐ Tongue swelling

Red or purple skin rash
☐ Red or purple skin rash

Area of rash (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Target lesions surrounded by macular erythema
☐ Target lesions

Hives
☐ Hives

Area of hives (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Blisters
☐ Blisters

Area of blisters (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Genitals ☐ Anal
☐ Back

Shedding
☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

Denuded skin areas
☐ Denuded skin areas

Area of denudation (select all that apply):

☐ Face ☐ Chest ☐ Abdomen
☐ Arms ☐ Legs ☐ Palms
☐ Soles ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_019_iGFR Procedures Form - V3.0

Section Title: I. iGFR Procedure

Upload source documents:

A1. Was the iGFR Performed?

Please Select:
- ○ Yes
- ○ No

If No, Reason:
(check all that apply)
- ☐ UTI
- ☐ BP too high
- ☐ Positive pregnancy test
- ☐ Hyperglycemia
- ☐ Hypoglycemia
- ☐ Vomiting
- ☐ Febrile
- ☐ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: II. iGFR Draw Times

A2. Date of iGFR:
Date of iGFR:

A3. iGFR Collections:
Start clock at end of Omnipaque injection* (No Sample) "0" time 00:00

A4. 120 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A5. 150 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A6. 180 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A7. 210 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A8. 240 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A9. Samples shipped to central lab?

Please Select: ○ Yes ○ No | Date Samples Shipped:

A10. Backup samples shipped to central lab?

Please Select: ○ Yes ○ No ○ NA | Date Backup Samples Shipped:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_025 Unscheduled Visit Reason - V1.0

Section Title: Unscheduled Visit

A1. Please select the reason for this Unscheduled Visit:
*
- ○ iGFR repeat or reattempt (Complete Forms 006 and 019 ONLY!)
- ○ Safety Check (Complete form(s) related to the safety check ONLY!)
- ○ Other please specify (Complete applicable form(s) ONLY!)

If Other reason for visit, please specify: *

A1a. Please select the visit where the iGFR procedure was performed or attempted that this procedure is to replace:
*
- ○ Visit 4
- ○ Visit 4a
- ○ Visit 7
- ○ Visit 11
- ○ Visit 16
- ○ Visit 17

A1b. If iGFR repeat or reattempt, please select the reason:
*
- ○ Invalid R2
- ○ Could not be completed
- ○ Protocol safety check

A1b1. If Invalid R2, please select which samples: *
- ○ Original and Backup sample
- ○ Only Original Sample

Backup sample not tested, please specify why: *

A1b2. Please select the reason the iGFR couldn't be completed: *
- ○ BP too high
- ○ Other

A1c. If Safety Check, please select all that apply:
*
- ☐ Blood Pressure
- ☐ Physical Exam
- ☐ Lab Result
- ☐ ECG
- ☐ Central Lab Specimen
- ☐ Skin Assessment
- ☐ Other Safety Check please specify

If Other Safety Check, please specify: *

A1d. Please select the visit where something occurred prompting this Safety Check (select None if not related to any visit):
*
- ○ Visit 1
- ○ Visit 1a
- ○ Eligibility Run-in
- ○ Visit 2
- ○ Visit 3
- ○ Visit 4
- ○ Visit 4a
- ○ Eligibility Randomization
- ○ Visit 5
- ○ Visit 6
- ○ Visit 7
- ○ Visit 8
- ○ Visit 9
- ○ Visit 10
- ○ Visit 11
- ○ Visit 12
- ○ Visit 13
- ○ Visit 14
- ○ Visit 15
- ○ Visit 16
- ○ Visit 17
- ○ Unscheduled Visit
- ○ None

A1d1. If Unscheduled Visit is selected, please select which number: *
- ○ (1)
- ○ (2)
- ○ (3)
- ○ (4)
- ○ (5)
- ○ (6)

Final Status:

PERL_035_Final Status Form - 2.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Final Status
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_035_Final Status Form - 2.0

Section Title: Final Status Form

A1. Final Status Date:
Date: *

A2. Primary reason for terminating participation in the study:
Please select: *
- ○ Completed study per protocol
- ○ Participant was determined to be ineligible
- ○ Participant withdrew consent
- ○ Investigator withdrew participant
- ○ Study terminated by Sponsor
- ○ Transferred to another site
- ○ Death
- ○ Lost to follow-up
- ○ Other

Transferred to site #:

New Subject ID:

If Other, Specify

Unmasking:

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Unmasking
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_041_Unmasking Report - V1.0

Section Title: A. Unmasking Report

A1. Date unmasking occurred:

Individual who was unmasked (check all that apply)

A2. a. ☐Subject

b. ☐Coordinator

c. ☐Principal Investigator or Co-Principal Investigator

d. ☐Other If Other, Specify:

What was the reason or event that caused the unmasking? (check all that apply)

A3. a. ☐Adverse Event **If checked, please complete AE Log form 020 or SAE form 045**

b. ☐Accidental Unblinding

c. ☐Inadvertent discourse by pharmacist

d. ☐Other If Other, Specify:

How did the unmasking occur? (check all that apply)

A4. a. ☐Pharmacist revealed verbally

b. ☐Unblinding from website

c. ☐Other If Other, Specify:

Initial Complications and Screening eGFR:

PERL_023I_Initial_Complication Questionnaire - 1.0
PERL_026_Historical eGFR Slope - 2.0

Investigator Name: _____ **Investigator Signature:** _____ **Date:** _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Initial Complications
and
Screening eGFR
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_023I_Initial_Complication Questionnaire - 1.0

Section Title: Macrovascular complications

A1. Date of Initial questionnaire completion:
*

Have you ever had any of the following before PERL:
"before PERL" means that event or condition first occurred prior to PERL visit 1.

A2. Heart attack (myocardial infarction, MI):

* ○ Yes ○ No ○ Unknown — At what age (first occurrence)? *

A3. Coronary artery bypass surgery (heart bypass, CABG):

* ○ Yes ○ No ○ Unknown — At what age (first occurrence)? *

A4. Angioplasty or stent in a coronary artery:

* ○ Yes ○ No ○ Unknown — At what age (first occurrence)? *

A5. Stroke, "mini-stroke" or TIA (transient ischemic attack):

* ○ Yes ○ No ○ Unknown — At what age (first occurrence)? *

A6. Congestive heart failure:

* ○ Yes ○ No ○ Unknown — At what age (first occurrence)? * — Were you ever hospitalized for congestive heart failure? * ○ Yes ○ No

A7. Irregular heart beat (arrhythmia, atrial fibrillation)

* ○ Yes ○ No ○ Unknown — At what age (first occurrence)? * — Were you ever hospitalized for irregular heart beat (arrhythmai, artrial fibrillation)? * ○ Yes ○ No

A8. Amputation (not related to trauma)

* ○ Yes ○ No ○ Unknown — Where was the amputation? * ○ Toe(s) ○ Foot ○ Below the knee ○ Above the knee ○ Other — Specify: *

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Initial Complications
and
Screening eGFR
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: CHF

B1. Select one of the following that best reflects your current health status:

*

- ☐ I have no limitation of my physical activity. Ordinary physical activity does not cause me undue fatigue, palpitation (irregular or strong heart beat sensations), or shortness of breath.
- ☐ I have slight limitation of physical activity. I am comfortable at rest, however ordinary physical activity causes me fatigue, palpitation (irregular or strong heart beat sensations), or shortness of breath.
- ☐ I have marked limitation of physical activity. I am comfortable at rest, however less than ordinary activity causes fatigue, palpitation (irregular or strong heart beat sensations), or shortness of breath.
- ☐ I am unable to carry on any physical activity without discomfort. I have symptoms of symptoms of heart failure at rest. If any physical activity is undertaken, my discomfort increases.

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Initial Complications
and
Screening eGFR
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Retinopathy

C1. Have you ever been diagnosed with diabetic retinopathy (diabetic eye disease)?

* ○ Yes ○ No ○ Unknown

C2. Have you had any of the following treatments for diabetic retinopathy:

C2a. Laser * ○ Yes ○ No

C2b. Eye injection * ○ Yes ○ No

C2c. Other eye surgery for retinopathy (vitrectomy) * ○ Yes ○ No

C3. Have you lost vision or become blind from diabetic retinopathy?

* ○ Yes ○ No

C4. When was your last eye exam by an eye specialist (dilated eye exam)?

Month ○ January ○ February ○ March ○ April ○ May ○ June ○ July ○ August ○ September ○ October ○ November ○ December

Year

☐ Date Unknown

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Initial Complications
and
Screening eGFR
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Neuropathy

Peripheral Neuropathy Diagnosis

D1. Have you been diagnosed with diabetic neuropathy?
*
- ○ Yes
- ○ No
- ○ Unknown

D2. Have you been diagnosed with Charcot foot?
*
- ○ Yes
- ○ No
- ○ Unknown

Peripheral Neuropathy Symptoms
In the questions below, please select the answers that best reflect your current health status.

D3. Are your feet and/or legs numb?
*
- ○ Yes
- ○ No

D4. Do you ever have any burning pain in your legs and/or feet?
*
- ○ Yes
- ○ No

D5. Does it hurt when the bed covers touch your skin?
*
- ○ Yes
- ○ No

D6. Are your symptoms worse at night?
*
- ○ Yes
- ○ No

Autonomic neuropathy (SAS)
In the questions below, please select the answers that best reflect your current health status.

D7. Do you have light headedness?
*
- ○ Yes
- ○ No

D8. Do you have a dry mouth or dry eyes?
*
- ○ Yes
- ○ No

D9. Are your feet pale or blue?
*
- ○ Yes
- ○ No

D10. Are your feet colder than the rest of your body?
*
- ○ Yes
- ○ No

D11. Is sweating in your feet decreased or absent (for example, after exercise or during hot weather)?
*
- ○ Yes
- ○ No

D12. Is sweating in your hands increased compared to the rest of your body?
*
- ○ Yes
- ○ No

D13. Do you have nausea, vomiting or bloating after eating a small meal?
*
- ○ Yes
- ○ No

D14. Do you have persistent diarrhea (more than 3 loose bowel movements per day)?
*
- ○ Yes
- ○ No

D15. Do you have persistent constipation (less than 1 bowel movement every other day)?
*
- ○ Yes
- ○ No

D16. Do you have leaking of urine?
*
- ○ Yes
- ○ No

D17. Do you have difficulty obtaining an erection?
*
- ○ Yes
- ○ No
- ○ Female

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Initial Complications
and
Screening eGFR
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Education

E1. Indicate the highest level of education

*
- ○ Some high school
- ○ High school graduate
- ○ Some college
- ○ College graduate
- ○ Graduate or professional degree

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Initial Complications
and
Screening eGFR
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_026_Historical eGFR Slope - 2.0

Section Title: Historical eGFR

Instructions: COMPLETE THIS FORM FOR SUBJECTS QUALIFIED BY ALBUMINURIA AT SCREENING AS INDICATED ON FORM PERL_016_ACR/AER Screening

Was the subject qualified for the study using eGFR slope as an eligibility criteria as indicated on PERL_016_ACR/AER Screening, selection of A1c?

* ○ Yes - End Form
○ No-Complete the below eGFR information

Declining kidney function is defined as an eGFR (CKD-EPI) decline ≥3.0 ml/min/1.73 m2/year estimated from all the available creatinine measurements (including the one at screening assessment) from the previous 3 years. If at least 3 serum creatinine measures are not available in the previous 3 years, then the slope can be derived from creatinine values from up to the previous 5 years. An EXCEL-based slope calculator is available on the PERL website. The eGFR values should be used to calculate the slope according to the following criteria:
• Most recent value is from screening (local lab value)
• The oldest value is the value that is closest to 3 years that is GREATER or EQUAL to 3 years ago, but no more than 5 years ago
• All other values between the most recent value and the oldest value should be used

Provide eGFR Slope Calculation Result: *

Date of Test	eGFR (ml/min/1.73 m^2)
Date of Test *	eGFR (ml/min/1.73 m^2) *
Date of Test *	eGFR (ml/min/1.73 m^2) *
Date of Test *	eGFR (ml/min/1.73 m^2) *
Date of Test	eGFR (ml/min/1.73 m^2)
Date of Test	eGFR (ml/min/1.73 m^2)
Date of Test	eGFR (ml/min/1.73 m^2)
Date of Test	eGFR (ml/min/1.73 m^2)
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Date of Test	eGFR (ml/min/1.73 m^2)
Date of Test	eGFR (ml/min/1.73 m^2)
Date of Test	eGFR (ml/min/1.73 m^2)

AE, Con Med, Compliance, BP Med, and Deviation Logs:

PERL_012_RAS and BP Medication Log - V3.0
PERL_013_Concomitant Medication Log - V2.0
PERL_013_pg2 Concomitant Medications Contd - 1.0
PERL_020_Adverse Event Log - V1.0
PERL_040_Protocol Deviation Log - V1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: AE, Con Med, Compliance, BP Med, and Deviation Logs
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_012_RAS and BP Medication Log - V3.0

Section Title: RASB Medication Status at Enrollment
Instructions: The following questions relate to the subject's RASB medication status at the time of enrollment in the study.

B1. Was the subject on a RASB medication at the time of enrollment in the study?
*
- ○ Yes
- ○ No

B2. Was the RASB medication dose at the time of enrollment in the study equivalent to at least 10 mg of Ramipril?
*
- ○ Yes (If **Yes**, enter RASB medication information in log)
- ○ No

B3. Was the RASB medication dose increased after enrollment in the study?
*
- ○ Yes
- ○ No

B4. Please enter the Start Date of the RASB dose increase after enrollment in the study:
* (then enter RASB medication information in log)

B5. Please select the reason the RASB medication was NOT increased:
(if "Participant opposed" or "Healthcare provider opposed" confirm a protocol deviation has been submitted)
*
- ○ Contraindications to higher RASB doses (then enter RASB medication information in log)
- ○ Participant opposed
- ○ Healthcare provider opposed
- ○ Other

If Other, please specify:
*

C1. Was RASB medication therapy initiated as part of the study?
*
- ○ Yes
- ○ No

C2. Was the RASB medication dose equivalent to at least 10 mg of Ramipril?
*
- ○ Yes (If **Yes**, enter RASB medication information in log)
- ○ No

C3. Please select the reason the RASB medication was NOT equivalent to at least 10 mg of Ramipril:
(if "Participant opposed" or "Healthcare provider opposed" confirm a protocol deviation has been submitted)
*
- ○ Contraindications to higher RASB doses (then enter RASB medication information in log)
- ○ Participant opposed
- ○ Healthcare provider opposed
- ○ Other

If Other, please specify:
*

C4. Please select the reason RASB medication therapy was NOT initiated as part of the study:
(if "Participant opposed" or "Healthcare provider opposed" confirm a protocol deviation has been submitted)
*
- ○ Contraindications or previous side effects
- ○ Normoalbuminuric and normotensive subject who qualified by slope
- ○ Participant opposed
- ○ Healthcare provider opposed
- ○ Other

If Other, please specify:
*

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: AE, Con Med, Compliance, BP Med, and Deviation Logs
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: RASB Medication Log

Instructions: **Enter ONLY RASB medications on this log. All other medications, including BP meds, are entered on Form 013 - Concomitant Medications Log.**

RASB Medication Name:	If Other RASB Specify Generic Name:	Total Daily Dose:	Dose Units:	If Other Units, Specify:	Subject started medication PRIOR to enrollment in the study:	Start Date:	Ongoing	Stop Date:	Stop Date Unknown	Reason Stopped:	If Other Reason Stopped, Specify:
○ Aliskiren ○ Azilsartan ○ Benazepril ○ Candesartan ○ Captopril ○ Enalapril ○ Eprosartan ○ Fosinopril ○ Irbesartan ○ Lisinopril ○ Losartan ○ Moexipril ○ Olmesartan ○ Perindopril ○ Quinapril ○ Ramipril ○ Telmisartan ○ Trandolapril ○ Valsartan ○ Other specify			○ mg ○ mcg ○ Other		○ Yes ○ No		☐		☐	○ Not tolerated/side effects ○ Cost prohibitive ○ Participant's decision ○ Healthcare provider's decision ○ Changed dosage ○ Changed RASB ○ Pregnancy or breast-feeding ○ Other	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: AE, Con Med, Compliance, BP Med, and Deviation Logs
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_013_Concomitant Medication Log - V2.0

Section Title: Concomitant Medication Log

Instructions: Enter all medications EXCEPT RASB meds on this log. RASB meds are to be entered on Form 012 - RASB Medication Log.

something in the Specify field.')" onmouseout="UnTip()">**Medication Name:** *	If Other Medication Name, Specify:	**Dose:**	G (grams) gtt (drops) ml (millilitre) cc (cubic centimetre; same as ml) drops (gtt) puffs (puffs) sprays (sprays) tabs (tablets) caps (capsules) IU (units)')" onmouseout="UnTip()">**Dose Units:**	If Other Dose Units, Specify:	TID (three times a day) QID (four times a day) PRN (when needed) EOD or QAD (every-other day) BIW (two times a week) TIW (three times a week) QW (every week) Q10D (every 10 days) Q2W (every 2 weeks) Q3W (every 3 weeks) QHS or HS (at bedtime) AC (before meals) CC (with meals) PC (after meals) QAM (each morning) QPM (each night) Q12H (every 12 hours) Q8H (every 8 hours) Q6H (every 6 hours) Q4H (every 4 hours) Q3H (every 3 hours) Q2H (every 2 hours)')" onmouseout="UnTip()">**Dose Frequency:**	If Other Dose Frequency, Specify:	**Indication:**	If Other Indication, Specify	**Start Date:**	**Subject started medication PRIOR to enrollment in the study:** Yes No	Ongoing	**Stop Date:**	Unknown	**Reason Stopped:**	If Other Reason, Specify

- Acebutolol
- Acetaminophen
- Alfuzosin HCl
- Alprazolam
- Amitriptyline HCL
- Amlodipine
- Amlodipine and atorvastatin
- Amoxicillin
- Amoxicillin and clavulanate
- Ampicillin
- Asprin
- Atenolol
- Lipitor (atorvastatin)
- Avanafil
- Azithromycin
- Bacitracin ointment
- Beclomethasone inhalation aerosol
- Betaxolol
- Bisoprolol fumarate
- Bisoprolol fumarate and hydrochlorothiazide
- Bumetanide
- Calcitriol
- Calcium Carbonate and Calcium Citrate
- Capsaicin cream
- Carteolol
- Carvedilol
- Cephalexin
- Cefazolin
- Cetirizine
- Chlorthalidone
- Ciprofloxacin
- Cisapride
- Citalopram hydrobromide
- Clindamycin
- Clindamycin topical
- Clopidogrel bisulfate
- Colsevelam
- Diltiazem
- Domperidone
- Doxazosin Mesylate
- Doxycycline
- Duloxetine
- Epoetin alfa and Darbepoetin alfa
- Erythromycin
- Esomeprazole
- Esterified Estrogens
- Estradiol
- Estradiol transdermal gel
- Estradiol transdermal patch
- Estradiol transdermal solution
- Estrogens - Conjugated
- Ethacrynic acid
- Evening Primrose Oil
- Ezetimibe
- Ezetimibe and simvastatin
- Fenofibrate
- Ferrous sulfate
- Fish oil
- Fluconazole
- Fludrocortisone Acetate
- Fluoxetine
- Fluticasone propionate
- Furosemide
- Gabapentin
- Gentamicin
- Glucagon
- Glucose tablets
- Guanabenz acetate
- Guanethidine monosulfate
- Guanfacine hydrochloride
- Insulin regular
- Hydorcortisone
- Hydralazine
- Hydrochlorothiazide
- Hydrocodone and acetaminophen
- Hydroxyzine
- Ibuprofen
- Insulin (type unknown)
- Novolog
- Insulin Degludec
- Insulin detemir
- Lantus
- Insulin glulisine
- Insulin NPH
- Humalog
- Insulin lispro
- Isosorbide mononitrate - dinitrate
- Ketorolac
- Labetalol HCl
- Lansoprazole
- Levofloxacin
- Levothyroxine
- Liothyronine
- Loratadine
- Lorazepam
- Lovastatin
- Lovastatin and niacin
- Metformin
- Methimazole
- Methyldopa
- Methyldopa and chlorothiazide
- Methyldopa and hydrochlorothiazide
- Methylphenidate
- Metoclopramide
- Metoclopramide oral dissolving tablet
- Metoprolol
- Metronidazole
- Miconazole
- Nadolol
- Nadolol and bendroflumethiazide
- Naproxen
- Nebivolol
- Niacin
- Nitroglycerin
- Omeprazole
- Oral contraceptive
- Oxycodone
- Oxycodone and acetaminophen
- Pantoprazole
- Paroxetine
- Penbutolol sulfate
- Penicillin
- Phenazopyridine
- Pindolol
- Pramlintide Acetate
- Pravastatin
- Prazosin Hydrochloride
- Prazosin hydrochloride and polythiazide
- Prednisone
- Pregabalin
- Propranolol
- Propylthiouracil (PTU)
- Prost/Phen injectable
- Rabeprazole
- Ranitidine HCL
- Reserpine
- Reserpine and chlorothiazide
- Reserpine and chlorthalidone
- Reserpine and hydralazine and hydrochlorothiazide
- Reserpine and hydrochlorothiazide
- Ramipril HCl

- mg
- mcg
- G
- gtt
- ml
- cc
- drops
- puffs
- sprays
- tabs
- caps
- IU
- Unknown
- Other

- QD
- BID
- TID
- QID
- PRN
- EOD
- BIW
- TIW
- QW
- Q10D
- Q2W
- Q3W
- QHS
- AC
- CC
- PC
- QAM
- QPM
- Q12H
- Q8H
- Q6H
- Q4H
- Q3H
- Q2H
- Unknown
- Other

- Allergies
- Anxiety
- Asthma
- CAD
- CHF
- Depression
- Diabetes
- Embolism
- Erectile disfunction
- Gastritis
- Gastroparesis
- GERD
- Glaucoma
- Headache
- Hyperlipidemia
- Hypertension
- Hypoglycemia
- Hypothyroidism
- Infection
- Neuropathy
- Nutritional Supplement
- Pain-Back
- Pain-Joint
- Pain-Surgical
- Pain-unspecified
- Phlebitis
- Retinopathy
- UTI
- Other
- Unknown

- Did not tolerate
- Cost prohibitive
- No longer required
- Changed dose
- Changed medication
- Unknown
- Other

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: AE, Con Med, Compliance, BP Med, and Deviation Logs
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_013_pg2 Concomitant Medications Contd - 1.0

Section Title: Concomitant Medications Page TWO

Instructions: This form is used ONLY when the initial Form_013 Con Meds form has reached the maximum data entry of 40 records.
Enter all medications EXCEPT RASB meds on this log. RASB meds are to be entered on Form 012 - RASB Medication Log.

something in the Specify field ')" onmouseout="UnTip()">**Medication Name:** *	If Other Medication Name, Specify:	**Dose:**	G (grams) gtt (drops) ml (millilitre) cc (cubic centimetre; same as ml) drops (gtt) puffs (puffs) sprays (sprays) tabs (tablets) caps (capsules) IU (units)')" onmouseout="UnTip()">**Dose Units:**	If Other Dose Units, Specify:	TID (three times a day) QID (four times a day) PRN (when needed) EOD or QAD (every-other day) BIW (two times a week) TIW (three times a week) QW (every week) Q10D (every 10 days) Q2W (every 2 weeks) Q3W (every 3 weeks) QHS or HS (at bedtime) AC (before meals) CC (with meals) PC (after meals) QAM (each morning) QPM (each night) Q12H (every 12 hours) Q8H (every 8 hours) Q6H (every 6 hours) Q4H (every 4 hours) Q3H (every 3 hours) Q2H (every 2 hours)')" onmouseout="UnTip()">**Dose Frequency:**	If Other Dose Frequency, Specify:	**Indication:**	If Other Indication, Specify	**Start Date:**	**Subject started medication PRIOR to enrollment in the study:** Yes No	Ongoing	**Stop Date:**	Unknown	**Reason Stopped:**	If Other Reason, Specify

○ Acebutolol ○ Acetaminophen ○ Alfuzosin HCl ○ Alprazolam ○ Amitriptyline HCL ○ Amlodipine ○ Amlodipine and atorvastatin ○ Amoxicillin ○ Amoxicillin and clavulanate ○ Ampicillin ○ Asprin ○ Atenolol ○ Lipitor (atorvastatin) ○ Avanafil ○ Azithromycin ○ Bacitracin ointment ○ Beclomethasone inhalation aerosol ○ Betaxolol ○ Bisoprolol fumarate ○ Bisoprolol fumarate and hydrochlorothiazide ○ Bumetanide ○ Calcitriol ○ Calcium Carbonate and Calcium Citrate ○ Capsaicin cream ○ Carteolol ○ Carvedilol ○ Cephalexin ○ Cefazolin ○ Cetirizine ○ Chlorthalidone ○ Ciprofloxacin ○ Cisapride ○ Citalopram hydrobromide ○ Clindamycin ○ Clindamycin topical ○ Clopidogrel bisulfate ○ Colsevelam ○ Diltiazem ○ Domperidone ○ Doxazosin Mesylate ○ Doxycycline ○ Duloxetine ○ Epoetin alfa and Darbepoetin alfa ○ Erythromycin ○ Esomeprazole ○ Esterified Estrogens ○ Estradiol ○ Estradiol transdermal gel ○ Estradiol transdermal patch ○ Estradiol transdermal solution ○ Estrogens - Conjugated ○ Ethacrynic acid ○ Evening Primrose Oil ○ Ezetimibe ○ Ezetimibe and simvastatin ○ Fenofibrate ○ Ferrous sulfate ○ Fish oil ○ Fluconazole ○ Fludrocortisone Acetate ○ Fluoxetine ○ Fluticasone propionate ○ Furosemide ○ Gabapentin ○ Gentamicin ○ Glucagon ○ Glucose tablets ○ Guanabenz acetate ○ Guanethidine monosulfate ○ Guanfacine hydrochloride ○ Insulin regular ○ Hydorcortisone ○ Hydralazine ○ Hydrochlorothiazide ○ Hydrocodone and acetaminophen ○ Hydroxyzine ○ Ibuprofen ○ Insulin (type unknown) ○ Novolog ○ Insulin Degludec ○ Insulin detemir ○ Lantus ○ Insulin glulisine ○ Insulin NPH ○ Humalog ○ Insulin lispro ○ Isosorbide mononitrate - dinitrate ○ Ketorolac ○ Labetalol HCl ○ Lansoprazole ○ Levofloxacin ○ Levothyroxine ○ Liothyronine ○ Loratadine ○ Lorazepam ○ Lovastatin ○ Lovastatin and niacin ○ Metformin ○ Methimazole ○ Methyldopa ○ Methyldopa and chlorothiazide ○ Methyldopa and hydrochlorothiazide ○ Methylphenidate ○ Metoclopramide ○ Metoclopramide oral dissolving tablet ○ Metoprolol ○ Metronidazole ○ Miconazole ○ Nadolol ○ Nadolol and bendroflumethiazide ○ Naproxen ○ Nebivolol ○ Niacin ○ Nitroglycerin ○ Omeprazole ○ Oral contraceptive ○ Oxycodone ○ Oxycodone and acetaminophen ○ Pantoprazole ○ Paroxetine ○ Penbutolol sulfate ○ Penicillin ○ Phenazopyridine ○ Pindolol ○ Pramlintide Acetate ○ Pravastatin ○ Prazosin Hydrochloride ○ Prazosin hydrochloride and polythiazide ○ Prednisone ○ Pregabalin ○ Propranolol ○ Propylthiouracil (PTU) ○ Prost/Phen injectable ○ Rabeprazole ○ Ranitidine HCL ○ Reserpine ○ Reserpine and chlorothiazide ○ Reserpine and chlorthalidone ○ Reserpine and hydralazine and hydrochlorothiazide ○ Reserpine and hydrochlorothiazide ○ Ramipril HCl		○ mg ○ mcg ○ G ○ gtt ○ ml ○ cc ○ drops ○ puffs ○ sprays ○ tabs ○ caps ○ IU ○ Unknown ○ Other		○ QD ○ BID ○ TID ○ QID ○ PRN ○ EOD ○ BIW ○ TIW ○ QW ○ Q10D ○ Q2W ○ Q3W ○ QHS ○ AC ○ CC ○ PC ○ QAM ○ QPM ○ Q12H ○ Q8H ○ Q6H ○ Q4H ○ Q3H ○ Q2H ○ Unknown ○ Other		○ Allergies ○ Anxiety ○ Asthma ○ CAD ○ CHF ○ Depression ○ Diabetes ○ Embolism ○ Erectile disfunction ○ Gastritis ○ Gastroparesis ○ GERD ○ Glaucoma ○ Headache ○ Hyperlipidemia ○ Hypertension ○ Hypoglycemia ○ Hypothyroidism ○ Infection ○ Neuropathy ○ Nutritional Supplement ○ Pain-Back ○ Pain-Joint ○ Pain-Surgical ○ Pain-unspecified ○ Phlebitis ○ Retinopathy ○ UTI ○ Other ○ Unknown		○	○	□		□	○ Did not tolerate ○ Cost prohibitive ○ No longer required ○ Changed dose ○ Changed medication ○ Unknown ○ Other	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: AE, Con Med, Compliance, BP Med, and Deviation Logs
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_020_Adverse Event Log - V1.0

Section Title: Adverse Events

Instructions:
Adverse Event: Choose an event from the drop down list. Enter one event per line. If the event is not in the list, choose Other and specify the event in the next column.
Onset Date: Enter the date the Adverse Event began. If complete date is unknown, enter an estimate. Partial dates are not accepted.
End Date: Enter the date the Adverse Event ended. If complete date is unknown, enter an estimate. Partial dates are not accepted. (If AE is ongoing, leave this field blank). When AE has ended, update this field with the AE end date.
Severity: Indicate the severity grade of the AE. See MOO for Grade definitions.
Expected or Unexpected: Indicate if this is an expected adverse event, as outlined in the protocol.
Relationship to Allopurinol and Ramipril: For each medication, indicate if it had a causal effect on that Adverse Event, as reported by the Clinician/Investigator.
Action Taken with Allopurinol: Indicate the action take with allopurinol in response to the AE. (Report action taken for ramipril such as dose change or discontinued, on Concomitant Medications Form).
Outcome: Indicate the outcome of the event.
Treatment Required: Indicate if medication or other treatment was required to treat this event. If yes, enter details on Concomitant Medication Log).

Adverse Event

Adverse Event *	If Other, Specify	Onset Date *	End Date	Severity	Expected or Unexpected	Relationship to Allopurinol	Relationship to Ramipril	Action taken with Allopurinol	Outcome	Treatment Required?
○ Abnormal ECG changes from baseline				○ Grade 1 Mild	○ Expected	○ Definite	○ Definite	○ None	○ Resolved without sequelae	○ Yes
○ Acute Joint/Foot pain				○ Grade 2 Moderate	○ Unexpected	○ Probable	○ Probable	○ Discontinued	○ Resolved with sequelae	○ No
○ Allergic reaction				○ Grade 3 Severe		○ Possible	○ Possible	○ Dose Reduced	○ Ongoing	
○ Allergic rhinitis						○ Not related	○ Not related	○ Temporarily discontinued	○ Unknown	
○ ALT elevation						○ Not assessable	○ Not assessable	○ Meds restarted		
○ Anemia										
○ Ascites										
○ Bladder infection										
○ Bronchial infection										
○ Cold symptoms										
○ Congestion										
○ Cough										
○ Elevated creatinine										
○ Dehydration										
○ Dermatitis										
○ Diarrhea										
○ Difficulty breathing										
○ Eczema										
○ Edema										
○ Elevated bilirubin										
○ Elevated transaminases										
○ Emesis										
○ Epistaxis										
○ Fever										
○ Flu-like symptoms										
○ Gastrointestinal disorder										
○ Gout										
○ Headache										
○ Hypertension										
○ Hypoalbuminemia										
○ Hypocalcemia										
○ Increased sleepiness										
○ Irritability										
○ Edema-limbs										
○ Leukocytosis										
○ Localized edema										
○ Low iron										
○ Nasal congestion										
○ Neutropenia										
○ Nocturia										
○ Polyuria										
○ Rash										
○ Reflux										
○ Sinus infection										
○ Skin infection										
○ Sore throat										
○ Strep pharyngitis										
○ Swelling of lips/tongue/throat/andgiodema										
○ Upper respiratory infection										
○ Urinary tract infection										
○ Urticaria										
○ Viral illness										
○ Vomiting										
○ Weight loss										
○ Weight gain										
○ Wheezing										
○ Worsening of diabetes										
○ Yellowing of eyes/skin										
○ Other										

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: AE, Con Med, Compliance, BP Med, and Deviation Logs
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_040_Protocol Deviation Log - V1.0

Section Title: Protocol Deviation

Instructions:

Please complete one row for each protocol deviation. Click "Add" to enter additional deviations.
Additional Comments are not required and should be entered only as necessary.

At which visit did the deviation occur? *	Deviation: *	If Other Deviation, Specify:	Study Procedure:	If Other Study Procedure, Specify:	Reason for Deviation: *	Additional Comments:
○ None (not visit related)	○ Missed visit		○ Vitals		○ Site error	
○ Visit 1	○ Informed Consent deviation		○ Anthropometrics		○ Participant refused	
○ Visit 2	○ Study medication dose error		○ Physical Exam		○ Participant too ill	
○ Visit 3	○ Study procedure not completed		○ Clinical Lab		○ Time constraints	
○ Visit 4	○ Study procedure performed incorrectly		○ iGFR		○ Unknown	
○ Visit 4a	○ Left arm used for BP		○ Skin Assessment		○ Other (Specify in Comments)	
○ Visit 5	○ Participant not seated for 5 minutes prior to BP		○ ECG			
○ Visit 6	○ Other (Specify)		○ Randomization			
○ Visit 7			○ Blinding			
○ Visit 8			○ Urine multistix			
○ Visit 9			○ Study Drug Compliance			
○ Visit 10			○ Other (Specify)			
○ Visit 11						
○ Visit 12						
○ Visit 13						
○ Visit 14						
○ Visit 15						
○ Visit 16						
○ Visit 17						

SAE:

PERL_045_Serious Adverse Event - V5.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: SAE
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_045_Serious Adverse Event - V5.0

Section Title: Serious Adverse Event

Please upload original source documents associated with this SAE

Was SAE expected?
A1. Please Select: ○ Yes ○ No

This AE fulfills the following criteria for being an SAE (check all that apply)
A2. a. ☐ Fatal
b. ☐ Disability
c. ☐ Congenital Anomaly
d. ☐ Life Threatening
e. ☐ Required Intervention to prevent permanent impairment/damage
f. ☐ Hospitalization initial or prolonged
g. ☐ Other

A2a. If Other, Specify:

SAE Diagnosis:
A3. Please provide brief diagnosis: *

SAE Description:
A4. (Includes symptoms and diagnostic tests)
SAE Description cont:

Specify Treatment for SAE:
A5. Please Specify:
Specify Treatment for SAE cont:

Age at time of SAE:
A5a. Age (Years)

Start Date:
A6. Start Date: (DD-MMM-YYYY) *
A6a. Start Time: (00:00 format 24 hr clock) ☐ Unknown Start Time

Outcome:
A7. Outcome:
○ Recovered/resolved without sequelae
○ Ongoing
○ Not recovered/not resolved
○ Recovered/resolved with sequelae
○ Fatal
○ Unknown

End Date:
A7a. End Date: (DD-MMM-YYYY)
A7b. End Time: (00:00 format 24 hr clock) ☐ Unknown End Time

Severity: Check MOO for definition
A8. Severity:
○ Grade 1 Mild
○ Grade 2 Moderate
○ Grade 3 Severe

Causality:
A9. Causality: (relationship to allopurinol/placebo)
○ Definite
○ Probable
○ Possible
○ Not related
○ Not assessable

Action Taken with allopurinol/placebo due to this event.
A10. Action:
○ Discontinued allopurinol/placebo
○ Allopurinol/placebo dose reduced
○ No Action Taken
○ Allopurinol/placebo interrupted
○ Subject has not yet started allopurinol/placebo
○ Participant has completed the treatment phase
Date of Treatment Phase Completed

If allopurinol/placebo discontinued or reduced, did SAE abate?
A10a. Please Select:
○ Yes
○ No
○ Unknown

If allopurinol/placebo was discontinued indicate date of last dose.

If allopurinol/placebo dose was reduced indicate date reduced was instituted and date full dose resumed.

A10c. Date reduced:
Date resumed: ☐ Full dose was not resume

If allopurinol/placebo dose was interrupted indicate stop/start dates.

A10d. Stop Date:
to Start Date:

Pilot Unscheduled Visit:

PERL_006_Blood Pressure and Measurements - P1.1
PERL_019_iGFR Procedures Form - P2.1
PERL_022_Study Drug Compliance and Exposure - V3.0
PERL_011_Skin Assessment - V3.0
PERL_008_Local Laboratory Results - V5.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_006_Blood Pressure and Measurements - P1.1

Section Title: Blood Pressure and Heart Rate
Subtitle:

Pilot Visit:
*
- ○ POST-RANDOMIZATION VISITS(V7)
- ○ POST-RANDOMIZATION VISITS(V8)
- ○ POST-RANDOMIZATION VISITS(V10)
- ○ POST-RANDOMIZATION VISITS(V11)
- ○ POST-RANDOMIZATION VISITS(V13)

Measurements:

A1. Weight: (kg) ☐ Not Done

A2. Height: (cm) ☐ Not Done

Upload Source Documents:

Blood Pressure:

B1. First Reading
B1a. Systolic: (mmHg)

B1b. Diastolic: (mmHg) ☐ BP Not Done

B1c. Heart Rate: (bpm) ☐ HR Not Done

B2. Second Reading
B2a. Systolic: (mmHg)

B2b. Diastolic: (mmHg) ☐ BP Not Done

B2c. Heart Rate: (bpm) ☐ HR Not Done

B3. Third Reading
B3a. Systolic: (mmHg)

B3b. Diastolic: (mmHg) ☐ BP Not Done

B3c. Heart Rate: (bpm) ☐ HR Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Average Blood Pressure and Heart Rate
Subtitle:

Calculated Fields:

BMI
BMI:

Blood Pressure
Systolic: (mmHg)

Diastolic: (mmHg)

Heart Rate: (bpm)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_019_iGFR Procedures Form - P2.1

Section Title: I. iGFR Procedure

Pilot Visit:

* ☐ POST-RANDOMIZATION VISITS(V7)
☐ POST-RANDOMIZATION VISITS(V8)
☐ POST-RANDOMIZATION VISITS(V10)
☐ POST-RANDOMIZATION VISITS(V11)
☐ POST-RANDOMIZATION VISITS(V13)

Upload source documents:

A1. Was the iGFR Performed?

Please Select: ☐ Yes
☐ No

If No, Reason:
(check all that apply)

☐ UTI
☐ BP too high
☐ Positive pregnancy test
☐ Hyperglycemia
☐ Hypoglycemia
☐ Vomiting
☐ Febrile
☐ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: II. iGFR Draw Times

A2. Date of iGFR:
Date of iGFR:

A3. iGFR Collections:
Start clock at end of Omnipaque injection* (No Sample) "0" time 00:00

A4. 120 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A5. 150 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A6. 180 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A7. 210 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A8. 240 minutes

Projected draw time for sample: | Actual draw time of sample (24 hour clock): (00:00) | Glucose value (mg/dl) | ☐ Not Done

A9. Samples shipped to central lab?

Please Select: ○ Yes ○ No | Date Samples Shipped:

A10. Backup samples shipped to central lab?

Please Select: ○ Yes ○ No ○ NA | Date Backup Samples Shipped:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_022_Study Drug Compliance and Exposure - V3.0

Section Title: Study Medication Log

Instructions: Refer to the MOO for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period.
The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and
ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

Has the subject permanently discontinued the study drug prior to this dosing period?:

* ○ Yes
○ No

will be the previous line Stop Date plus 1 day.")" onmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
	☐ Unknown		☐ Unknown	○ 0 ○ 100 ○ 200 ○ 300 ○ 400 (mg/day)	○ No change ○ Permanently discontinued ○ Temporarily discontinued ○ Change in dosage ○ Started treatment ○ Restarted treatment ○ Other Specify		☐ Lab safety assessment results ☐ Allopurinol contraindicated ☐ Off-label allopurinol treatment required ☐ Pregnancy or breastfeeding ☐ End-stage renal disease ☐ Per protocol change dose after 1st month ☐ Change in eGFR ☐ Started treatment ☐ Restarted treatment ☐ Other Specify	

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Study Drug Exposure

Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.

1a. Date started using drug vials:

☐ Unknown

1b. Date stopped using drug vials:

☐ Unknown

Difference in days:

1c. Number of pills should have taken if there were no Discontinuations:

☐ Unknown

Please explain why the number of pills the subject should have taken is Unknown:

2. Number of pills instructed not to take:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills instructed not to take:

3. Number of pills should have taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills should have taken:

4. Number of pills dispensed:
(by vial because the number can be different for each vial)
Vial A: *

Vial B: *

Vial C: *

Vial D: *

Total number of pills dispensed:

5. Were pills returned in individual vials:
*
○ Yes
○ No
○ Pills not returned

Number of Pills Returned:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills returned:

Total number of pills returned:

6. Number of pills taken:
(by vial because the number can be different for each vial)
Vial A:

Vial B:

Vial C:

Vial D:

Total number of pills taken:

Total number of pills taken:

7. Select the reason Drug Compliance cannot be calculated at this visit:
*
○ Subject did not return pills
○ Pills were thrown away
○ Pills were lost
○ Start date and/or Stop date unknown
○ Not applicable
○ Other

If Other, Specify:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: % Compliant Calculation

B1. Percent Compliant
(if total pills taken reported by the 4 individual vials)

B2. Percent Compliant
(if vials not returned and total pills taken reported as a total only)

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document

Instructions: Don't forget to upload your source document!

- **Go to the Source Document event**
- **Open the PERL_022_Source Documents form**
- **Upload your source document to the appropriate visit field**

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

* ☐Confirm form is complete and source document uploaded.

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_011_Skin Assessment - V3.0

Section Title: Skin Assessment

Indicate who performed this skin assessment:
Select: *
- ○ Participant Self-Assessment
- ○ Clinician Assessment

Was any rash present during the assessment?
*
- ○ Yes
- ○ No
- ○ Not Assessed

A1. Has the participant had any of the following pre-rash Stevens-Johnson Syndrome (SJS) symptoms?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Fever
- ☐ Fever

Duration: (days)

Maximum temperature: Celsius or Farenheit:
- ○ ºC
- ○ ºF
- ☐ Unknown temperature

Skin tenderness
- ☐ Skin tenderness

Sore throat
- ☐ Sore throat

Photophobia
- ☐ Photophobia

Burning eyes
- ☐ Burning eyes

Itching eyes
- ☐ Itching eyes

Cough productive of thick and purulent sputum
- ☐ Cough

Headache
- ☐ Headache

Malaise
- ☐ Malaise

Arthralgia
- ☐ Arthralgia

A2. During assessment, was any swelling or rash noted?
Select:
- ○ Yes
- ○ No
- ○ Not Assessed

Select all that apply:

Burning rash
- ☐ Burning rash

Skin pain
- ☐ Skin pain

Facial swelling
- ☐ Facial swelling

Tongue swelling
- ☐ Tongue swelling

Red or purple skin rash
- ☐ Red or purple skin rash

Area of rash (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Target lesions surrounded by macular erythema
- ☐ Target lesions

Hives
- ☐ Hives

Area of hives (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Blisters
- ☐ Blisters

Area of blisters (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Genitals
- ☐ Anal
- ☐ Back

Shedding
- ☐ Shedding (sloughing) of skin

Area of shedding (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

Denuded skin areas
- ☐ Denuded skin areas

Area of denudation (select all that apply):
- ☐ Face
- ☐ Chest
- ☐ Abdomen
- ☐ Arms
- ☐ Legs
- ☐ Palms
- ☐ Soles
- ☐ Back

A3. During assessment was any mucous membrane involvement noted?

Select:
○ Yes
○ No
○ Not Assessed

Select all that apply:

Oral mucosa

☐ Oral mucosa

Oral mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Nasal mucosa

☐ Nasal mucosa

Nasal mucosa (select all that apply):

☐ Erythema ☐ Edema ☐ Sloughing

☐ Blistering ☐ Ulceration/erosion ☐ Necrosis/crust

Eyes

☐ Eyes

Eyes (select all that apply):

☐ Excessive tearing ☐ Hyperemia ☐ Congestion

☐ Scarring

Urinary tract

☐ Urinary tract

Urinary Tract (select all that apply):

☐ Dysuria ☐ Urinary retention

Pulmonary

☐ Pulmonary

Pulmonary (select all that apply):

☐ Dyspnea ☐ Productive cough ☐ Pulmonary edema

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_008_Local Laboratory Results - V5.0

Section Title: Section A. Chemistry
Subtitle:
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.

Upload source documents:

Chemistry:

A1. Potassium:	(mmol/L)	Date Collected:	☐ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	☐ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section B. CBC
Subtitle:

B1. Hemoglobin:	(gm/dl)	Date Collected:	☐ Not Done
B2. Hematocrit:	(%)	Date Collected:	☐ Not Done
B3. Platelets:	(mmol)	Date Collected:	☐ Not Done
B4. RBC:	(million cells/mcL)	Date Collected:	☐ Not Done
B5. WBC:	(cells/mcL)	Date Collected:	☐ Not Done

B5a. Neutrophils:	(%)	☐ Not Done
B5b. Lymphocytes:	(%)	☐ Not Done
B5c. Monocytes:	(%)	☐ Not Done
B5d. Eosinophils:	(%)	☐ Not Done
B5e. Basophils:	(%)	☐ Not Done

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section C. Pregnancy Test

C1. Urine Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

C2. Serum Pregnancy Test Result:
- ○ Positive
- ○ Negative
- ○ Not Done
- ○ Not Applicable

Date of test:

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section D. Urine Multistix

Date Urine Collected: ☐ Not Done

D1. Leukocytes:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D2. Nitrites:
- ○ Negative
- ○ Positive

D3. Protein:
- ○ Negative
- ○ Trace
- ○ 30
- ○ 100
- ○ 300
- ○ 2000+

D4. Blood
- ○ Negative
- ○ Positive

D4a. Blood – Non Hemolyzed:
- ○ None
- ○ Trace
- ○ Moderate

D4b. Blood – Hemolyzed:
- ○ None
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

D6. Ketones:
- ○ Negative
- ○ Trace
- ○ Small
- ○ Moderate
- ○ Large

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: Pilot Unscheduled Visit
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

Section Title: Section E. eGFR
Subtitle:

E1. Indicate visit for which this eGFR values applies:

☐ Visit 1
☐ Visits 6-15

E2. Use central lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Central lab creatinine value

E3. Use local lab creatinine value to calculate eGFR
Click Here to Calculate eGFR
Local lab creatinine value

E4. eGFR: (mls/min/1.73m^2) Date Collected: ☐ Not Done

ESRD:

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site: _____
Event Name: ESRD
Event Date: _____

Study Subject ID:_____
Study Subject DOB:_____

PERL_028_ESRD - 1.0

Section Title: ESRD

A1. Date of ESRD diagnosis
*

A2. eGFR at diagnosis
*

A3. Form of treatment (check all that apply)
*

- ☐ Hemodialysis
- ☐ Transplant
- ☐ Peritoneal dialysis
- ☐ Other

A3a. Specify: *