UTI ENDPOINTS CLASSIFICATION AND ADJUDICATION FORM

ID NUMBER: | | | | | | | |

FORM CODE: ADJ
VERSION: A 10/23/07

Contact Occasion | | SEQ # | |

Instructions: *This form is to be completed by each assigned Endpoints Committee reviewer for every Study Adjudication Packet, documenting the review and adjudication of Study Endpoints.*

A. MCID Number

1. Primary MCID Number associated with adjudication packet: ..... | | | | | | | | BLIND_MCID

B. FEVER

2. Was there a documented fever of at least 100.4˚F or 38˚C, measured anywhere on the body either at home or at a medical facility? ..... Y N → **Go to Item 6** ADA2

3. Was there a documented fever of at least 100.4˚ F or 38˚C, ***within 24 hours*** of a (positive) urine collection? ..... Y N → **Go to Item 6** ADA3

4. Measurement source of fever (occurring within 24 hours)?
   - Home ..... H
   - During medical visit ..... M
   - Both (home and during medical visit) ..... B

   ADA4

5. Data source of fever (within 24 hours) report:
   - MCN form ..... N
   - MCA form ..... A
   - Both MCN and MCA ..... B

   ADA5

C. SYMPTOMS

6. Was there documentation of UTI symptoms occurring with this event (list below)? ..... Y N → **Go to Item 9** ADA6

7. Was there documentation of UTI symptoms occurring ***within 24 hours*** of a (positive) urine collection? ..... Y N → **Go to Item 9** ADA7

8. For each of the symptoms listed below, indicate whether there is documentation of occurrence occurring ***within 24 hrs*** of the urine culture, and indicate the source of the report. Select one answer for each column (Y=yes, N=no, U=unknown, X=does not apply).

Symptoms Documented within 24 hrs of Urine Culture Collection

		1. MCN	2. MCA Parent Complaint	3. MCA Medical Findings
a.	Suprapubic, abdominal, or flank pain or tenderness	ADA8A1 Y N U	ADA8A2 Y N U	Y N U ADA8A3
b.	Urinary urgency, frequency, hesitancy	ADA8B1 Y N U	ADA8B2 Y N U	Y N U ADA8B3
c.	Dysuria	ADA8C1 Y N U	ADA8C2 Y N U	Y N U ADA8C3
d.	Foul smelling urine	ADA8D1 Y N U	ADA8D2 Y N U	Y N U ADA8D3
e.	Failure to thrive (<= 4 months old)	ADA8E1 Y N U X	ADA8E2 Y N U X	Y N U X ADA8E3
f.	Dehydration (<= 4 months old)	ADA8F1 Y N U X	ADA8F2 Y N U X	Y N U X ADA8F3
g.	Hypothermia (<= 4 months old)	ADA8G1 Y N U X	ADA8G2 Y N U X	Y N U X ADA8G3

D. PYURIA

9. Was urine tested for pyuria? ..... Y N → **Go to Item 12** ADA9

10. Date of urine sample for pyuria assessment (mm/dd/yyyy): ..... __/__/____ ADA10

11. Pyuria results:
    - Positive Leukocyte Esterase (≥ trace) L
    - Positive WBC count (≥ 10 WBC/mm^3 or ≥ 5 WBC/hpf) ..... W
    - Both (positive leukocyte and WBC) ..... B
    - No pyuria present ..... N

    ADA11

E. CULTURE

12. Was a urine culture performed? ..... Y N → **Go to Item 15** ADA12

13. Date of urine culture sample collection (mm/dd/yyyy): ..... __/__/____ ADA13

14. Positive culture based on study requirements ..... Y N U ADA14
    - Single primary organism, (neither lactobacillus nor candida)
    - ≥ 50,000 CFU/ml (catheterized or suprapubic) OR
    - ≥100,000 CFU/ml (clean-voided Specimen)
    - Single contaminating organism present < 5,000 cfu/ml

At the 11/13/07 Steering Committee meeting it was decided to change the cutpoint from < 5,000 cfu/ml to < 10,000 cfu/ml

F. ADMINISTRATIVE INFORMATION

15. Endpoint Assessment Result:
    - Definite study UTI ..... D
    - Persistent UTI (a treated study UTI, never resolved) ..... P → **Go to Item 17**
    - Not a study UTI, possibly a clinical UTI ..... C → **Go to Item 17**
    - No study UTI, not a clinical UTI ..... N → **Go to Item 17**

    ADA15

16. What kind of study UTI occurred:
    - Febrile UTI ($_F$UTI) ..... F
    - Symptomatic Non-febrile UTI ($_S$UTI) ..... S

    ADA16

17: Comments: ..... Y N ADA17

_____

_____

18. Date of endpoint review/adjudication (mm/dd/yyyy): ..... __/__/____ ADA18

19. Method of data collection *(circle one)*:
    - Computer C
    - Paper ..... P

    ADA19

20. Endpoint Reviewer's initials (if adjudication, record initials of all participants): a. ___ b. ___ c. ___ BLIND_STAFF_ID

ADVERSE EVENTS FORM

RMVUR
Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:								FORM CODE: AEF VERSION: B 10/12/09	Contact Occasion		SEQ #	

Participant Name: _____ Line Number

Instructions: *This form is to be completed for all study medication side effects, adverse events, or serious adverse events reported during the study. If item 14 is 'Y' and item 17 is 'C, D, or E' then complete MEDWATCH form FDA 3500A.*

A. SIDE EFFECTS AND (SERIOUS) ADVERSE EVENTS

1. Onset date of side effect/(serious) adverse event (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ AEF1

2a. **[PC]** Diagnosis or symptom: _____ AEF2A

2b. **[PC]** Costart Preferred Term: _____ AEF2B

3. How often did your child have the [problem] since our last study contact (mm/dd/yyyy)? *(Read responses, circle one.)*
   - Rarely ..... R
   - Sometimes ..... S
   - Often ..... O
   - Not Applicable ..... N

   AEF3

   AEF2C - COSTART CODE Value entered into the DMS based on what was entered in item AEF2B

4. How much did the [problem] affect your child's activities? *(Read responses, circle one.)*
   - None ..... N
   - A little L
   - A lot ..... A

   AEF4

5. When your child had the [problem], was it *(read responses, circle one):*
   - Mild ..... M
   - Moderate ..... D
   - Severe ..... S
   - Not Applicable ..... N

   AEF5

6. Overall, how much did the [problem] bother your child? *(Read responses, circle one.)*
   - None ..... N
   - A little L
   - A lot ..... A

   AEF6

7. Do you think the [problem] was caused by the study medication? *(Read responses, circle one.)*
   - No ..... N → **Go to Item 9**
   - Yes ..... Y
   - Don't know ..... D → **Go to Item 9**

   AEF7

Participant Name: _____

8. Overall, how much of a problem has this medication side effect been for your child? *(Read responses, circle one.)*

Not a problem	N
Mild problem	M
Moderate problem	D
Severe problem	S

AEF8

AEFA9

9 a. Did you seek any medical care for this [problem]? ..... Y → **Complete MCN/MCA** N → **Go to Item 11**

b. Where did the medical care take place?

Emergency room visit	E
Hospitalization	H
Both emergency room and hospitalization	B
Other	O

If other, specify _____

AEFB9B

10. **[PC]** Record assigned MCID #: ..... | | | | | | | |

NOTE: Report the MCID # found on the MCN and MCA forms that correspond to this [problem].

BLIND_MCID

11. **[PC]** How severe was the side effect/(serious) adverse event? (Circle one.)

Note: Refer to QxQ for standardized criteria on severity.

Mild	M
Moderate	D
Severe	S
Life-threatening	L
Death	E

AEF11

12. **[PC]** Study action taken:

	Yes		No	
a. None	Y	→ **Go to Item 13**	N	AEF12A
b. Treated at RIVUR clinic	Y		N	AEF12B
c. Referred	Y		N	AEF12C
d. Study drug temporary discontinued	Y		N	AEF12D
e. Study drug permanently discontinued	Y		N	AEF12E
f. Medical intervention	Y		N	AEF12F
g. Surgical intervention	Y		N	AEF12G
h. Hospitalization	Y		N	AEF12H
i. Other	Y		N	AEF12I

If other, specify _____

13. **[PC]** Does this [problem] fit the definition of an SAE? ..... Y N → **Go to Item 22** AEF13

B. SERIOUS ADVERSE EVENT

14. **[PC]** Was this an unexpected serious adverse event? ..... Y N AEF14

Participant Name: _____

15. **[PC]** Describe more fully the serious adverse event: ..... Y AEF15

_____

_____

_____

_____

16. **[PC]** Category of SAE:

a.	Death ..... Y	N	AEF16A
b.	Immediately life-threatening ..... Y	N	AEF16B
c.	Persistent / significant disability / incapacity ..... Y	N	AEF16C
d.	Hospitalization / prolonged hospitalization ..... Y	N	AEF16D
e.	Serious as assessed by the Investigator ..... Y	N	AEF16E
f.	Laboratory toxicity ..... Y	N	AEF16F
g.	Other ..... Y	N	AEF16G

If other, specify:_____

17. **[PC]** Relationship of serious adverse event to study medication *(circle one)*:

Definitely unrelated ..... A
Unlikely to be related ..... B
Possibly related C
Probably related ..... D
Definitely related ..... E

AEF17

18. **[PC]** Relationship of serious adverse event to study research *(circle one)*:

Definitely unrelated ..... A
Unlikely to be related ..... B
Possibly related C
Probably related ..... D
Definitely related ..... E

AEF18

19. **[PC]** Outcome of event at time of reporting *(circle one)*:

Resolved ..... A
Recovered with minor sequelae ..... B
Recovered with major sequelae C
Condition still present ..... D → **Go to Item 21**
Condition continues to worsen ..... E → **Go to Item 21**
Patient died ..... F

AEF19

20. **[PC]** Date of event resolution or death (mm/dd/yyyy): ..... | | | / | | / | | | | | AEF20

21. **[PC]** SAE reviewed and authorized by (name of investigator):

BLIND_AUTHORITY

C. ADMINISTRATIVE INFORMATION

22. Date of data collection (mm/dd/yyyy): ..... __/__/____ AEF22

23. Method of data collection *(circle one)*:

    Computer C
    Paper ..... P

    AEF23

24. Recorder's initials: ..... BLIND_STAFF_ID

ADVERSE EVENTS FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: AEF
VERSION: A 10/24/07

Contact Occasion | | | SEQ # | |

Participant Name: _____ Line Number | |

Instructions: *This form is to be completed for all study medication side effects and serious adverse events reported during the study. If item 14 is 'Y' and item 17 is 'C, D, or E' then complete MEDWATCH form FDA 3500A.*

A. SIDE EFFECTS AND SERIOUS ADVERSE EVENTS

1. Onset date of side effect/serious adverse event (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ AEF1

2a. **[PC]** Diagnosis or symptom: _____ AEF2A

2b. **[PC]** Costart Preferred Term: _____ AEF2B

3. How often did your child have the [problem] since our last study contact (mm/dd/yyyy)? *(Read responses, circle one.)*

Rarely	R
Sometimes	S
Often	O
Not Applicable	N

AEF3

AEF2C - COSTART CODE Value entered into the DMS based on what was entered in item AEF2B

4. How much did the [problem] affect your child's activities? *(Read responses, circle one.)*

None	N
A little	L
A lot	A

AEF4

5. When your child had the [problem], was it *(read responses, circle one):*

Mild	M
Moderate	D
Severe	S
Not Applicable	N

AEF5

6. Overall, how much did the [problem] bother your child? *(Read responses, circle one.)*

None	N
A little	L
A lot	A

AEF6

7. Do you think the [problem] was caused by the study medication? *(Read responses, circle one.)*

No	N	→ **Go to Item 9**
Yes	Y	
Don't know	D	→ **Go to Item 9**

AEF7

Participant Name: _____

8. Overall, how much of a problem has this medication side effect been for your child? *(Read responses, circle one.)*
   - Not a problem ..... N
   - Mild problem ..... M
   - Moderate problem ..... D
   - Severe problem ..... S

   AEF8

9. Did you seek any medical care for this [problem]? ..... Y → **Complete MCN** N → **Go to Item 11** AEF9

10. **[PC]** Record assigned MCID #: ..... | | | | | | | | BLIND_MCID
    NOTE: Report the MCID # found on the MCN and MCA forms that correspond to this [problem].

11. **[PC]** How severe was the side effect/serious adverse event? (Circle one.)
    Note: Refer to QxQ for standardized criteria on severity.
    - Mild ..... M
    - Moderate ..... D
    - Severe ..... S
    - Life-threatening L
    - Death ..... E

    AEF11

12. **[PC]** Study action taken:

		Yes		No	
a.	None	Y → **Go to Item 13**		N	AEF12A
b.	Treated at RIVUR clinic	Y		N	AEF12B
c.	Referred	Y		N	AEF12C
d.	Study drug temporary discontinued	Y		N	AEF12D
e.	Study drug permanently discontinued	Y		N	AEF12E
f.	Medical intervention	Y		N	AEF12F
g.	Surgical intervention	Y		N	AEF12G
h.	Hospitalization	Y		N	AEF12H
i.	Other	Y		N	AEF12I

    If other, specify _____

13. **[PC]** Does this [problem] fit the definition of an SAE? ..... Y N → **Go to Item 22** AEF13

B. SERIOUS ADVERSE EVENT

14. **[PC]** Was this an unexpected serious adverse event? ..... Y N AEF14

15. **[PC]** Describe more fully the serious adverse event: ..... Y AEF15

_____

_____

_____

_____

Participant Name: _____

16. **[PC]** Category of SAE:

a.	Death ..... Y	N	AEF16A
b.	Immediately life-threatening ..... Y	N	AEF16B
c.	Persistent / significant disability / incapacity ..... Y	N	AEF16C
d.	Hospitalization / prolonged hospitalization ..... Y	N	AEF16D
e.	Serious as assessed by the Investigator ..... Y	N	AEF16E
f.	Laboratory toxicity ..... Y	N	AEF16F
g.	Other ..... Y	N	AEF16G

If other, specify: _____

17. **[PC]** Relationship of serious adverse event to study medication *(circle one)*:

Definitely unrelated ..... A
Unlikely to be related ..... B
Possibly related C
Probably related ..... D
Definitely related ..... E

AEF17

18. **[PC]** Relationship of serious adverse event to study research *(circle one)*:

Definitely unrelated ..... A
Unlikely to be related ..... B
Possibly related C
Probably related ..... D
Definitely related ..... E

AEF18

19. **[PC]** Outcome of event at time of reporting *(circle one)*:

Resolved ..... A
Recovered with minor sequelae ..... B
Recovered with major sequelae C
Condition still present ..... D → **Go to Item 21**
Condition continues to worsen ..... E → **Go to Item 21**
Patient died ..... F

AEF19

20. **[PC]** Date of event resolution or death (mm/dd/yyyy): ..... | | / | | / | | | | AEF20

21. **[PC]** SAE reviewed and authorized by (name of investigator):

																				BLIND_AUTHORITY

ID NUMBER:							

FORM CODE: AEF
VERSION: A 10/24/07

Contact Occasion | | SEQ # | |

Line Number | |

Participant Name: _____

C. ADMINISTRATIVE INFORMATION

22. Date of data collection (mm/dd/yyyy): ..... | | | / | | / | | | | | AEF22

23. Method of data collection *(circle one)*:

Computer C
Paper ..... P

AEF23

24. Recorder's initials: ..... | | | BLIND STAFF ID

BASELINE DEMOGRAPHIC FORM

RMVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: BDF
VERSION: A 01/26/07

Contact Occasion | | |

SEQ # | | |

Participant Name: _____

Instructions: *This form is completed during baseline data collection, based on parent/guardian response. Y, N, U, R indicates Yes, No, Unknown, Refused.*

A. ETHNICITY / RACE

1. Is your child of Hispanic ethnicity (origin)? ..... Y N U R BDFA1

2. Which of the following best describes your child's race? *(Answer each.)*
   - a. White ..... Y N U R BDFA2A
   - b. Black or African-American ..... Y N U R BDFA2B
   - c. Asian ..... Y N U R BDFA2C
   - d. Native Hawaiian or Other Pacific Islander ..... Y N U R BDFA2D
   - e. American Indian or Alaska Native ..... Y N U R BDFA2E
   - f. Other ..... Y N U R BDFA2F
     1. If other, please specify: _____ BDFA2F1

See additional derived race variables in derv_nikkk1

B. HOME / EDUCATION / OCCUPATION

3. How many days per week does your child live in the **primary** household, the home in which your child lives most of the time? ..... ☐ BDFA3

4. What is the number of adults (aged 18 years or older) living in the primary household? ..... ☐ BDFA4

5. What is the number of children (aged less than 18 years) living in the primary household? ..... ☐ BDFA5

6a. What is the highest level of education completed by the primary care-giver? *(Circle one.)* BDFA6A

- Less than high school ..... A
- Some high school ..... B
- High School diploma/GED C
- Some college or 2-year degree/certificate ..... D
- College graduate ..... E
- Post-graduate ..... F
- Refused ..... G
- Unknown ..... H

6b. What is the primary care-giver's sex? ..... M F BDFA6B

7a. What is the highest level of education completed by the secondary care-giver? *(Circle one.)* BDFA7A

- Less than high school ..... A
- Some high school ..... B
- High School diploma/GED C
- Some college or 2-year degree/certificate ..... D
- College graduate ..... E
- Post-graduate ..... F
- Refused ..... G
- Unknown ..... H
- No secondary care-giver ..... I → Go to Item 8

7b. What is the secondary care-giver's sex? ..... M F BDFA7B

C. RESOURCE INFORMATION

8. What is the current total annual income in your child's primary household? *(Use BDF Response Card #1.)* ..... ☐ BDFA8

- Under $13,500 ..... A
- $13,500 – 23,499 ..... B
- $23,500 – 33,499 C
- $33,500 – 57,999 ..... D
- $58,000 – 99,999 ..... E
- $100,000 – 149,999 ..... F
- $150,000 and above ..... G
- Don't know ..... H
- Refused I

9. What medical insurance does your child currently have? *(Answer each.)*

a.	Commercial insurance	Y	N	U	R	BDFA9A
b.	Tricare (formerly CHAMPUS)	Y	N	U	R	BDFA9B
c.	Medicaid or other state-promoted program	Y	N	U	R	BDFA9C
d.	No insurance	Y	N	U	R	BDFA9D
e.	Other	Y	N	U	R	BDFA9E

1. If other, please specify: _____ BDFA9E1

10. Is your child's primary household currently receiving public assistance (include WIC, food stamps, SSI)? *(Circle one.)* ..... Y N U R BDFA10

D. ADMINISTRATIVE INFORMATION

11. **[PC]** Date of demographic interview (mm/dd/yyyy): ..... | | / | | / | | | | | BDFA11

12. **[PC]** Method of data collection *(circle one)*:

Computer C
Paper..... P

BDFA12

13. **[PC]** Interviewer's initials: ..... | | | BLIND_STAFF_ID

BASELINE MEDICAL HISTORY FORM

ID NUMBER:							

FORM CODE: BMH
VERSION: A 01/25/07

Contact Occasion | | | SEQ # | |

Participant Name: _____

Instructions: *This form should be completed during the child's baseline clinic visit with input from the parent(s)/guardian.*

A. NATAL HISTORY

1. Was your child ever breastfed? ..... Y N → **Go to Item 4** BMHA1

2. What age did you add formula or other foods to your child's diet (months)? ..... | | BMHA2
(99=currently breastfed only)

3. What age did your child stop breastfeeding (months)? ..... | | BMHA3
(99=currently breastfed)

B. MEDICATION HISTORY

4. How many times in the past 6 months has your child been prescribed antibiotics for illnesses such as ear infections, bronchitis, and other respiratory tract infections? ..... | | BMHA4

5. Has your child ever been prescribed a prophylactic antibiotic that was taken longer than 3 months? ..... Y N BMHA5

6. Is your child currently taking any prescription or over-the-counter medications, including anti-microbials? ..... Y → **Complete CMF** N BMHA6

C. VOIDING HISTORY

7. Has your child been toilet-trained for urine during the day (out of diapers and pull-ups, wearing underwear)? ..... Y N → **Go to Item 9** BMHA7

8. How old was your child when he/she began urinating in the toilet or potty by him/herself during the day (months)? ..... | | BMHA8

D. BOWEL HISTORY

9. Has your child been toilet-trained for bowel movements? ..... Y N → **Go to Item 12** BMHA9

10. How old was your child when he/she began defecating in the toilet or potty by him/herself (months)? ..... | | BMHA10

11. Since toilet/potty training, has your child had a history of soiling his/her underwear with stool? ..... Y N BMHA11

12. During the last 2 months, how many bowel movements did your child have per week on average? ..... | | BMHA12

13. Does your child have a history of constipation? ..... Y N BMHA13

14. Has your child ever been treated for constipation? ..... Y N BMHA14

E. FAMILIAL MEDICAL HISTORY

15. Does your child have any blood relatives with any of the following medical conditions?
(Circle one for each family category. An X response indicates not applicable.)

		1. Full or Half-Siblings					2. Parents					3. Grandparents			
a.	Recurrent childhood UTIs	Y	N	U	X	BMHA15A1	Y	N	U	BMHA15A2		Y	N	U	BMHA15A3
b.	Vesicoureteral reflux	Y	N	U	X	BMHA15B1	Y	N	U	BMHA15B2		Y	N	U	BMHA15B3
c.	Hypertension	Y	N	U	X	BMHA15C1	Y	N	U	BMHA15C2		Y	N	U	BMHA15C3
d.	Chronic kidney disease	Y	N	U	X	BMHA15D1	Y	N	U	BMHA15D2		Y	N	U	BMHA15D3
e.	Dialysis treatment	Y	N	U	X	BMHA15E1	Y	N	U	BMHA15E2		Y	N	U	BMHA15E3
f.	Kidney transplant	Y	N	U	X	BMHA15F1	Y	N	U	BMHA15F2		Y	N	U	BMHA15F3

F. ADMINISTRATIVE INFORMATION

16. **[PC]** Date of data collection (mm/dd/yyyy): ..... | |/| |/| | | | | BMHA16

17. **[PC]** Method of data collection *(circle one)*:
Computer C
Paper ..... P
BMHA17

18. **[PC]** Interviewer's initials: ..... | | | BLIND_STAFF_ID

Blood Specimen Results Form

ID NUMBER:								FORM CODE: BSR VERSION: A 06/28/07	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *Complete this form from medical records abstraction to report on all local laboratory results at baseline and end-of-study, or at any time during the study when a blood specimen is drawn.*

A. BLOOD COUNT (CBC)

1. Are CBC test results available? BSRA1
   - Yes ..... Y
   - No, sample inadequate ..... I → **Do Item 2, then go to Item 7**
   - No, other reason ..... O
   - a. If other, specify: _____ → **Go to Item 7** BSRA1A
2. Date CBC sample drawn (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ BSRA2
3. White blood cell count (WBC) (countx10^9/L) ..... ☐☐.☐ BSRA3
4. Hemoglobin (Hgb) (g/dL) ..... ☐☐.☐ BSRA4
5. Hematocrit (Hct) (%) ..... ☐☐.☐ BSRA5
6. Platelet count (countx10^9/L) ..... ☐☐☐ BSRA6

B. METABOLIC / ELECTROLYTE RESULTS

7. Are metabolic/electrolyte test results available? BSRA7
   - Yes ..... Y
   - No, electrolytes not required at this contact ..... C → **Go to Item 15**
   - No, sample inadequate ..... I → **Do Item 8, then go to Item 15**
   - No, other reason ..... O
   - a. If other, specify: _____ → **Go to Item 15** BSRA7A
8. Date metabolic/electrolyte blood drawn (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ BSRA8
9. BUN (mg/dL) ..... ☐☐ BSRA9
10. Creatinine (mg/dL) ..... ☐.☐ BSRA10
11. Sodium (mmol/L) ..... ☐☐☐ BSRA11
12. Potassium (mmol/L) ..... ☐.☐ BSRA12

13. Chloride (mmol/L) ..... | | | | BSRA13

14. Carbon dioxide (mmol/L) ..... | | | . | | BSRA14

C. ADMINISTRATIVE INFORMATION

15. Date of data collection (mm/dd/yyyy): ..... | | / | | / | | | | | BSRA15

16. Method of data collection *(circle one)*:

Computer C
Paper ..... P
BSRA16

17. Recorder's initials: ..... | | | BLIND_STAFF_ID

CENTRAL LAB BLOOD RESULTS FORM

RMUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:								FORM CODE: CLR VERSION: B 04/14/10	Contact Occasion		SEQ #	0	0

Instructions: *Central lab personnel will complete this form from central lab blood specimens.*

A. SPECIMEN DESCRIPTION

1. Date sample drawn at site (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ CLRB1

2. Indicate the appearance of the serum:

   No hemolysis 0
   Pink (slight hemolysis) 1 CLRB2
   Red/light red (moderate hemolysis) 2
   Dark red (gross hemolysis) 3

B. CYSTATIN-C RESULTS

3. Are cystatin C results available?

   Yes ..... Y CLRB3
   No ..... N
   If N, please specify reason: _____ → **Go to Item 6**

4. Date of cystatin C analysis (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ CLRB4

5. Cystatin C (mg/L) ..... ☐.☐☐ CLRB5

C. CREATININE RESULTS

6. Are serum creatinine results available?

   Yes ..... Y CLRB6
   No ..... N
   If N, please specify reason: _____ → **Go to Item 9**

7. Date of serum creatinine analysis (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ CLRB7

8. Serum creatinine (mg/dL) ..... ☐.☐☐ CLRB8

D. HIGH SENSITIVITY C REACTIVE PROTEIN (hs-CRP) RESULTS

9. Are hs-C reactive protein results available?

   Yes ..... Y CLRB9
   No ..... N
   If N, please specify reason: _____ → **Go to Item 12**

10. Date of hs-C reactive protein analysis (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ CLRB10

11. hs-C reactive protein (mg/L) ..... ☐☐.☐ CLRB11

E. ADMINISTRATIVE INFORMATION

12. Date of data entry (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ CLRB12

13. Method of data collection *(circle one)*:

    Computer C
    Paper ..... P

    CLRB13

14. Recorder's initials: ..... ☐☐☐ BLIND_STAFF_ID

Concomitant Medication Form

ID NUMBER:								FORM CODE: CMF VERSION: B 07/18/08	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *Complete this form to provide information on current concomitant medication use. See DMS follow-up report for summary of previous concomitant medication use, and review participant diary with parent. Medication codes are listed in the Manual of Procedures and in the DMS medication look-up table.*

A. ADMINISTRATIVE INFORMATION

1. Date of data collection (mm/dd/yyyy): ..... __/__/____ CMF1

2. Method of data collection *(circle one)*:
   Computer C
   Paper ..... P
   CMF2

3. a. Recorder's initials: ..... ___ BLIND_STAFF_ID

   b. Is contact considered a 'Missed Contact'? ..... Y→**Exit form** **N** CMFB3B

B. CONCOMITANT MEDICATION USE

4. Is the child currently taking medication (baseline), or, have there been any changes in their medication use since the last contact?..... Y N →**Exit form** CMF4

CMF5B - CMF28B (DMS only): Medication Preferred Name selected from list using the Master Drug Data Base v2 from Medi-Span

CMF5C - CMF28C (DMS only): Medication Code

	Medication	**Date Start**	**E. Date Stop** *If continuing use 00/00/0000*	**F. Reason Medication Taken**
5.	CMF5A	CMF5D __ __ / __ __ / 20__ __	CMF5E __ __ / __ __ / 20__ __	CMFB5F
6.	CMF6A	CMF6D __ __ / __ __ / 20__ __	CMF6E __ __ / __ __ / 20__ __	CMFB6F
7.	CMF7A	CMF7D __ __ / __ __ / 20__ __	CMF7E __ __ / __ __ / 20__ __	CMFB7F
8.	CMF8A	CMF8D __ __ / __ __ / 20__ __	CMF8E __ __ / __ __ / 20__ __	CMFB8F
9.	CMF9A	CMF9D __ __ / __ __ / 20__ __	CMF9E __ __ / __ __ / 20__ __	CMFB9F
10.	CMF10A	CMF10D __ __ / __ __ / 20__ __	CMF10E __ __ / __ __ / 20__ __	CMFB10F
11.	CMF11A	CMF11D __ __ / __ __ / 20__ __	CMF11E __ __ / __ __ / 20__ __	CMFB11F

ID NUMBER:								FORM CODE: CMF VERSION: B 07/18/08	Contact Occasion		SEQ #	

	A. Medication	D. Date Start	E. Date Stop *If continuing use 00/00/0000*	F. Reason Medication Taken
12.	CMF12A	CMF12D __ __ / __ __ / 20__ __	CMF12E __ __ / __ __ / 20__ __	CMFB12F
13.	CMF13A	CMF13D __ __ / __ __ / 20__ __	CMF13E __ __ / __ __ / 20__ __	CMFB13F
14.	CMF14A	CMF14D __ __ / __ __ / 20__ __	CMF14E __ __ / __ __ / 20__ __	CMFB14F
15.	CMF15A	CMF15D __ __ / __ __ / 20__ __	CMF15E __ __ / __ __ / 20__ __	CMFB15F
16.	CMF16A	CMF16D __ __ / __ __ / 20__ __	CMF16E __ __ / __ __ / 20__ __	CMFB16F
17.	CMF17A	CMF17D __ __ / __ __ / 20__ __	CMF17E __ __ / __ __ / 20__ __	CMFB17F
18.	CMF18A	CMF18D __ __ / __ __ / 20__ __	CMF18E __ __ / __ __ / 20__ __	CMFB18F
19.	CMF19A	CMF19D __ __ / __ __ / 20__ __	CMF19E __ __ / __ __ / 20__ __	CMFB19F
20.	CMF20A	CMF20D __ __ / __ __ / 20__ __	CMF20E __ __ / __ __ / 20__ __	CMFB20F
21.	CMF21A	CMF21D __ __ / __ __ / 20__ __	CMF21E __ __ / __ __ / 20__ __	CMFB21F
22.	CMF22A	CMF22D __ __ / __ __ / 20__ __	CMF22E __ __ / __ __ / 20__ __	CMFB22F
23.	CMF23A	CMF23D __ __ / __ __ / 20__ __	CMF23E __ __ / __ __ / 20__ __	CMFB23F
24.	CMF24A	CMF24D __ __ / __ __ / 20__ __	CMF24E __ __ / __ __ / 20__ __	CMFB24F
25.	CMF25A	CMF25D __ __ / __ __ / 20__ __	CMF25E __ __ / __ __ / 20__ __	CMFB25F
26.	CMF26A	CMF26D __ __ / __ __ / 20__ __	CMF26E __ __ / __ __ / 20__ __	CMFB26F
27.	CMF27A	CMF27D __ __ / __ __ / 20__ __	CMF27E __ __ / __ __ / 20__ __	CMFB27F
28.	CMF28A	CMF28D __ __ / __ __ / 20__ __	CMF28E __ __ / __ __ / 20__ __	CMFB28F

Concomitant Medication Form

ID NUMBER:								FORM CODE: CMF VERSION: A 11/27/07	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *Complete this form to provide information on current concomitant medication use. See DMS follow-up report for summary of previous concomitant medication use, and review participant diary with parent. Medication codes are listed in the Manual of Procedures and in the DMS medication look-up table.*

A. ADMINISTRATIVE INFORMATION

1. Date of data collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ CMF1

2. Method of data collection *(circle one)*:
   Computer ..... C CMF2
   Paper ..... P

3. Recorder's initials: ..... ☐☐☐ BLIND_STAFF_ID

B. CONCOMITANT MEDICATION USE

4. Is the child currently taking medication (baseline), or, have there been any changes in their medication use since the last contact? ..... Y N → **Exit form** CMF4

CMF5B - CMF28B (DMS only): Medication Preferred Name selected from list using the Master Drug Data Base v2 from Medi-Spa

CMF5C - CMF28C (DMS only): Medication Code

	Medication	**B. Date Start**	**C. Date Stop**
5.	CMF5A	CMF5D __ __ / __ __ / 20__ __	CMF5E __ __ / __ __ / 20__ __
6.	CMF6A	CMF6D __ __ / __ __ / 20__ __	CMF6E __ __ / __ __ / 20__ __
7.	CMF7A	CMF7D __ __ / __ __ / 20__ __	CMF7E __ __ / __ __ / 20__ __
8.	CMF8A	CMF8D __ __ / __ __ / 20__ __	CMF8E __ __ / __ __ / 20__ __
9.	CMF9A	CMF9D __ __ / __ __ / 20__ __	CMF9E __ __ / __ __ / 20__ __
10.	CMF10A	CMF10D __ __ / __ __ / 20__ __	CMF10E __ __ / __ __ / 20__ __
11.	CMF11A	CMF11D __ __ / __ __ / 20__ __	CMF11E __ __ / __ __ / 20__ __

ID NUMBER:								FORM CODE: CMF VERSION: A 11/27/07	Contact Occasion		SEQ #	

	A. Medication	B. Date Start	C. Date Stop
12.	CMF12A	CMF12D __ __ / __ __ / 20__ __	CMF12E __ __ / __ __ / 20__ __
13.	CMF13A	CMF13D __ __ / __ __ / 20__ __	CMF13E __ __ / __ __ / 20__ __
14.	CMF14A	CMF14D __ __ / __ __ / 20__ __	CMF14E __ __ / __ __ / 20__ __
15.	CMF15A	CMF15D __ __ / __ __ / 20__ __	CMF15E __ __ / __ __ / 20__ __
16.	CMF16A	CMF16D __ __ / __ __ / 20__ __	CMF16E __ __ / __ __ / 20__ __
17.	CMF17A	CMF17D __ __ / __ __ / 20__ __	CMF17E __ __ / __ __ / 20__ __
18.	CMF18A	CMF18D __ __ / __ __ / 20__ __	CMF18E __ __ / __ __ / 20__ __
19.	CMF19A	CMF19D __ __ / __ __ / 20__ __	CMF19E __ __ / __ __ / 20__ __
20.	CMF20A	CMF20D __ __ / __ __ / 20__ __	CMF20E __ __ / __ __ / 20__ __
21.	CMF21A	CMF21D __ __ / __ __ / 20__ __	CMF21E __ __ / __ __ / 20__ __
22.	CMF22A	CMF22D __ __ / __ __ / 20__ __	CMF22E __ __ / __ __ / 20__ __
23.	CMF23A	CMF23D __ __ / __ __ / 20__ __	CMF23E __ __ / __ __ / 20__ __
24.	CMF24A	CMF24D __ __ / __ __ / 20__ __	CMF24E __ __ / __ __ / 20__ __
25.	CMF25A	CMF25D __ __ / __ __ / 20__ __	CMF25E __ __ / __ __ / 20__ __
26.	CMF26A	CMF26D __ __ / __ __ / 20__ __	CMF26E __ __ / __ __ / 20__ __
27.	CMF27A	CMF27D __ __ / __ __ / 20__ __	CMF27E __ __ / __ __ / 20__ __
28.	CMF28A	CMF28D __ __ / __ __ / 20__ __	CMF28E __ __ / __ __ / 20__ __

Concomitant Medication Form

ID NUMBER:								FORM CODE: CMF VERSION: A 12/05/06	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *Complete this form to provide information on current concomitant medication use. See DMS follow-up report for summary of previous concomitant medication use, and review participant diary with parent. Medication codes are listed in the Manual of Procedures and in the DMS medication look-up table.*

A. ADMINISTRATIVE INFORMATION

1. Date of data collection (mm/dd/yyyy): ..... __/__/____ CMF1

2. Method of data collection *(circle one)*:
   Computer C
   Paper ..... P
   CMF2

3. Recorder's initials: ..... ___ BLIND_STAFF_ID

B. CONCOMITANT MEDICATION USE

4. Have there been any changes in the child's concomitant medication use since the last contact? ..... Y N → **Exit form** CMF4

CMF5B - CMF28B (DMS only): Medication Preferred Name selected from list

CMF5C - CMF28C (DMS only): Medication Code

	A. Medication	B. Date Start	C. Date Stop
5.	CMF5A	CMF5D __ __ / __ __ / 20__ __	CMF5E __ __ / __ __ / 20__ __
6.	CMF6A	CMF6D __ __ / __ __ / 20__ __	CMF6E __ __ / __ __ / 20__ __
7.	CMF7A	CMF7D __ __ / __ __ / 20__ __	CMF7E __ __ / __ __ / 20__ __
8.	CMF8A	CMF8D __ __ / __ __ / 20__ __	CMF8E __ __ / __ __ / 20__ __
9.	CMF9A	CMF9D __ __ / __ __ / 20__ __	CMF9E __ __ / __ __ / 20__ __
10.	CMF10A	CMF10D __ __ / __ __ / 20__ __	CMF10E __ __ / __ __ / 20__ __
11.	CMF11A	CMF11D __ __ / __ __ / 20__ __	CMF11E __ __ / __ __ / 20__ __

ID NUMBER:								FORM CODE: CMF VERSION: A 12/05/06	Contact Occasion		SEQ #	

	A. Medication	B. Date Start	C. Date Stop
12.	CMF12A	CMF12D __ __ / __ __ / 20__ __	CMF12E __ __ / __ __ / 20__ __
13.	CMF13A	CMF13D __ __ / __ __ / 20__ __	CMF13E __ __ / __ __ / 20__ __
14.	CMF14A	CMF14D __ __ / __ __ / 20__ __	CMF14E __ __ / __ __ / 20__ __
15.	CMF15A	CMF15D __ __ / __ __ / 20__ __	CMF15E __ __ / __ __ / 20__ __
16.	CMF16A	CMF16D __ __ / __ __ / 20__ __	CMF16E __ __ / __ __ / 20__ __
17.	CMF17A	CMF17D __ __ / __ __ / 20__ __	CMF17E __ __ / __ __ / 20__ __
18.	CMF18A	CMF18D __ __ / __ __ / 20__ __	CMF18E __ __ / __ __ / 20__ __
19.	CMF19A	CMF19D __ __ / __ __ / 20__ __	CMF19E __ __ / __ __ / 20__ __
20.	CMF20A	CMF20D __ __ / __ __ / 20__ __	CMF20E __ __ / __ __ / 20__ __
21.	CMF21A	CMF21D __ __ / __ __ / 20__ __	CMF21E __ __ / __ __ / 20__ __
22.	CMF22A	CMF22D __ __ / __ __ / 20__ __	CMF22E __ __ / __ __ / 20__ __
23.	CMF23A	CMF23D __ __ / __ __ / 20__ __	CMF23E __ __ / __ __ / 20__ __
24.	CMF24A	CMF24D __ __ / __ __ / 20__ __	CMF24E __ __ / __ __ / 20__ __
25.	CMF25A	CMF25D __ __ / __ __ / 20__ __	CMF25E __ __ / __ __ / 20__ __
26.	CMF26A	CMF26D __ __ / __ __ / 20__ __	CMF26E __ __ / __ __ / 20__ __
27.	CMF27A	CMF27D __ __ / __ __ / 20__ __	CMF27E __ __ / __ __ / 20__ __
28.	CMF28A	CMF28D __ __ / __ __ / 20__ __	CMF28E __ __ / __ __ / 20__ __

RMUR
Randomized Intervention for Children with Vesicoureteral Reflux

DRUG DISCONTINUATION FORM

ID NUMBER:								FORM CODE: DDF VERSION: A 04/19/07	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *This form is completed to document all temporary or permanent discontinuations for study drug. This form will be linked by the assigned MCID number to the AEF and MCN form associated with the event resulting in drug discontinuation.*

A. STUDY MEDICATION DISCONTINUATION

1. Date of discontinuation (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ DDFA1

2. Type of discontinuation:
   - Temporary discontinuation..... T
   - Permanent discontinuation ..... D

   DDFA2

3. MCID number assigned from corresponding AEF or MCN: ..... ☐☐☐☐☐☐☐ BLIND_MCID

4. Reason for discontinuation:
   - Side effects ..... S
   - Treatment failure..... F
   - Other ..... O

   DDFA4

   a. If other, please specify: _____

5. Discontinuation was reviewed and authorized by (name of investigator):

   ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ BLIND_AUTHORITY

B. ADMINISTRATIVE INFORMATION

6. Date of data collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ DDFA6

7. Method of data collection *(circle one)*:
   - Computer C
   - Paper..... P

   DDFA7

8. Recorder's initials: ..... ☐☐☐ BLIND_STAFF_ID

DMSA RESULTS FORM

Version A of this form was used for pilot study

ID NUMBER: | | | | | | | |

FORM CODE: DMF
VERSION: B 05/04/07

Contact Occasion | | SEQ # | |

Instructions: *This form should be completed by the reference radiologist. Affix the participant ID label above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. The coding for pyelonephritis and scarring include mild: 1-2 segments, moderate: 3-4 segments, severe: >4 segments, global atrophy: diffusely scarred, shrunken kidney.*

A. LOCAL REPORT DATA

1. Date of DMSA scan (mm/dd/yyyy): ..... | | / | | / | | | | | DM_1

2. Administered dose Tc-99m DMSA (millicuries): ..... | | . | | DM_2

3. Differential renal function (%): a. Right ..... | | DM_3A

b. Left ..... | | DM_3B

B. IMAGE READING RESULTS

4. Pyelonephritis: DM_4A

	None	Mild	Moderate	Severe	
a. Right	A	B	C	D	→ **If A, skip Q5a**
b. Left	A	B	C	D	→ **If A, skip Q5b**

DM_4B

5a. Right segments involved with pyelonephritis *(check all that apply)*:

DM_5A1 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ DM_5A12

DM_5A2 DM_5A4 DM_5A6 DM_5A8 DM_5A10

DM_5A3 DM_5A5 DM_5A7 DM_5A9 DM_5A11

5b. Left segments involved with pyelonephritis *(check all that apply)*:

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ DM_5B12

DM_5B1 DM_5B3 DM_5B5 DM_5B7 DM_5B9 DM_5B11

DM_5B2 DM_5B4 DM_5B6 DM_5B8 DM_5B10

6. Scarring:

	None	Mild	Moderate	Severe	Global Atrophy	
a. Right	A	B	C	D	E	→ **If A or E, skip Q7a**
b. Left	A	B	C	D	E	→ **If A or E, skip Q7b**

DM_6A

DM_6B

7a. Right segments with scarring *(check all that apply)*:

DM_7A1 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ DM_7A12

DM_7A2 DM_7A4 DM_7A6 DM_7A8 DM_7A10

DM_7A3 DM_7A5 DM_7A7 DM_7A9 DM_7A11

7b. Left segments with scarring *(check all that apply)*:

DM_7B1 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ DM_7B12

DM_7B3 DM_7B5 DM_7B7 DM_7B9 DM_7B11

DM_7B2 DM_7B4 DM_7B6 DM_7B8 DM_7B10

8. Quality of film:

Adequate ..... A
Inadequate I

DM_8

C. COMPARISON WITH BASELINE

9. Was there new scarring since the baseline image?

Yes ..... Y
No ..... N
Not applicable X

DMB9

D. ADMINISTRATIVE INFORMATION

10. Date of reading (mm/dd/yyyy): ..... | | / | | / | | | | |

DM_9

11. Method of data collection *(circle one)*:

Computer C
Paper ..... P

DM_10

12. Radiologist's initials: ..... | | |

BLIND_STAFF_ID

DMSA Sedation Form

ID NUMBER: | | | | | | | | FORM CODE: DSF
VERSION: A 02/07/07 Contact Occasion | | | SEQ # | |

Participant Name: _____

Instructions: *Complete this form for every DMSA to provide information on possible sedation.*

A. DMSA PROCEDURE

1. Date of DMSA procedure (mm/dd/yyyy): ..... | | / | | / | | | | | DSFA1

2. Was this an interim DMSA following a UTI? ..... Y N → **Go to Item 4** DSFA2
   Note: Not a protocol baseline, 12 months, or end-of-study scan.

3. Record the MCID # associated with the UTI event ..... | | | | | | | | BLIND_MCID
   NOTE: Report the MCID # found on the MCN and MCA forms that correspond to the UTI event.

4. Was sedation used during the radiological procedure?
   Yes ..... Y
   No ..... N → **Go to Item 11** DSFA4
   Unknown ..... U → **Go to Item 11**

B. SEDATION

	Medication Used for Sedation:		Medication Dose (mg/kg):		General Anesthesia:	
5.	Chloral hydrate	a. Y N DSFA5A	b. |||.| DSFA5B		c. Y N U	DSFA5C
6.	Diazepam (Valium)	a. Y N DSFA6A	b. |||.| DSFA6B		c. Y N U	DSFA6C
7.	Fentanyl	a. Y N DSFA7A	b. |||.| DSFA7B		c. Y N U	DSFA7C
8.	Midazolam (Versed)	a. Y N DSFA8A	b. |||.| DSFA8B		c. Y N U	DSFA8C
9.	Pentobarbital	a. Y N DSFA9A	b. |||.| DSFA9B		c. Y N U	DSFA9C
10.	Other Drug	a. Y N DSFA10A	b. |||.| DSFA10B		c. Y N U	DSFA10C

d. If other, specify: DSFA10D _____

C. ADMINISTRATIVE INFORMATION

11. Date of data collection (mm/dd/yyyy): ..... | | / | | / | | | | | DSFA11

12. Method of data collection *(circle one)*:
    Computer C
    Paper ..... P DSFA12

13. Recorder's initials: ..... | | | BLIND_STAFF_ID

DES TREATMENT FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:								FORM CODE: DTF VERSION: A 8/7/08	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *This form is completed at baseline, 12 month, and end-of-study visits. This form is administered only if the child is* ***toilet-trained*** *AND if the participant's* ***DVQ score*** *is* ***>6*** *for females or* ***>9*** *for males.*

A. DES TREATMENT

1. Is the child participating in a timed voiding program? ..... Y N DTFA1
2. Is the child using miralax or other cathartics for DES? ..... Y N DTFA2
3. Is the child using any medical therapies for DES? ..... Y N→**Go to Item 4** DTFA3
   a. Anti-cholinergics ..... Y N DTFA3A
   b. DDAVP ..... Y N DTFA3B
   c. Imipramine ..... Y N DTFA3C
   d. Alpha blockers ..... Y N DTFA3D
4. Is the child using a bedwetting alarm? ..... Y N DTFA4
5. Is the child using biofeedback therapy? ..... Y N DTFA5

B. ADMINISTRATIVE INFORMATION

6. Date of data collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ DTFA6
7. Method of data collection *(circle one)*:
   Computer C
   Paper ..... P
   DTFA7
8. Recorder's initials: ..... ☐☐☐ BLIND_STAFF_ID

DV QUESTIONNAIRE

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:								FORM CODE: DVQ VERSION: A 9/19/06	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *This form is completed by the child and parent at baseline, 12 month, and end-of-study visits. The questionnaire is intended to collect information about the child. This questionnaire is administered only if the child is* ***toilet-trained.*** *Please circle the most appropriate response for each item.*

A. Child Response with Parent Help:

During the past month:	Almost never	Less than ½ the time	About ½ the time	Almost every time	Not applicable	
1. When I peed it hurt.	A	B	C	D	N	DVQA1
2. I tried to hold only my pee by crossing my legs, squatting, or doing a pee dance.	A	B	C	D	N	DVQA2
3. When I had to pee, I could not wait	A	B	C	D	N	DVQA3
4. I had to push to pee.	A	B	C	D	N	DVQA4
5. I went to the bathroom to pee only once or twice per day.	A	B	C	D	N	DVQA5
6. I wet my underwear with pee during the day.	A	B	C	D	N	DVQA6
7. When I wet myself with pee, my underwear was soaked.	A	B	C	D	N	DVQA7
8. I had to push for my bowel movements to come out.	A	B	C	D	N	DVQA8
9. I usually did not have a bowel movement every day.	A	B	C	D	N	DVQA9

B. Parent/Guardian Response:

10. During the past month, has your child experienced any stressful events, such as: a new baby, a new school, home problems (divorce/death), a new home, abuse (sexual/physical), school problems, or serious accident/injury? ..... Y N DVQA10

11. a. During the last 2 months, did your child have a stool that blocked the toilet? ..... Y N → **Go to Item 12** DVQA11A

    b. If yes, indicate how often:

    Never ..... A
    Once per month ..... B
    Two or three times per month ..... C DVQA11B
    Once per week ..... D
    More than once per week ..... E

12. a. During the last 2 months, did your child hold onto his/her stool by crossing the legs or squatting? ..... Y N → **Go to Item 13**

DVQA12A

b. If yes, indicate how often:

Never ..... A
Once per month ..... B
Two or three times per month C
Once per week ..... D
More than once per week ..... E

DVQA12B

13. a. During the last 2 months, did your child complain of pain while having a bowel movement? ..... Y N → **Go to Item 14**

DVQA13A

b. If yes, indicate how often:

Never ..... A
Once per month ..... B
Two or three times per month C
Once per week ..... D
More than once per week ..... E

DVQA13B

14. a. Over the last 2 months, did your child have bowel movements in his/her underwear? ..... Y N → **Stop**

DVQA14A

b. If yes, indicate how often:

Never ..... A
Once per month ..... B
Two or three times per month C
Once per week ..... D
More than once per week ..... E

DVQA14B

Thank you!

C. Administrative Use Only

15. Date of Form (mm/dd/yyyy) ..... |_|_|/|_|_|/|_|_|_|_| DVQA15

16. Reviewer's initials: ..... |_|_|_| BLIND_STAFF_ID

ELIGIBILITY AND RANDOMIZATION FORM

ID NUMBER: | | | | | | | |

FORM CODE: ERF
VERSION: E 02/08/11

Contact Occasion | |

SEQ # | |

Participant Name: _____

Instructions: *Complete this form for RIVUR-eligible children. The form is completed during the child's eligibility and randomization clinic visit to document the child meeting all eligibility criteria. Enter data into the data management system (DMS) to run the randomization procedure.* ***Note: the index UTI refers to the UTI immediately preceding randomization.*** *The date of the index UTI is the date of the urine collection resulting in positive culture.*

A. ADMINISTRATIVE INFORMATION

1. a. **[PC]** Date of randomization (TODAY) (mm/dd/yyyy): ..... __/__/____ ERF1

   b. **[PC]** Beginning work-up date of the most recent (index) UTI? ..... __/__/____ ERFC1B

   c. **[PC]** Date of consent (mm/dd/yyyy): ..... __/__/____ ERF52

   d. **[PC]** Method of data collection *(circle one)*:
   Computer C
   Paper ..... P
   ERF54

   e. **[PC]** Interviewer's initials: ..... ___ BLIND_STAFF_ID

B. AGE

2. Child's date of birth (mm/dd/yyyy): ..... __/__/____ ERF2

3. **[PC]** Age in months: ..... **[determined by DMS]** ERF3

		Yes	No	Not Applicable	
4.	If child's age < 6 months, was gestational age ≥ 34 weeks?	Y	N → **Ineligible**	X	ERF4
5.	**[PC]** Is child's age ≥ 2 months and < 72 months (6 yrs)?	Y	N → **Ineligible**		ERF5
6.	a. Has your child had more than one UTI?	Y	N → **Go to Item 7**		ERFC6A

   b. How many? ..... ___ → **Ineligible if >2** ERFC6B

   c. Did your child receive a VUR diagnosis prior to the second UTI? .... Y → **Ineligible** N ERFC6C

   d. Did your child take prophylactic anti-microbials for UTI prior to the second UTI? ..... Y → **Ineligible** N ERFC6D

C. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the index UTI event? ..... Y N → **Go to Item 14** ERF7

8. a. What was your child's highest measured temperature 24 hrs prior to or following the initial index UTI work-up? ..... ☐☐☐.☐ ERFB8A

   b. Temperature measurement units *(circle one)*:

   ˚F ..... F
   ˚C ..... C ERFB8B

9. What was the temperature measurement route? *(circle one)*: ERF10

   Oral ..... O
   Axillary ..... A
   Tympanic ..... T
   Rectal ..... R
   Unknown ..... U

10. What location was the temperature measured? *(Circle one)*: ERF11

    Home ..... H
    Medical care professional ..... M

11. a. What was the highest measured temperature during the index UTI? ..... ☐☐☐.☐ ERF8A

    b. Temperature measurement units *(circle one)*:

    ˚F ..... F
    ˚C ..... C ERF8B

    c. What was the date of the highest temperature (mm/dd/yyyy)? ..... ☐☐/☐☐/☐☐☐☐ ERF9

12. What was the total duration of fever prior to index UTI antimicrobial treatment (hrs)? ..... ☐☐☐ ERF12

13. What was the time from index UTI antimicrobial treatment to a sustained (> 24 hrs) normal temperature (hrs)? ..... ☐☐☐ ERFB13

14. Were the following symptoms present within 24 hrs prior to or following the initial UTI work-up?

	Yes	No	Unknown	
a. Suprapubic, abdominal, or flank pain or tenderness	Y	N	U	ERFC14A
b. Urinary urgency	Y	N	U	ERFC14B
c. Urinary frequency	Y	N	U	ERFC14C

	Yes	No	Unknown	Not Applicable	
d. Urinary hesitancy	Y	N	U		ERFC14D
e. Dysuria	Y	N	U		ERFC14E
f. Foul-smelling urine	Y	N	U		ERFC14F
g. Failure to thrive (if child ≤ 4 mo.)	Y	N	U	X	ERFC14G
h. Dehydration (if child ≤ 4 mo.)	Y	N	U	X	ERFC14H
i. Hypothermia (if child ≤ 4 mo.)	Y	N	U	X	ERFC14I

15. What was the total number of days that your child experienced these symptoms? ..... ☐☐ ERFB15

16. **[PC]** Was there a temperature ≥ 100.4˚F or 38˚C *(see Q8)* **OR** were urinary tract symptoms *(see Q14)* present 24 hrs prior to or following the initial index UTI work-up? ..... Y N → **Ineligible** ERFC16

D. INDEX UTI URINALYSIS RESULTS

17. a. **[PC]** Date of dipstick urine collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERFB17A

b. **[PC]** Dipstick results - leukocyte esterase *(circle one)*: ERF17A

- Negative ..... A
- Trace ..... B
- Small (+) C
- Moderate (++) ..... D
- Large (+++) ..... E

c. **[PC]** Dipstick results - nitrite *(circle one)*: ERF17B

- Negative ..... N
- Positive ..... P

18. a. **[PC]** Date of microscopy urine collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERFB18A

b. **[PC]** WBC *(Enter count. Use 999.999 for values ≥ 999.999)*: ..... ☐☐☐.☐☐☐ ERFB18B

c. **[PC]** Reporting units for WBC microscopy *(circle one)*:

- WBC/mm^3 ..... A
- WBC/hpf ..... B

ERF18B

19. **[PC]** Was pyuria present, noted as either leukocyte esterase on dipstick greater than or equal to trace *(see Q17b)* **OR** WBC ≥ 10 WBC/mm^3 or WBC ≥ 5 WBC/hpf *(see Q18)*? ..... Y N → **Ineligible** ERFB19

E. INDEX UTI URINE CULTURE RESULTS

20. a. **[PC]** Date of urine collection for culture (mm/dd/yyyy): ..... | | / | | / | | | | | ERFB20A

b. **[PC]** Method of urine collection *(circle one)*: ERF20

Catheterization ..... A

Suprapubic aspiration ..... B

Clean voided C

Bag collected ..... D → **Ineligible**

Unknown ..... E → **Ineligible**

21. a. **[PC]** Did the urine culture show a single primary organism that was neither lactobacillus nor candida? ..... Y N → **Ineligible** ERFB21A

b. **[PC]** How many organisms were present? ..... | → **Ineligible if more than 2** ERFB21B

22. a. **[PC]** Primary organism *(select from list)*: ..... | | ERFB22A

b. **[PC]** Data type from primary organism culture results *(circle one):* ERFB22B

= (equal to) ..... A → **Skip field c2**

> (greater than) ..... B → **Skip field c2**

≥ (greater than or equal to) ..... C → **Skip field c2**

< (less than) ..... D → **Skip field c2**

≤ (less than or equal to) ..... E → **Skip field c2**

Range ..... F

c. **[PC]** Colony count (CFU/ml) of primary organism: ..... c1. | | | | | | - c2. | | | | | | ERFB22C1 ERFB22C2

23. a. **[PC]** Secondary organism *(select from list)*: ..... | | ERFB23A

b. **[PC]** Data type from secondary organism culture results *(circle one):* ERFB23B

= (equal to) ..... A → **Skip field c2**

> (greater than) ..... B → **Skip field c2**

≥ (greater than or equal to) ..... C → **Skip field c2**

< (less than) ..... D → **Skip field c2**

≤ (less than or equal to) ..... E → **Skip field c2**

Range ..... F

c. **[PC]** Colony count (CFU/ml) of secondary organism: ..... c1. | | | | | | - c2. | | | | | | ERFB23C1 ERFB23C2

24. a. **[PC]** Was the colony count for the primary organism ≥ 50,000 CFU/ml in catheterized or suprapubic specimens **OR** ≥100,000 CFU/ml in clean-voided specimen? *(See Q22.)* ..... Y N → **Ineligible** ERFB24A

b. **[PC]** Was the colony count for the secondary organism ≤ 10,000 CFU/ml? *(See Q23.)* ..... Y N → **Ineligible** ERFC24B

F. INDEX UTI TREATMENT

25. **[PC]** How many different antimicrobials were prescribed to treat the index UTI? *(Describe in Q26-Q29.)* ERF25

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:	
26. **[PC]**	a. ERF26A	b. ERF26B	c. ERF26C	d. Y N U	ERF26D
27. **[PC]**	a. ERF27A	b. ERF27B	c. ERF27C	d. Y N U	ERF27D
28. **[PC]**	a. ERF28A	b. ERF28B	c. ERF28C	d. Y N U	ERF28D
29. **[PC]**	a. ERF29A	b. ERF29B	c. ERF29C	d. Y N U	ERF29D

30. **[PC]** a. Was the index UTI treated at least 7 days? *(Sum Q26c, Q27c, Q28c, and Q29c.)* Y N → **Ineligible** ERF30A

[PC] b. Was the index UTI appropriately treated at least 7 days with an effective drug? *(Sum Q26c, Q27c, Q28c, and Q29c only where corresponding Q26d, Q27d, Q28d, and Q29d='Y'.)* ..... Y N ERF30B

31. **[PC]** Was a follow-up negative urine culture documented 1-14 days after completion of therapy? ..... Y N → **Ineligible if Item 30b is N** ERF31

32. **[PC]** Date of follow-up urine culture (mm/dd/yyyy): ERF32

G. VCUG LOCAL REPORT

33. **[PC]** Date of VCUG (mm/dd/yyyy): ERF33

34. **[PC]** Is date of VCUG within 112 days after index UTI? ..... Y N → **Ineligible** ERFC34

35. **[PC]** Does the VCUG demonstrate grade I, II, III or IV reflux in at least one ureter? ..... Y N → **Ineligible** ERF35

36. **[PC]** Is grade V reflux present in either ureter? ..... Y → **Ineligible** N ERF36

37. **[PC]** Does the VCUG show the following bladder abnormalities?

a. Ureterocele ..... Y → **Ineligible** N ERF37A

b. Urethral valve ..... Y → **Ineligible** N ERF37B

H. RENAL ULTRASOUND LOCAL REPORT

38. a. **[PC]** Date of ultrasound (mm/dd/yyyy): ____/____/____ ERF38

b. **[PC]** Is date of ultrasound within 112 days prior to or after index UTI? Y N → **Ineligible** ERFC38B

39. **[PC]** Does the ultrasound show the following urologic abnormalities?

a. Gr 4 Hydronephrosis w/renal parenchyma atrophy ..... Y → **Ineligible** N ERF39A

b. Ureterocele ..... Y → **Ineligible** N ERF39B

c. Solitary kidney ..... Y → **Ineligible** N ERF39C

d. Profoundly small kidney (more than 2 SD below mean) ..... Y → **Ineligible** N ERF39D

e. Multicystic dysplastic kidney ..... Y → **Ineligible** N ERF39E

f. Pelvic kidney ..... Y → **Ineligible** N ERF39F

g. Fused kidney ..... Y → **Ineligible** N ERF39G

h. Neurogenic bladder ..... Y → **Ineligible** N ERF39H

I. OTHER MEDICAL EXCLUSIONS

40. Does your child have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (i.e. VATER–VACTERL association, Townes-Brock syndrome, cat eye syndrome, Casamassima-Morton-Nance syndrome, renal coloboma syndrome, branchio-oto-renal syndrome, Frasier syndrome, congenital immunodeficiency, or acquired immunodeficiency)? ..... Y → **Ineligible** N ERF40

41. Does your child have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (i.e. GI conditions, liver or kidney failure, malignancy, complex cardiac diseases)? ..... Y → **Ineligible** N ERF41

42. Is trimethoprim or sulfa contraindicated due to an intolerance or known allergy, inadequate renal or hepatic function, G6PD deficiency or other reasons? ..... Y → **Ineligible** N ERF42

43. Do the parents or siblings have a history of anaphylactic reaction to sulfa? ..... Y → **Ineligible** N ERF43

44. Has your child ever had renal or bladder surgery? ..... Y → **Ineligible** N ERF44

J. AVAILABILITY

45. Is your child currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown? ..... Y → **Ineligible** N ERF45

46. a. Is your child currently taking continuous antimicrobial prophylaxis? ..... Y N → **Go to Item 47** ERF46

b. Is the family willing to discontinue current prophylaxis to begin RIVUR treatment? ..... Y N → **Ineligible** ERFB46B

47. Is there any reason that would make completing the study protocol impossible (i.e. administering daily oral medication, visiting the clinic semiannually for data collection, or receiving bimonthly phone calls from study staff)? ..... Y→**Ineligible** N ERF47

48. Does the family have plans to move to an area that will make it no longer convenient for study participation? ..... Y→**Ineligible** N ERF48

K. RECENT FEVER AND PYURIA

49. Has your child had a temperature ≥ 100.4˚F or 38˚C anytime in the last **24** hours? ..... Y→**Stop** N ERFD49

50. a. **[PC]** Was pyuria present on today's urine dipstick, or the previous urine dipstick, noted as leukocyte esterase ≥ trace **OR** microscopy results of WBC ≥ 10 WBC/mm^3 or WBC ≥ 5 WBC/hpf? ... Y N→**Go to Item 51** ERFB50

b. **[PC]** Is this an attempt at randomization following pyuria present (either on dip or microscopy) at a previous randomization visit? ..... Y N→**Stop** ERFD50B

c. **[PC]** Date of last randomization attempt (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERFD50C

d. **[PC]** Is there a negative culture from a specimen collected at the previous randomization attempt when pyuria was present? ..... Y N→**Stop** ERFD50D

L. RANDOMIZATION

51. **[PC]** Eligibility criteria reviewed and randomization authorized by (name of investigator): BLIND_AUTHORITY

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Note: *choosing 'Y' to question #52 will initiate randomization. Items on this form will not be able to be changed following the randomization procedure. Please verify that the responses you have entered above are accurate before continuing.*

52. **[PC]** Do you wish to randomize this child to a treatment group? ..... Y N ERF51

ELIGIBILITY AND RANDOMIZATION FORM

ID NUMBER: | | | | | | | |

FORM CODE: ERF
VERSION: D 8/29/08

Contact Occasion | |

SEQ # | |

Participant Name: _____

Instructions: *Complete this form for RIVUR-eligible children. The form is completed during the child's eligibility and randomization clinic visit to document the child meeting all eligibility criteria. Enter data into the data management system (DMS) to run the randomization procedure.* ***Note: the index UTI refers to the UTI immediately preceding randomization.*** *The date of the index UTI is the date of the urine collection resulting in positive culture.*

A. ADMINISTRATIVE INFORMATION

1. a. **[PC]** Date of randomization (TODAY) (mm/dd/yyyy): ..... __/__/____ ERF1

   b. **[PC]** Beginning work-up date of the most recent (index) UTI? ..... __/__/____ ERFC1B

   c. **[PC]** Date of consent (mm/dd/yyyy): ..... __/__/____ ERF52

   d. **[PC]** Method of data collection *(circle one)*:
   Computer C
   Paper ..... P
   ERF54

   e. **[PC]** Interviewer's initials: ..... ___ BLIND_STAFF_ID

B. AGE

2. Child's date of birth (mm/dd/yyyy): ..... __/__/____ ERF2

3. **[PC]** Age in months: ..... **[determined by DMS]** ERF3

		Yes	No	Not Applicable	
4.	If child's age < 6 months, was gestational age ≥ 34 weeks?	Y	N → **Ineligible**	X	ERF4
5.	**[PC]** Is child's age ≥ 2 months and < 72 months (6 yrs)?	Y	N → **Ineligible**		ERF5
6.	a. Has your child had more than one UTI?	Y	N → **Go to Item 7**		ERFC6A
	b. How many?		→ **Ineligible if >2**		ERFC6B
	c. Did your child receive a VUR diagnosis prior to the second UTI?	Y → **Ineligible**	N		ERFC6C
	d. Did your child take prophylactic anti-microbials for UTI prior to the second UTI?	Y → **Ineligible**	N		ERFC6D

C. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the index UTI event? ..... Y N → **Go to Item 14** ERF7

8. a. What was your child's highest measured temperature 24 hrs prior to or following the initial index UTI work-up? ..... | | | . | | ERFB8A

   b. Temperature measurement units *(circle one)*:

   ˚F ..... F
   ˚C ..... C ERFB8B

9. What was the temperature measurement route? *(circle one)*: ERF10

   Oral ..... O
   Axillary ..... A
   Tympanic ..... T
   Rectal ..... R
   Unknown ..... U

10. What location was this temperature measured? *(Circle one)*: ERF11

    Home ..... H
    Medical care professional ..... M

11. a. What was the highest measured temperature during the index UTI? ..... | | | . | | ERF8A

    b. Temperature measurement units *(circle one)*:

    ˚F ..... F
    ˚C ..... C ERF8B

    c. What was the date of the highest temperature (mm/dd/yyyy)? ..... | | / | | / | | | | ERF9

12. What was the total duration of fever prior to index UTI antimicrobial treatment (hrs)? ..... | | | ERF12

13. What was the time from index UTI antimicrobial treatment to a sustained (> 24 hrs) normal temperature (hrs)? ..... | | | ERFB13

14. Were the following symptoms present within 24 hrs prior to or following the initial UTI work-up?

	Yes	No	Unknown	
a. Suprapubic, abdominal, or flank pain or tenderness	Y	N	U	ERFC14A
b. Urinary urgency	Y	N	U	ERFC14B
c. Urinary frequency	Y	N	U	ERFC14C

		Yes	No	Unknown	Not Applicable	
d.	Urinary hesitancy	Y	N	U		ERFC14D
e.	Dysuria	Y	N	U		ERFC14E
f.	Foul-smelling urine	Y	N	U		ERFC14F
g.	Failure to thrive (if child ≤ 4 mo.)	Y	N	U	X	ERFC14G
h.	Dehydration (if child ≤ 4 mo.)	Y	N	U	X	ERFC14H
i.	Hypothermia (if child ≤ 4 mo.)	Y	N	U	X	ERFC14I

15. What was the total number of days that your child experienced these symptoms? ..... ☐☐ ERFB15

16. **[PC]** Was there a temperature ≥ 100.4˚F or 38˚C *(see Q8)* **OR** were urinary tract symptoms *(see Q14)* present 24 hrs prior to or following the initial index UTI work-up? ..... Y N → **Ineligible** ERFC16

D. INDEX UTI URINALYSIS RESULTS

17. a. **[PC]** Date of dipstick urine collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERFB17A

b. **[PC]** Dipstick results - leukocyte esterase *(circle one)*: ERF17A

- Negative ..... A
- Trace ..... B
- Small (+) C
- Moderate (++) ..... D
- Large (+++) ..... E

c. **[PC]** Dipstick results - nitrite *(circle one)*: ERF17B

- Negative ..... N
- Positive ..... P

18. a. **[PC]** Date of microscopy urine collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERFB18A

b. **[PC]** WBC *(Enter count. Use 999.999 for values ≥ 999.999)*: ..... ☐☐☐.☐☐☐ ERFB18B

c. **[PC]** Reporting units for WBC microscopy *(circle one)*:

- WBC/mm^3 ..... A
- WBC/hpf ..... B

ERF18B

19. **[PC]** Was pyuria present, noted as either leukocyte esterase on dipstick greater than or equal to trace *(see Q17b)* **OR** WBC ≥ 10 WBC/mm^3 or WBC ≥ 5 WBC/hpf *(see Q18)*? ..... Y N → **Ineligible** ERFB19

E. INDEX UTI URINE CULTURE RESULTS

20. a. **[PC]** Date of urine collection for culture (mm/dd/yyyy): ERFB20A

b. **[PC]** Method of urine collection *(circle one)*: ERF20

Catheterization ..... A

Suprapubic aspiration ..... B

Clean voided C

Bag collected ..... D → **Ineligible**

Unknown ..... E → **Ineligible**

21. a. **[PC]** Did the urine culture show a single primary organism that was neither lactobacillus nor candida? ..... Y N → **Ineligible** ERFB21A

b. **[PC]** How many organisms were present? ..... → **Ineligible if more than 2** ERFB21B

22. a. **[PC]** Primary organism *(select from list)*: ERFB22A

b. **[PC]** Data type from primary organism culture results *(circle one)*: ERFB22B

= (equal to) ..... A → **Skip field c2**

> (greater than) ..... B → **Skip field c2**

≥ (greater than or equal to) ..... C → **Skip field c2**

< (less than) ..... D → **Skip field c2**

≤ (less than or equal to) ..... E → **Skip field c2**

Range ..... F

c. **[PC]** Colony count (CFU/ml) of primary organism: ..... c1. ERFB22C1 - c2. ERFB22C2

23. a. **[PC]** Secondary organism *(select from list)*: ERFB23A

b. **[PC]** Data type from secondary organism culture results *(circle one)*: ERFB23B

= (equal to) ..... A → **Skip field c2**

> (greater than) ..... B → **Skip field c2**

≥ (greater than or equal to) ..... C → **Skip field c2**

< (less than) ..... D → **Skip field c2**

≤ (less than or equal to) ..... E → **Skip field c2**

Range ..... F

c. **[PC]** Colony count (CFU/ml) of secondary organism: ..... c1. ERFB23C1 - c2. ERFB23C2

24. a. **[PC]** Was the colony count for the primary organism ≥ 50,000 CFU/ml in catheterized or suprapubic specimens **OR** ≥100,000 CFU/ml in clean-voided specimen? *(See Q22.)* ..... Y N → **Ineligible** ERFB24A

b. **[PC]** Was the colony count for the secondary organism ≤ 10,000 CFU/ml? *(See Q23.)* ..... Y N → **Ineligible** ERFB24B

F. INDEX UTI TREATMENT

25. **[PC]** How many different antimicrobials were prescribed to treat the index UTI? *(Describe in Q26-Q29.)* ERF25

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
26. **[PC]**	a. ERF26A	b. ERF26B	c. ERF26C	d. Y N U ERF26D
27. **[PC]**	a. ERF27A	b. ERF27B	c. ERF27C	d. Y N U ERF27D
28. **[PC]**	a. ERF28A	b. ERF28B	c. ERF28C	d. Y N U ERF28D
29. **[PC]**	a. ERF29A	b. ERF29B	c. ERF29C	d. Y N U ERF29D

30. **[PC]** a. Was the index UTI treated at least 7 days? *(Sum Q26c, Q27c, Q28c, and Q29c.)* Y N → **Ineligible** ERF30A

[PC] b. Was the index UTI appropriately treated at least 7 days with an effective drug? *(Sum Q26c, Q27c, Q28c, and Q29c only where corresponding Q26d, Q27d, Q28d, and Q29d='Y'.)* ..... Y N ERF30B

31. **[PC]** Was a follow-up negative urine culture documented 1-14 days after completion of therapy? ..... Y N → **Ineligible if Item 30b is N** ERF31

32. **[PC]** Date of follow-up urine culture (mm/dd/yyyy): ERF32

G. VCUG LOCAL REPORT

33. **[PC]** Date of VCUG (mm/dd/yyyy): ERF33

34. **[PC]** Is date of VCUG within 112 days after index UTI? ..... Y N → **Ineligible** ERFC34

35. **[PC]** Does the VCUG demonstrate grade I, II, III or IV reflux in at least one ureter? ..... Y N → **Ineligible** ERF35

36. **[PC]** Is grade V reflux present in either ureter? ..... Y → **Ineligible** N ERF36

37. **[PC]** Does the VCUG show the following bladder abnormalities?

    a. Ureterocele ..... Y→**Ineligible** N ERF37A

    b. Urethral valve ..... Y→**Ineligible** N ERF37B

H. RENAL ULTRASOUND LOCAL REPORT

38. a. **[PC]** Date of ultrasound (mm/dd/yyyy): ..... | | | / | | | / | | | | | ERF38

    b. **[PC]** Is date of ultrasound within 112 days after index UTI? ..... Y N→**Ineligible** ERFC38B

39. **[PC]** Does the ultrasound show the following urologic abnormalities?

    a. Hydronephrosis with renal parenchyma atrophy ..... Y→**Ineligible** N ERF39A

    b. Ureterocele ..... Y→**Ineligible** N ERF39B

    c. Solitary kidney ..... Y→**Ineligible** N ERF39C

    d. Profoundly small kidney (more than 2 SD below mean) ..... Y→**Ineligible** N ERF39D

    e. Multicystic dysplastic kidney ..... Y→**Ineligible** N ERF39E

    f. Pelvic kidney ..... Y→**Ineligible** N ERF39F

    g. Fused kidney ..... Y→**Ineligible** N ERF39G

    h. Neurogenic bladder ..... Y→**Ineligible** N ERF39H

I. OTHER MEDICAL EXCLUSIONS

40. Does your child have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (i.e. VATER–VACTERL association, Townes-Brock syndrome, cat eye syndrome, Casamassima-Morton-Nance syndrome, renal coloboma syndrome, branchio-oto-renal syndrome, Frasier syndrome, congenital immunodeficiency, or acquired immunodeficiency)? ..... Y→**Ineligible** N ERF40

41. Does your child have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (i.e. GI conditions, liver or kidney failure, malignancy, complex cardiac diseases)? ..... Y→**Ineligible** N ERF41

42. Is trimethoprim or sulfa contraindicated due to an intolerance or known allergy, inadequate renal or hepatic function, G6PD deficiency or other reasons? ..... Y→**Ineligible** N ERF42

43. Do the parents or siblings have a history of anaphylactic reaction to sulfa? ..... Y→**Ineligible** N ERF43

44. Has your child ever had renal or bladder surgery? ..... Y→**Ineligible** N ERF44

J. AVAILABILITY

45. Is your child currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown? ..... Y→**Ineligible** N ERF45

46. a. Is your child currently taking continuous antimicrobial prophylaxis? ..... Y N→**Go to Item 47** ERF46

    b. Is the family willing to discontinue current prophylaxis to begin RIVUR treatment? ..... Y N→**Ineligible** ERFB46B

47. Is there any reason that would make completing the study protocol impossible (i.e. administering daily oral medication, visiting the clinic semiannually for data collection, or receiving bimonthly phone calls from study staff)? ..... Y→**Ineligible** N ERF47

48. Does the family have plans to move to an area that will make it no longer convenient for study participation? ..... Y→**Ineligible** N ERF48

K. RECENT FEVER AND PYURIA

49. Has your child had a temperature ≥ 100.4˚F or 38˚C anytime in the last **24** hours? ..... Y→**Stop** N ERFD49

50. a. **[PC]** Was pyuria present on <u>today's</u> urine dipstick, noted as leukocyte esterase ≥ trace **OR** microscopy results of WBC ≥ 10 WBC/mm^3 or WBC ≥ 5 WBC/hpf? ..... Y N→**Go to Item 51** ERFB50

    b. **[PC]** Is this an attempt at randomization following pyuria present (either on dip or microscopy) at a previous randomization visit? ..... Y N→**Stop** ERFD50B

    c. **[PC]** Date of last randomization attempt (mm/dd/yyyy): ..... | | / | | / | | | | ERFD50C

    d. **[PC]** Is there a <u>negative culture</u> from a specimen collected at the previous randomization attempt when pyuria was present? ..... Y N→**Stop** ERFD50D

L. RANDOMIZATION

51. **[PC]** Eligibility criteria reviewed and randomization authorized by (name of investigator): BLIND_AUTHORITY

Note: *choosing 'Y' to question #52 will initiate randomization. Items on this form will not be able to be changed following the randomization procedure. Please verify that the responses you have entered above are accurate before continuing.*

52. **[PC]** Do you wish to randomize this child to a treatment group? ..... Y N ERF51

ELIGIBILITY AND RANDOMIZATION FORM

ID NUMBER: | | | | | | | |

FORM CODE: ERF
VERSION: C 2/21/08

Contact Occasion | |

SEQ # | |

Participant Name: _____

Instructions: *Complete this form for RIVUR-eligible children. The form is completed during the child's eligibility and randomization clinic visit to document the child meeting all eligibility criteria. Enter data into the data management system (DMS) to run the randomization procedure.* ***Note: the index UTI refers to the UTI immediately preceding randomization.*** *The date of the index UTI is the date of the urine collection resulting in positive culture.*

A. ADMINISTRATIVE INFORMATION

1. a. **[PC]** Date of randomization (TODAY) (mm/dd/yyyy): ..... __/__/____ ERF1

   b. **[PC]** Beginning work-up date of the most recent (index) UTI? ..... __/__/____ ERFC1B

   c. **[PC]** Date of consent (mm/dd/yyyy): ..... __/__/____ ERF52

   d. **[PC]** Method of data collection *(circle one)*:
   Computer C
   Paper ..... P
   ERF54

   e. **[PC]** Interviewer's initials: ..... ___ BLIND_STAFF_ID

B. AGE

2. Child's date of birth (mm/dd/yyyy): ..... __/__/____ ERF2

3. **[PC]** Age in months: ..... **[determined by DMS]** ERF3

		Yes	No	Not Applicable	
4.	If child's age < 6 months, was gestational age ≥ 34 weeks?	Y	N → **Ineligible**	X	ERF4
5.	**[PC]** Is child's age ≥ 2 months and < 72 months (6 yrs)?	Y	N → **Ineligible**		ERF5
6.	a. Has your child had more than one UTI?	Y	N → **Go to Item 7**		ERFC6A
	b. How many?		→ **Ineligible if >2**		ERFC6B
	c. Did your child receive a VUR diagnosis prior to the second UTI?	Y → **Ineligible**	N		ERFC6C
	d. Did your child take prophylactic anti-microbials for UTI prior to the second UTI?	Y → **Ineligible**	N		ERFC6D

C. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the index UTI event? ..... Y N → **Go to Item 14** ERF7

8. a. What was your child's highest measured temperature 24 hrs prior to or following the initial index UTI work-up? ..... ☐☐☐.☐ ERFB8A

   b. Temperature measurement units *(circle one)*:

   ˚F ..... F
   ˚C ..... C ERFB8B

9. What was the temperature measurement route? *(circle one)*: ERF10

   Oral ..... O
   Axillary ..... A
   Tympanic ..... T
   Rectal ..... R
   Unknown ..... U

10. What location was this temperature measured? *(Circle one)*: ERF11

    Home ..... H
    Medical care professional ..... M

11. a. What was the highest measured temperature during the index UTI? ..... ☐☐☐.☐ ERF8A

    b. Temperature measurement units *(circle one)*:

    ˚F ..... F
    ˚C ..... C ERF8B

    c. What was the date of the highest temperature (mm/dd/yyyy)? ..... ☐☐/☐☐/☐☐☐☐ ERF9

12. What was the total duration of fever prior to index UTI antimicrobial treatment (hrs)? ..... ☐☐☐ ERF12

13. What was the time from index UTI antimicrobial treatment to a sustained (> 24 hrs) normal temperature (hrs)? ..... ☐☐☐ ERFB13

14. Were the following symptoms present within 24 hrs prior to or following the initial UTI work-up?

	Yes	No	Unknown	
a. Suprapubic, abdominal, or flank pain or tenderness	Y	N	U	ERFC14A
b. Urinary urgency	Y	N	U	ERFC14B
c. Urinary frequency	Y	N	U	ERFC14C

	Yes	No	Unknown	Not Applicable
d. Urinary hesitancy	Y	N	U	ERFC14D
e. Dysuria	Y	N	U	ERFC14E
f. Foul-smelling urine	Y	N	U	ERFC14F
g. Failure to thrive (if child ≤ 4 mo.)	Y	N	U	X ERFC14G
h. Dehydration (if child ≤ 4 mo.)	Y	N	U	X ERFC14H
i. Hypothermia (if child ≤ 4 mo.)	Y	N	U	X ERFC14I

15. What was the total number of days that your child experienced these symptoms? ..... ☐☐ ERFB15

16. **[PC]** Was there a temperature ≥ 100.4˚F or 38˚C *(see Q8)* **OR** were urinary tract symptoms *(see Q14)* present 24 hrs prior to or following the initial index UTI work-up? ..... Y N → **Ineligible** ERFC16

D. INDEX UTI URINALYSIS RESULTS

17. a. **[PC]** Date of dipstick urine collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERFB17A

b. **[PC]** Dipstick results - leukocyte esterase *(circle one)*: ERF17A

- Negative ..... A
- Trace ..... B
- Small (+) C
- Moderate (++) ..... D
- Large (+++) ..... E

c. **[PC]** Dipstick results - nitrite *(circle one)*: ERF17B

- Negative ..... N
- Positive ..... P

18. a. **[PC]** Date of microscopy urine collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERFB18A

b. **[PC]** WBC *(Enter count. Use 999.999 for values ≥ 999.999)*: ..... ☐☐☐.☐☐☐ ERFB18B

c. **[PC]** Reporting units for WBC microscopy *(circle one)*:

- WBC/mm^3 ..... A
- WBC/hpf ..... B

ERF18B

19. **[PC]** Was pyuria present, noted as either leukocyte esterase on dipstick greater than or equal to trace *(see Q17b)* **OR** WBC ≥ 10 WBC/mm^3 or WBC ≥ 5 WBC/hpf *(see Q18)*? ..... Y N → **Ineligible** ERFB19

E. INDEX UTI URINE CULTURE RESULTS

20. a. **[PC]** Date of urine collection for culture (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERFB20A

b. **[PC]** Method of urine collection *(circle one)*: ERF20

Catheterization ..... A

Suprapubic aspiration ..... B

Clean voided C

Bag collected ..... D → **Ineligible**

Unknown ..... E → **Ineligible**

21. a. **[PC]** Did the urine culture show a single primary organism that was neither lactobacillus nor candida? ..... Y N → **Ineligible** ERFB21A

b. **[PC]** How many organisms were present? ..... ☐ → **Ineligible if more than 2** ERFB21B

22. a. **[PC]** Primary organism *(select from list)*: ..... ☐☐ ERFB22A

b. **[PC]** Data type from primary organism culture results *(circle one):* ERFB22B

= (equal to) ..... A → **Skip field c2**

> (greater than) ..... B → **Skip field c2**

≥ (greater than or equal to) ..... C → **Skip field c2**

< (less than) ..... D → **Skip field c2**

≤ (less than or equal to) ..... E → **Skip field c2**

Range ..... F

c. **[PC]** Colony count (CFU/ml) of primary organism: ..... c1. ERFB22C1 ☐☐☐☐☐☐ - c2. ERFB22C2 ☐☐☐☐☐☐

23. a. **[PC]** Secondary organism *(select from list)*: ..... ☐☐ ERFB23A

b. **[PC]** Data type from secondary organism culture results *(circle one):* ERFB23B

= (equal to) ..... A → **Skip field c2**

> (greater than) ..... B → **Skip field c2**

≥ (greater than or equal to) ..... C → **Skip field c2**

< (less than) ..... D → **Skip field c2**

≤ (less than or equal to) ..... E → **Skip field c2**

Range ..... F

c. **[PC]** Colony count (CFU/ml) of secondary organism: ..... c1. ERFB23C1 ☐☐☐☐☐☐ - c2. ERFB23C2 ☐☐☐☐☐☐

24. a. **[PC]** Was the colony count for the primary organism ≥ 50,000 CFU/ml in catheterized or suprapubic specimens **OR** ≥100,000 CFU/ml in clean-voided specimen? *(See Q22.)* ..... Y N → **Ineligible** ERFB24A

b. **[PC]** Was the colony count for the secondary organism ≤ 10,000 CFU/ml? *(See Q23.)* ..... Y N → **Ineligible** ERFC24B

F. INDEX UTI TREATMENT

25. **[PC]** How many different antimicrobials were prescribed to treat the index UTI? *(Describe in Q26-Q29.)* ERF25

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:	
26. **[PC]**	a. ERF26A	b. ERF26B	c. ERF26C	d. Y N U	ERF26D
27. **[PC]**	a. ERF27A	b. ERF27B	c. ERF27C	d. Y N U	ERF27D
28. **[PC]**	a. ERF28A	b. ERF28B	c. ERF28C	d. Y N U	ERF28D
29. **[PC]**	a. ERF29A	b. ERF29B	c. ERF29C	d. Y N U	ERF29D

30. **[PC]** a. Was the index UTI treated at least 7 days? *(Sum Q26c, Q27c, Q28c, and Q29c.)* Y N → **Ineligible** ERF30A

[PC] b. Was the index UTI appropriately treated at least 7 days with an effective drug? *(Sum Q26c, Q27c, Q28c, and Q29c only where corresponding Q26d, Q27d, Q28d, and Q29d='Y'.)* ..... Y N ERF30B

31. **[PC]** Was a follow-up negative urine culture documented 1-14 days after completion of therapy? ..... Y N → **Ineligible if Item 30b is N** ERF31

32. **[PC]** Date of follow-up urine culture (mm/dd/yyyy): ERF32

G. VCUG LOCAL REPORT

33. **[PC]** Date of VCUG (mm/dd/yyyy): ERF33

34. **[PC]** Is date of VCUG within 112 days after index UTI? ..... Y N → **Ineligible** ERFC34

35. **[PC]** Does the VCUG demonstrate grade I, II, III or IV reflux in at least one ureter? ..... Y N → **Ineligible** ERF35

36. **[PC]** Is grade V reflux present in either ureter? ..... Y → **Ineligible** N ERF36

37. **[PC]** Does the VCUG show the following bladder abnormalities?

a. Ureterocele ..... Y→**Ineligible** N ERF37A

b. Urethral valve ..... Y→**Ineligible** N ERF37B

H. RENAL ULTRASOUND LOCAL REPORT

38. a. **[PC]** Date of ultrasound (mm/dd/yyyy): ..... | | | / | | | / | | | | | ERF38

b. **[PC]** Is date of ultrasound within 112 days after index UTI? ..... Y N→**Ineligible** ERFC38B

39. **[PC]** Does the ultrasound show the following urologic abnormalities?

a. Hydronephrosis with renal parenchyma atrophy ..... Y→**Ineligible** N ERF39A

b. Ureterocele ..... Y→**Ineligible** N ERF39B

c. Solitary kidney ..... Y→**Ineligible** N ERF39C

d. Profoundly small kidney (more than 2 SD below mean) ..... Y→**Ineligible** N ERF39D

e. Multicystic dysplastic kidney ..... Y→**Ineligible** N ERF39E

f. Pelvic kidney ..... Y→**Ineligible** N ERF39F

g. Fused kidney ..... Y→**Ineligible** N ERF39G

h. Neurogenic bladder ..... Y→**Ineligible** N ERF30H

I. OTHER MEDICAL EXCLUSIONS

40. Does your child have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (i.e. VATER–VACTERL association, Townes-Brock syndrome, cat eye syndrome, Casamassima-Morton-Nance syndrome, renal coloboma syndrome, branchio-oto-renal syndrome, Frasier syndrome, congenital immunodeficiency, or acquired immunodeficiency)? ..... Y→**Ineligible** N ERF40

41. Does your child have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (i.e. GI conditions, liver or kidney failure, malignancy, complex cardiac diseases)? ..... Y→**Ineligible** N ERF41

42. Is trimethoprim or sulfa contraindicated due to an intolerance or known allergy, inadequate renal or hepatic function, G6PD deficiency or other reasons? ..... Y→**Ineligible** N ERF42

43. Do the parents or siblings have a history of anaphylactic reaction to sulfa? ..... Y→**Ineligible** N ERF43

44. Has your child ever had renal or bladder surgery? ..... Y→**Ineligible** N ERF44

J. AVAILABILITY

45. Is your child currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown? ..... Y→**Ineligible** N ERF45

46. a. Is your child currently taking continuous antimicrobial prophylaxis? ..... Y N→**Go to Item 47** ERF46

    b. Is the family willing to discontinue current prophylaxis to begin RIVUR treatment? ..... Y N→**Ineligible** ERFB46B

47. Is there any reason that would make completing the study protocol impossible (i.e. administering daily oral medication, visiting the clinic semiannually for data collection, or receiving bimonthly phone calls from study staff)? ..... Y→**Ineligible** N ERF47

48. Does the family have plans to move to an area that will make it no longer convenient for study participation? ..... Y→**Ineligible** N ERF48

K. RECENT FEVER AND PYURIA

49. Has your child had a temperature ≥ 100.4˚F or 38˚C anytime in the last three days? ..... Y→**Stop** N ERF49

50. **[PC]** Was pyuria present on today's urine dipstick, noted as leukocyte esterase ≥ trace **OR** microscopy results of WBC ≥ 10 WBC/mm^3 or WBC ≥ 5 WBC/hpf? ..... Y→**Stop** N ERFB50

L. RANDOMIZATION

51. **[PC]** Eligibility criteria reviewed and randomization authorized by (name of investigator): BLIND_AUTHORITY

Note: *choosing 'Y' to question #52 will initiate randomization. Items on this form will not be able to be changed following the randomization procedure. Please verify that the responses you have entered above are accurate before continuing.*

52. **[PC]** Do you wish to randomize this child to a treatment group? ..... Y N ERF51

ELIGIBILITY AND RANDOMIZATION FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:								FORM CODE: ERF VERSION: B 08/14/07	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *Complete this form for RIVUR-eligible children. The form is completed during the child's eligibility and randomization clinic visit to document the child meeting all eligibility criteria. Enter data into the data management system (DMS) to run the randomization procedure.*

A. AGE

1. **[PC]** Date of clinic visit (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERF1
2. Child's date of birth (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERF2
3. **[PC]** Age in months: ..... **[determined by DMS]** ERF3

		Yes	No	Not Applicable	
4.	If child's age < 6 months, was gestational age ≥ 34 weeks?	Y	N → **Ineligible**	X	ERF4
5.	**[PC]** Is child's age ≥ 2 months and < 72 months (6 yrs)?	Y	N → **Ineligible**		ERF5
6.	Is this your child's first UTI?	Y	N → **Ineligible**		ERF6

B. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the UTI event? ..... Y N → **Go to Item 14** ERF7
8. a. What was your child's highest measured temperature ± 24 hrs of the urine collection that diagnosed the UTI? ..... ☐☐☐.☐ ERFB8A

   b. Temperature measurement units *(circle one)*:

   ˚F ..... F
   ˚C C
   ERFB8B

9. What was the temperature measurement route? *(circle one)*: ERF10

   Oral ..... O
   Axillary ..... A
   Tympanic ..... T
   Rectal ..... R
   Unknown ..... U

10. What location was this temperature measured? *(Circle one)*: ERF11

Home ..... H

Medical care professional ..... M

11. a. What was the highest measured temperature during the UTI? ..... ☐☐☐.☐ ERF8A

b. Temperature measurement units *(circle one)*:

˚F ..... F

˚C ..... C ERF8B

c. What was the date of the highest temperature (mm/dd/yyyy)? ..... ☐☐/☐☐/☐☐☐☐ ERF9

12. What was the total duration of fever prior to UTI antimicrobial treatment (hrs)? ..... ☐☐☐ ERF12

13. What was the time from UTI antimicrobial treatment to a sustained (> 24 hrs) normal temperature (hrs)? ..... ☐☐☐ ERFB13

14. Were the following symptoms present ± 24 hrs of the urine collection that diagnosed the UTI?

	Yes	No	Unknown	Not Applicable	
a. Suprapubic, abdominal, or flank pain or tenderness	Y	N	U		ERFB14A
b. Urinary urgency	Y	N	U		ERFB14B
c. Urinary frequency	Y	N	U		ERFB14C
d. Urinary hesitancy	Y	N	U		ERFB14D
e. Dysuria	Y	N	U		ERFB14E
f. Foul-smelling urine	Y	N	U		ERFB14F
g. Failure to thrive (if child ≤ 4 mo.)	Y	N	U	X	ERFB14G
h. Dehydration (if child ≤ 4 mo.)	Y	N	U	X	ERFB14H
i. Hypothermia (if child ≤ 4 mo.)	Y	N	U	X	ERFB14I

15. What was the total number of days that your child experienced these symptoms? ..... ☐☐ ERFB15

16. **[PC]** Was there a temperature ≥ 100.4˚F or 38˚C *(see Q8)* **OR** were urinary tract symptoms *(see Q14)* present ± 24 hrs of the urine collection that diagnosed the UTI? ..... Y N → **Ineligible** ERFB16

C. INDEX UTI URINALYSIS RESULTS

17. a. **[PC]** Date of dipstick urine collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERFB17A

b. **[PC]** Dipstick results - leukocyte esterase *(circle one)*: ERF17A

Negative ..... A
Trace ..... B
Small (+) C
Moderate (++) ..... D
Large (+++) ..... E

c. **[PC]** Dipstick results - nitrite *(circle one)*: ERF17B

Negative ..... N
Positive ..... P

18. a. **[PC]** Date of microscopy urine collection (mm/dd/yyyy): ..... __/__/____ ERFB18A

b. **[PC]** WBC *(Enter count. Use 999.999 for values ≥ 999.999)*: ..... ___.___ ERFB18B

c. **[PC]** Reporting units for WBC microscopy *(circle one)*:

WBC/mm^3 ..... A
WBC/hpf ..... B

ERF18B

19. **[PC]** Was pyuria present, noted as either leukocyte esterase on dipstick greater than or equal to trace *(see Q17b)* **OR** WBC ≥ 10 WBC/mm^3 or WBC ≥ 5 WBC/hpf *(see Q18)*? ..... Y N → **Ineligible** ERFB19

D. INDEX UTI URINE CULTURE RESULTS

20. a. **[PC]** Date of urine collection for culture (mm/dd/yyyy): ..... __/__/____ ERFB20A

b. **[PC]** Method of urine collection *(circle one)*: ERF20

Catheterization ..... A
Suprapubic aspiration ..... B
Clean voided C
Bag collected ..... D → **Ineligible**
Unknown ..... E → **Ineligible**

21. a. **[PC]** Did the urine culture show a single primary organism that was neither lactobacillus nor candida? ..... Y N → **Ineligible** ERFB21A

b. **[PC]** How many organisms were present? ..... ___ → **Ineligible if more than 2** ERFB21B

22. a. **[PC]** Primary organism *(select from list)*: ..... __ ERFB22A

b. **[PC]** Data type from primary organism culture results *(circle one):* ERFB22B

= (equal to) ..... A → **Skip field c2**
> (greater than) ..... B → **Skip field c2**
≥ (greater than or equal to) ..... C → **Skip field c2**
< (less than) ..... D → **Skip field c2**
≤ (less than or equal to) ..... E → **Skip field c2**
Range ..... F

c. **[PC]** Colony count (CFU/ml) of primary organism: ..... c1. [ERFB22C1] - c2. [ERFB22C2]

23. a. **[PC]** Secondary organism *(select from list)*: ..... [ERFB23A]

b. **[PC]** Data type from secondary organism culture results *(circle one):* ERFB23B

= (equal to) ..... A → **Skip field c2**
> (greater than) ..... B → **Skip field c2**
≥ (greater than or equal to) ..... C → **Skip field c2**
< (less than) ..... D → **Skip field c2**
≤ (less than or equal to) ..... E → **Skip field c2**
Range ..... F

c. **[PC]** Colony count (CFU/ml) of secondary organism: ..... c1. [ERFB23C1] - c2. [ERFB23C2]

24. a. **[PC]** Was the colony count for the primary organism ≥ 50,000 CFU/ml in catheterized or suprapubic specimens **OR** ≥100,000 CFU/ml in clean-voided specimen? *(See Q22.)* ..... Y N → **Ineligible** ERFB24A

b. **[PC]** Was the colony count for the secondary organism < 5,000 CFU/ml? *(See Q23.)* ..... Y N → **Ineligible** ERFB24B

E. INDEX UTI TREATMENT

25. **[PC]** How many different antimicrobials were prescribed to treat the index UTI? *(Describe in Q26-Q29.)* ..... [ERF25]

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
26. **[PC]**	a. [ERF26A]	b. [ERF26B]	c. [ERF26C]	d. Y N U [ERF26D]
27. **[PC]**	a. [ERF27A]	b. [ERF27B]	c. [ERF27C]	d. Y N U [ERF27D]
28. **[PC]**	a. [ERF28A]	b. [ERF28B]	c. [ERF28C]	d. Y N U [ERF28D]

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
29. **[PC]**	a. ERF29A	b. ERF29B	c. ERF29C	d. Y N U ERF29D

30. **[PC]** a. Was the index UTI treated at least 7 days? *(Sum Q26c, Q27c, Q28c, and Q29c.)* Y N → **Ineligible** ERF30A

[PC] b. Was the index UTI appropriately treated at least 7 days with an effective drug? *(Sum Q26c, Q27c, Q28c, and Q29c only where corresponding Q26d, Q27d, Q28d, and Q29d='Y'.)* ..... Y N ERF30B

31. **[PC]** Was a follow-up negative urine culture documented 1-14 days after completion of therapy? ..... Y N → **Ineligible if Item 30b is N** ERF31

32. **[PC]** Date of follow-up urine culture (mm/dd/yyyy): ERF32

F. VCUG LOCAL REPORT

33. **[PC]** Date of VCUG (mm/dd/yyyy): ERF33

34. **[PC]** Is date of VCUG within 70 days after index UTI? ..... Y N → **Ineligible** ERFB34

35. **[PC]** Does the VCUG demonstrate grade I, II, III or IV reflux in at least one ureter? ..... Y N → **Ineligible** ERF35

36. **[PC]** Is grade V reflux present in either ureter? ..... Y → **Ineligible** N ERF36

37. **[PC]** Does the VCUG show the following bladder abnormalities?

a. Ureterocele ..... Y → **Ineligible** N ERF37A

b. Urethral valve ..... Y → **Ineligible** N ERF37B

G. RENAL ULTRASOUND LOCAL REPORT

38. a. **[PC]** Date of ultrasound (mm/dd/yyyy): ERF38

b. **[PC]** Is date of ultrasound within 70 days after index UTI? ..... Y N → **Ineligible** ERFB38B

39. **[PC]** Does the ultrasound show the following urologic abnormalities?

a. Hydronephrosis with renal parenchyma atrophy ..... Y → **Ineligible** N ERF39A

b. Ureterocele ..... Y → **Ineligible** N ERF39B

c. Solitary kidney ..... Y → **Ineligible** N ERF39C

d. Profoundly small kidney (more than 2 SD below mean) ..... Y → **Ineligible** N ERF39D

e. Multicystic dysplastic kidney ..... Y → **Ineligible** N ERF39E

f. Pelvic kidney ..... Y → **Ineligible** N ERF39F

g. Fused kidney ..... Y→**Ineligible** N ERF39G

h. Neurogenic bladder ..... Y→**Ineligible** N ERF39H

H. OTHER MEDICAL EXCLUSIONS

40. Does your child have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (i.e. VATER–VACTERL association, Townes-Brock syndrome, cat eye syndrome, Casamassima-Morton-Nance syndrome, renal coloboma syndrome, branchio-oto-renal syndrome, Frasier syndrome, congenital immunodeficiency, or acquired immunodeficiency)? ..... Y→**Ineligible** N ERF40

41. Does your child have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (i.e. GI conditions, liver or kidney failure, malignancy, complex cardiac diseases)? ..... Y→**Ineligible** N ERF41

42. Is trimethoprim or sulfa contraindicated due to an intolerance or known allergy, inadequate renal or hepatic function, G6PD deficiency or other reasons? ..... Y→**Ineligible** N ERF42

43. Do the parents or siblings have a history of anaphylactic reaction to sulfa? ..... Y→**Ineligible** N ERF43

44. Has your child ever had renal or bladder surgery? ..... Y→**Ineligible** N ERF44

I. AVAILABILITY

45. Is your child currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown? ..... Y→**Ineligible** N ERF45

46. a. Is your child currently taking continuous antimicrobial prophylaxis? ..... Y N→**Go to Item 47** ERF46

    b. Is the family willing to discontinue current prophylaxis to begin RIVUR treatment? ..... Y N→**Ineligible** ERFB46B

47. Is there any reason that would make completing the study protocol impossible (i.e. administering daily oral medication, visiting the clinic semiannually for data collection, or receiving bimonthly phone calls from a nurse)? ..... Y→**Ineligible** N ERF47

48. Does the family have plans to move to an area that will make it no longer convenient for study participation? ..... Y→**Ineligible** N ERF48

J. RANDOMIZATION

49. Has your child had a temperature ≥ 100.4˚F or 38˚C anytime in the last three days? ..... Y→**Go to Item 52** N ERF49

50. **[PC]** Was pyuria present on today's urine dipstick, noted as leukocyte esterase ≥ trace? ..... Y→**Go to Item 52** N ERFB50

ID NUMBER:								FORM CODE: ERF VERSION: B 08/14/07	Contact Occasion		SEQ #	

Note: *choosing 'Y' to question #51 will initiate randomization. Some items on this form will not be able to be changed following the randomization procedure. Please verify that the responses you have entered are accurate before continuing.*

51. **[PC]** Do you wish to randomize this child to a treatment group?..... Y N ERF51

K. ADMINISTRATIVE INFORMATION

52. **[PC]** Date of consent (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERF52

53. **[PC]** Method of data collection *(circle one)*:

Computer C
Paper..... P

ERF54

54. **[PC]** Interviewer's initials: ..... ☐☐☐ BLIND_STAFF_ID

55. **[PC]** Eligibility criteria reviewed and randomization authorized by (name of investigator): BLIND_AUTHORITY

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

ELIGIBILITY AND RANDOMIZATION FORM

ID NUMBER: | | | | | | | |

FORM CODE: ERF
VERSION: A 04/16/07

Contact Occasion | |

SEQ # | |

Participant Name: _____

Instructions: *Complete this form for RIVUR-eligible children. The form is completed during the child's eligibility and randomization clinic visit to document the child meeting all eligibility criteria. Enter data into the data management system (DMS) to run the randomization procedure.*

A. AGE

1. **[PC]** Date of clinic visit (mm/dd/yyyy): ..... | | / | | / | | | | | ERF1

2. Child's date of birth (mm/dd/yyyy): ..... | | / | | / | | | | | ERF2

3. **[PC]** Age in months: ..... **[determined by DMS]** ERF3

	Yes	No	Not Applicable	
4. If child's age < 6 months, was gestational age ≥ 34 weeks?	Y	N → **Ineligible**	X	ERF4
5. Is child's age ≥ 2 months and < 72 months (6 yrs)?	Y	N → **Ineligible**		ERF5
6. Are you able to assess that this is your child's first UTI?	Y	N → **Ineligible**		ERF6

B. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the UTI event? ..... Y N → **Go to Item 14** ERF7

8. a. What was your child's highest measured temperature? ..... | | | . | | ERF8A

b. Temperature measurement units *(circle one)*:

˚F ..... F
˚C C

ERF8B

c. **[PC]** Was there a temperature ≥ 100.4˚F or 38˚C? ..... Y N → **Go to Item 14** ERFA8C

9. What was the date of highest temperature (mm/dd/yyyy)? ..... | | / | | / | | | | | ERF9

10. What was the temperature measurement route? *(circle one)*: ERF10

Oral ..... O
Axillary ..... A
Tympanic ..... T
Rectal ..... R
Unknown ..... U

11. What location was the highest temperature measured? *(Circle one)*: ERF11

Home ..... H

Medical care professional ..... M

12. What was the duration of fever prior to treatment (hrs)? ..... | | | ERF12

13. What was the time from treatment to normal temperature (hrs)? ..... | | | ERF13

14. Were the following symptoms present during the index UTI?

	Yes	No	Unknown	Not Applicable
a. Suprapubic, abdominal, or flank pain or tenderness ERFA14A	Y	N	U	
b. Urinary urgency ERFA14B	Y	N	U	
c. Urinary frequency ERFA14C	Y	N	U	
d. Urinary hesitancy ERFA14D	Y	N	U	
e. Dysuria ERFA14E	Y	N	U	
f. Foul-smelling urine ERFA14F	Y	N	U	
g. Failure to thrive (if child ≤ 4 mo.) ERFA14G	Y	N	U	X
h. Dehydration (if child ≤ 4 mo.) ERFA14H	Y	N	U	X
i. Hypothermia (if child ≤ 4 mo.) ERFA14I	Y	N	U	X

15. **[PC]** Was there a temperature ≥ 100.4˚F or 38˚C *(see Q8c)* **OR** were urinary tract symptoms *(see Q14)* present during the index UTI? ..... Y N → **Ineligible** ERFA15

C. INDEX UTI URINALYSIS RESULTS

16. **[PC]** Date of urine collection (mm/dd/yyyy): ..... | |/| |/| | | | | ERFA16

17. **[PC]** Urinalysis dipstick results:

a. Leukocyte esterase *(circle one)*: ERF17A

Negative ..... A

Trace ..... B

Small (+) C

Moderate (++) ..... D

Large (+++) ..... E

b. Nitrite *(circle one)*: ERF17B

Negative ..... N

Positive ..... P

18. **[PC]** Urinalysis microscopy results:

    a. WBC *(enter 000 for <1, 999 for >150)*: ..... | | | ERFA18A

    b. Reporting units for WBC microscopy *(circle one)*:
    WBC/mm^3 ..... A
    WBC/hpf ..... B ERF18B

19. **[PC]** Was pyuria present, noted as either leukocyte esterase on dipstick greater than or equal to 1+ *(see Q17a)* **OR** WBC ≥ 10 WBC/mm^3 or WBC ≥ 5 WBC/hpf *(see Q18)*? ..... Y N → **Ineligible** ERFA19

D. INDEX UTI URINE CULTURE RESULTS

20. **[PC]** Method of urine collection *(circle one)*: ERF20
    Catheterization ..... A
    Suprapubic aspiration ..... B
    Clean voided C
    Bag collected ..... D → **Ineligible**
    Unknown ..... E → **Ineligible**

21. **[PC]** Did the urine culture show a single organism? ..... Y N → **Ineligible** ERFA21

22. **[PC]** Colony count (CFU/ml): ..... | | | | | | | ERFA22

23. **[PC]** Was the colony count ≥ 50,000 CFU/ml in catheterized or suprapubic specimens **OR** ≥ 100,000 CFU/ml in clean-voided specimen? *(See Q22.)* ..... Y N → **Ineligible** ERFA23

24. **[PC]** Isolated organism *(code from list)*: ..... | | ERFA24

E. INDEX UTI TREATMENT

25. **[PC]** How many different antimicrobials were prescribed to treat the index UTI? *(Describe in Q26-Q29.)* ..... | ERF25

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
26. **[PC]**	a. ERF26A	b. __/__/____ ERF26B	c. ERF26C	d. Y N U ERF26D
27. **[PC]**	a. ERF27A	b. __/__/____ ERF27B	c. ERF27C	d. Y N U ERF27D

ID NUMBER: | | | | | | | | FORM CODE: ERF
VERSION: A 04/16/07 Contact Occasion | | | SEQ # | |

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
28. **[PC]**	a. ERF28A	b. ERF28B	c. ERF28C	d. Y N U ERF28D
29. **[PC]**	a. ERF29A	b. ERF29B	c. ERF29C	d. Y N U ERF29D

30. **[PC]** a. Was the index UTI treated at least 7 days? *(Sum Q26c, Q27c, Q28c, and Q29c.)* Y N → **Ineligible** ERF30A

[PC] b. Was the index UTI appropriately treated at least 7 days with an effective drug? *(Sum Q26c, Q27c, Q28c, and Q29c only where corresponding Q26d, Q27d, Q28d, and Q29d='Y'.)* ..... Y → **Go to Item 33** N ERF30B

31. **[PC]** Was a follow-up negative urine culture documented 1-14 days after completion of therapy? ..... Y N → **Ineligible** ERF31

32. **[PC]** Date of follow-up urine culture (mm/dd/yyyy): ..... | | | / | | | / | | | | | ERF32

F. VCUG LOCAL REPORT

33. **[PC]** Date of VCUG (mm/dd/yyyy): ..... | | | / | | | / | | | | | ERF33

34. **[PC]** Is date of VCUG within 42 days after index UTI? ..... Y N → **Ineligible** ERFA34

35. **[PC]** Does the VCUG demonstrate grade I, II, III or IV reflux in at least one ureter? ..... Y N → **Ineligible** ERF35

36. **[PC]** Is grade V reflux present in either ureter? ..... Y → **Ineligible** N ERF36

37. **[PC]** Does the VCUG show the following bladder abnormalities?

a. Ureterocele ..... Y → **Ineligible** N ERF37A

b. Urethral valve ..... Y → **Ineligible** N ERF37B

G. RENAL ULTRASOUND LOCAL REPORT

38. **[PC]** Date of ultrasound (mm/dd/yyyy): ..... | | | / | | | / | | | | | ERF38

39. **[PC]** Does the ultrasound show the following urologic abnormalities?

a. Hydronephrosis with renal parenchyma atrophy ..... Y → **Ineligible** N ERF39A

b. Ureterocele ..... Y → **Ineligible** N ERF39B

c. Solitary kidney ..... Y → **Ineligible** N ERF39C

d. Profoundly small kidney (> 2 SD below mean) ..... Y → **Ineligible** N ERF39D

e. Multicystic dysplastic kidney ..... Y → **Ineligible** N ERF39E

f. Pelvic kidney ..... Y→**Ineligible** N ERF39F

g. Fused kidney ..... Y→**Ineligible** N ERF39G

h. Neurogenic bladder ..... Y→**Ineligible** N ERF39H

H. OTHER MEDICAL EXCLUSIONS

40. Does your child have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (i.e. VATER–VACTERL association, Townes-Brock syndrome, cat eye syndrome, Casamassima-Morton-Nance syndrome, renal coloboma syndrome, branchio-oto-renal syndrome, Frasier syndrome, congenital immunodeficiency, or acquired immunodeficiency)? ..... Y→**Ineligible** N ERF40

41. Does your child have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (i.e. GI conditions, liver or kidney failure, malignancy, complex cardiac diseases)? ..... Y→**Ineligible** N ERF41

42. Is trimethoprim or sulfa contraindicated due to an intolerance or known allergy, inadequate renal or hepatic function, G6PD deficiency or other reasons? ..... Y→**Ineligible** N ERF42

43. Do the parents or siblings have a history of anaphylactic reaction to sulfa? ..... Y→**Ineligible** N ERF43

44. Has your child ever had renal or bladder surgery? ..... Y→**Ineligible** N ERF44

I. AVAILABILITY

45. Is your child currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown? ..... Y→**Ineligible** N ERF45

46. Is your child currently taking continuous antimicrobial prophylaxis? .... Y→**Ineligible** N ERF46

47. Is there any reason that would make completing the study protocol impossible (i.e. administering daily oral medication, visiting the clinic semiannually for data collection, or receiving bimonthly phone calls from a nurse)? ..... Y→**Ineligible** N ERF47

48. Does the family have plans to move to an area that will make it no longer convenient for study participation? ..... Y→**Ineligible** N ERF48

J. RANDOMIZATION

49. Has your child had a temperature ≥ 100.4˚F or 38˚C anytime in the last three days? ..... Y→**Go to Item 52** N ERF49

50. **[PC]** Was pyuria present on today's urine dipstick, noted as leukocyte esterase ≥ 1+? ..... Y→**Go to Item 52** N ERFA50

Note: *choosing 'Y' to question #51 will initiate randomization. Some items on this form will not be able to be changed following the randomization procedure. Please verify that the responses you have entered are accurate before continuing.*

51. **[PC]** Do you wish to randomize this child to a treatment group?..... Y N ERF51

K. ADMINISTRATIVE INFORMATION

52. **[PC]** Date of consent (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERF52

53. **[PC]** Date of eligibility determination (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ERFA53

54. **[PC]** Method of data collection *(circle one)*:
    Computer C
    Paper..... P
    ERF54

55. **[PC]** Interviewer's initials: ..... ☐☐☐ BLIND_STAFF_ID

56. **[PC]** Eligibility criteria reviewed and randomization authorized by (name of investigator): BLIND_AUTHORITY

EXIT FORM

ID NUMBER:							

FORM CODE: EXF
VERSION: B 3/22/10

Contact Occasion | | SEQ # | |

Participant Name: _____

Instructions: *This form should be completed by project staff at the exit clinic visit or upon notification of withdrawal.*
***Important: Study Coordinator should not share his/her responses with the participant.*

A. STUDY COORDINATOR'S GUESS

1. **[PC]** What treatment group do you believe the participant was assigned? *(circle one)*:
   Active Drug ..... A
   Inactive Drug I
   EXF1

2. **[PC]** How certain are you that the participant was randomized to that treatment group? *(circle one)*:
   Very Certain V
   Fairly Certain ..... F
   Uncertain ..... U → Go to Item 4
   EXF2

3. What makes you believe the participant was randomized into that treatment group? EXF3 _____
   _____

B. PARTICIPANT'S GUESS

We very much appreciate your participation in RIVUR and have two final questions related to the study medication. Your child received either active antibiotic prophylaxis or a similarly appearing liquid (inactive drug).

4. Which do you think you received, antibiotic or inactive drug? Guessing is okay.
   Active Drug ..... A
   Inactive Drug I
   EXF4

5. How certain are you about this?
   Very Certain V
   Fairly Certain ..... F
   Uncertain ..... U → Go to Item 7
   EXF5

6. What makes you believe that your child was receiving an active drug or inactive drug? EXF6 _____
   _____

C. FUTURE VUR TREATMENT PLANS

7. Are there future VUR treatment plans beyond surveillance of the child?
   Yes ..... Y
   No ..... N → Go to Item 14
   EXFB7

ID NUMBER:								FORM CODE: EXF VERSION: B 3/22/10	Contact Occasion		SEQ #	

Participant Name: _____

Which of the following post-RIVUR VUR treatment options are being undertaken or considered by the family?

8. a. Anti-microbial prophylaxis:

Yes, definitely ..... Y
Yes, being considered C
No..... N → Go to Item 9a
Unknown ..... U → Go to Item 9a
Treatment not available or not applicable..... X → Go to Item 9a

EXFB8A

b. Anti-microbial Code: ☐☐☐ EXF8B

If other, please record 500 and specify:_____

9. a. Reimplantation surgery:

Yes, definitely ..... Y
Yes, being considered C
No..... N → Go to Item 10a
Unknown ..... U → Go to Item 10a
Treatment not available or not applicable..... X → Go to Item 10a

EXFB9A

If 'Y' or 'C' specify procedure details:_____

b. If scheduled or completed, specify date (mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐ EXFB9B

10. a. Deflux injection:

Yes, definitely ..... Y
Yes, being considered C
No..... N → Go to Item 11
Unknown ..... U → Go to Item 11
Treatment not available or not applicable..... X → Go to Item 11

EXFB10A

If 'Y' or 'C' specify procedure details:_____

b. If scheduled or completed, specify date (mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐ EXFB10B

Participant Name: _____

11. Refer to another healthcare provider:

Yes, definitely ..... Y
Yes, being considered C
No..... N
Unknown ..... U
Treatment not available or not applicable..... X

EXFB11

If 'Y' or 'C' specify provider subspecialty: _____

12 a. Repeat VCUG (after the 24-month VCUG):

Yes, definitely ..... Y
Yes, being considered C
No..... N → Go to Item 13
Unknown ..... U → Go to Item 13
Treatment not available or not applicable..... X → Go to Item 13

EXFB12A

If 'Y' or 'C' specify procedure details:_____

b. If scheduled or completed, specify date (mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐ EXFB12B

13. Other treatment of management for VUR:

Yes, definitely ..... Y
Yes, being considered C
No..... N

EXFB13

If 'Y' or 'C' specify other treatment details:_____

D. ADMINISTRATIVE INFORMATION

14. Date of data collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ EXF7

15. Method of data collection *(circle one)*:

Computer C
Paper..... P

EXF8

16. Recorder's initials: . ..... ☐☐☐ BLIND_STAFF_ID

EXIT FORM

ID NUMBER:							

FORM CODE: EXF
VERSION: A 5/21/09

Contact Occasion | | | SEQ # | | |

Participant Name: _____

Instructions: *This form should be completed by project staff at the exit clinic visit or upon notification of withdrawal.*
***Important: Study Coordinator should not share his/her responses with the participant.*

A. STUDY COORDINATOR'S GUESS

1. **[PC]** What treatment group do you believe the participant was assigned? *(circle one)*:
   - Active Drug ..... A
   - Inactive Drug I

   EXF1

2. **[PC]** How certain are you that the participant was randomized to that treatment group? *(circle one)*:
   - Very Certain V
   - Fairly Certain ..... F
   - Uncertain ..... U → Go to Item 4

   EXF2

3. What makes you believe the participant was randomized into that treatment group? _____ EXF3
   _____

B. PARTICIPANT'S GUESS

We very much appreciate your participation in RIVUR and have two final questions related to the study medication. Your child received either active antibiotic prophylaxis or a similarly appearing liquid (inactive drug).

4. Which do you think you received, antibiotic or inactive drug? Guessing is okay.
   - Active Drug ..... A
   - Inactive Drug I

   EXF4

5. How certain are you about this?
   - Very Certain V
   - Fairly Certain ..... F
   - Uncertain ..... U → Go to Item 7

   EXF5

6. What makes you believe that your child was receiving an active drug or inactive drug? _____ EXF6
   _____

C. ADMINISTRATIVE INFORMATION

7. Date of data collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ EXF7

8. Method of data collection *(circle one)*:
   - Computer C
   - Paper ..... P

   EXF8

9. Recorder's initials: . ..... ☐☐☐ BLIND_STAFF_ID

PROTOCOL SCHEDULED FOLLOW-UP CONTACT FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: FUP
VERSION: C 07/18/08

Contact Occasion | | | SEQ # | |

Participant Name: _____

Instructions: *This form will be completed at each protocol scheduled telephone or clinic follow-up contact, whether the contact is completed or not.*

A. CONTACT INFORMATION

1. **[PC]** Type of contact *(circle one)*:

FUP1

- Regularly scheduled protocol clinic visit ..... A → **Go to Item 3**
- Regularly scheduled protocol phone contact ..... B → **Go to Item 3**
- Protocol phone contact replacing protocol clinic visit ..... C → **Go to Item 3**
- Protocol clinic visit replacing protocol phone contact ..... D → **Go to Item 3**
- Missed protocol scheduled contact ..... E

2. **[PC]** Indicate the main reason the contact was missed *(circle one):*

FUP2

- Participant refused ..... A → **Go to Item 23**
- Participant incapacitated ..... B → **Go to Item 23**
- Participant withdrew consent ..... C → **Complete ICT** → **Go to Item 23**
- Participant location unknown ..... D → **Go to Item 23**
- Oversight ..... E → **Go to Item 23**
- Participant died ..... F → **Complete AEF, MCA, MCN** → **Go to Item 23**
- Unknown ..... G → **Go to Item 23**
- Unable to contact family after repeated attempts ..... H → **Go to Item 23**

B. SIDE EFFECTS/ SERIOUS ADVERSE EVENTS and MEDICAL CARE HISTORY

FUPB3A

3a. **[PC]** Since the last protocol study contact on (mm/dd/yyyy), does the parent/caregiver, or the RIVUR clinic staff feel the child has experienced any side effects that are possibly associated with the study medication? ..... Y → **Complete AEF for each** N → **Go to Item 3c**

Note: *Question parent/guardian, review parent diary, and review Follow-up Summary Report.*

3b. **[PC]** Possible side effect determined by:

FUPB3B

- Parent/Guardian ..... P
- Clinic Staff C
- Both ..... B

3c. **[PC]** Since the last protocol study contact on (mm/dd/yyyy), has the child had any new health problems that fit the study definition of a serious adverse event? ..... Y → **Complete AEF for each** N FUPB3C
Note: *Question parent/guardian, review parent diary, and review Follow-up Summary Report.*

4. **[PC]** Since the last study contact, has the child had urine collected for analysis **OR** received medical care for symptoms that include fever, rash, abdominal or flank pain, diarrhea or loose stools, urinary urgency, painful urination, foul-smelling urine, or for children less than 4 months old, failure to thrive, dehydration, or hypothermia? ..... Y N → **Go to Item 7** FUPC4
Note: *Question parent/guardian, review parent diary, and review family contacts to clinic since last protocol-scheduled follow-up contact.*

5. **[PC]** Since the last protocol-scheduled follow-up contact, how many times has the child received medical care that requires collection of medical records? ..... | | → **MCN, MCA, (USR) for each** FUPC5

6. **[PC]** Record the MCID numbers (or affix labels) associated with medical care visits reported in item 5 above. Items 6a2 – 6j2 (column #2) are indicators of a required associated MCN form. This field is automatically pre-filled as 'Y' upon data entry in the DMS for each MCID number listed. If after assigning an MCID number, it is eventually determined that a medical visit did not actually occur, the indicator in column #2 should be set to 'N' so an MCN form is no longer expected.
Note: Space has been provided for notes, to help you keep track of MCID numbers. (Not data entered.)

	1. MCID Number	2. (Y/N)	Notes (not data entered):
a1.	BLIND_MCID6A1	a2.	FUP6A2
b1.	BLIND_MCID6B1	b2.	FUP6B2
c1.	BLIND_MCID6C1	c2.	FUP6C2
d1.	BLIND_MCID6D1	d2.	FUP6D2
e1.	BLIND_MCID6E1	e2.	FUP6E2
f1.	BLIND_MCID6F1	f2.	FUP6F2
g1.	BLIND_MCID6G1	g2.	FUP6G2
h1.	BLIND_MCID6H1	h2.	FUP6H2
i1.	BLIND_MCID6I1	i2.	FUP6I2
j1.	BLIND_MCID6J1	j2.	FUP6J2

7. Since our last study contact, has your child been treated with any prescription or over-the-counter medications? ..... Y → **Add to the CMF** N FUP7

C. STUDY MEDICATION STATUS

8. **[PC]** What is the child's current study medication status at this contact?
Note: A subject is considered discontinued only if done so by study staff and documented with DDF form, otherwise the participant is considered 'on study medication' regardless of adherence.

On study medication	A	
Temporarily discontinue medication today	B →	**Complete DDF**
Medication was temporarily discontinued at a previous contact	C →	**Go to Item 16**
Permanently discontinue medication today	D →	**Complete DDF**
Medication was permanently discontinued at a previous contact	E →	**Go to Item 17**

FUP8

D. STUDY MEDICATION INTERVIEW

9. Did your child take study medication today? ..... Y N FUP9

10. Sometimes doses of medication are missed. How often did your child miss a dose during the past week?

Never	A
1-2 times	B
3-4 times	C
> 4 times	D
Don't know	E
Medication was temporarily discontinued	F

FUP10

11. Overall, during the past two months, how often did your child take the study medication?

Takes medication every day	A →	**Go to Item 14**
Takes medication almost every day	B →	**Go to Item 14**
Takes medication approximately 75-90% of the time	C	
Takes medication approximately 50-74% of the time	D	
Takes medication approximately 25-49% of the time	E	
Seldom takes medication (occasionally but less than 25%)	F	
Does not take study medication	G	

FUP11

12. What is the primary reason that you did not give your child study medication every day or almost every day?

Forgetfulness	A
Medication was misplaced	B
Child experienced side effects	C
Child refuses to take medication	D
Parent felt child did not need the medication	E
Medication was temporarily discontinued	F
Other reason	G

Specify: _____

FUP12

13. **[PC]** If the child is not taking study medication, but should, can the parent/guardian be persuaded to resume giving the medication?

    Yes, parent/guardian to resume giving medication ..... Y
    No, parent/guardian will not give medication ..... N

    FUP13

14. Overall, how satisfied or dissatisfied are you with the medication your child is receiving *(read responses)*?

    Very satisfied ..... A
    Satisfied ..... B
    Indifferent C
    Dissatisfied ..... D
    Very dissatisfied ..... E
    Does not take study medication ..... F

    FUP14

15. Based on your child's response, how would you rate the taste of the medication *(read responses)*?

    Very pleasant ..... A
    Pleasant ..... B
    Neither pleasant nor unpleasant C
    Unpleasant ..... D
    Very unpleasant ..... E
    Does not take study medication ..... F

    FUP15

E. MEDICATION DISPENSING

16. a. **[PC]** Is medication being <u>returned</u> at this contact?

    Yes ..... Y → **Complete MRF**
    No ..... N

    FUPB16A

    b. **[PC]** Is medication being <u>dispensed</u> at this contact?

    Yes ..... Y → **Complete MDD**
    No ..... N

    FUP16

F. INTERIM VOIDING HISTORY

17. What is the status of your child's toilet-training for urine during the day (that is, out of diapers and pull-ups, wearing underwear)?
    Note: *See DMS Follow-Up Summary report.*

    Trained since last study contact ..... T
    Not trained ..... N → **Go to 19**
    Previously trained ..... P → **Go to 19**

    FUP17

18. How old was your child when he/she began urinating in the toilet or potty by him/herself during the day? (months) ..... | |

    FUP18

G. INTERIM BOWEL HISTORY

19. What is the status of your child's toilet-training for bowel movements? **Note:** *See DMS Follow-Up Summary report*.

    Trained since last study contact ..... T
    Not trained ..... N → **Go to 22**
    Previously trained ..... P → **Go to 22**

FUP19

20. How old was your child when he/she began defecating in the toilet or potty by him/herself? (months)..... | |

FUP20

21. Since toilet/potty training, has your child had a history of soiling his/her underwear with stool?..... Y N

FUP21

22. During the last 2 months, how many bowel movements did your child have per week on average? ..... | |

FUP22

H. ADMINISTRATIVE INFORMATION

23. **[PC]** Date of data collection (mm/dd/yyyy): ..... | |/| |/| | | | |

FUP23

24. **[PC]** Method of data collection *(circle one)*:

    Computer C
    Paper..... P

FUP24

25. **[PC]** Interviewer's or Examiner's initials: ..... | | |

BLIND_STAFF_ID

PROTOCOL SCHEDULED FOLLOW-UP CONTACT FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: FUP
VERSION: B 10/18/07

Contact Occasion | | |

SEQ # | |

Participant Name: _____

Instructions: *This form will be completed at each protocol scheduled telephone or clinic follow-up contact.*

A. CONTACT INFORMATION

1. **[PC]** Type of contact *(circle one)*:

   Regularly scheduled protocol clinic visit ..... A → **Go to Item 3**
   Regularly scheduled protocol phone contact ..... B → **Go to Item 3**
   Protocol phone contact replacing protocol clinic visit ..... C → **Go to Item 3**
   Protocol clinic visit replacing protocol phone contact ..... D → **Go to Item 3**
   Missed protocol scheduled contact ..... E

   FUP1

2. **[PC]** Indicate the main reason the contact was missed *(circle one):*

   Participant refused ..... A → **Go to Item 23**
   Participant incapacitated ..... B → **Go to Item 23**
   Participant withdrew consent ..... C → **Complete ICT** → **Go to Item 23**
   Participant location unknown ..... D → **Go to Item 23**
   Oversight ..... E → **Go to Item 23**

   FUP2

   Participant died ..... F → **Complete AEF, MCA, MCN** → **Go to Item 23**

   Unknown ..... G → **Go to Item 23**

B. SIDE EFFECTS/ SERIOUS ADVERSE EVENTS and MEDICAL CARE HISTORY

3a. **[PC]** Since the last protocol study contact on (mm/dd/yyyy), does the parent/caregiver, or the RIVUR clinic staff feel the child has experienced any side effects that are possibly associated with the study medication? ..... Y → **Complete AEF for each** N → **Go to Item 3c**

Note: *Question parent/guardian, review parent diary, and review Follow-up Summary Report.*

FUPB3A

3b. **[PC]** Possible side effect determined by:

   Parent/Guardian ..... P
   Clinic Staff C
   Both ..... B

FUPB3B

3c. **[PC]** Since the last protocol study contact on (mm/dd/yyyy), has the child had any new health problems that fit the study definition of a serious adverse event? ..... Y → **Complete AEF for each** N FUPB3C
Note: *Question parent/guardian, review parent diary, and review Follow-up Summary Report.*

4. **[PC]** Since the last study contact, has the child received medical care for any reason?..... Y N → **Go to Item 7** FUP4
Note: *Question parent/guardian, review parent diary, and review Follow-up Summary Report.*

5. **[PC]** How many times has the child received medical care since the last study contact?..... | | → **Complete MCN & MCA for each** FUP5

6. **[PC]** Record the MCID numbers (or affix labels) associated with medical care visits reported in item 5 above.
Items 6a2 – 6j2 (column #2) are indicators of a required associated MCN form. This field is automatically pre-filled as 'Y' upon data entry in the DMS for each MCID number listed. If after assigning an MCID number, it is eventually determined that a medical visit did not actually occur, the indicator in column #2 should be set to 'N' so an MCN form is no longer expected.
Note: Space has been provided for notes, to help you keep track of MCID numbers. (Not data entered.)

	1. MCID Number	**2. (Y/N)**	**Notes (not data entered):**
a1.	BLIND_MCID6A1	a2.	FUP6A2
b1.	BLIND_MCID6B1	b2.	FUP6B2
c1.	BLIND_MCID6C1	c2.	FUP6C2
d1.	BLIND_MCID6D1	d2.	FUP6D2
e1.	BLIND_MCID6E1	e2.	FUP6E2
f1.	BLIND_MCID6F1	f2.	FUP6F2
g1.	BLIND_MCID6G1	g2.	FUP6G2
h1.	BLIND_MCID6H1	h2.	FUP6H2
i1.	BLIND_MCID6I1	i2.	FUP6I2
j1.	BLIND_MCID6J1	j2.	FUP6J2

7. Since our last study contact, has your child been treated with any prescription or over-the-counter medications?..... Y → **Complete CMF** N FUP7

C. STUDY MEDICATION STATUS

8. **[PC]** What is the child's current study medication status at this contact?
   Note: A subject is considered discontinued only if done so by study staff and documented with DDF form, otherwise the participant is considered 'on study medication' regardless of adherence.

   On study medication ..... A
   Temporarily discontinue medication today ..... B → **Complete DDF**
   Medication was temporarily discontinued at a previous contact .. C → **Go to Item 16**
   Permanently discontinue medication today ..... D → **Complete DDF**
   Medication was permanently discontinued at a previous contact.. E → **Go to Item 17**

FUP8

D. STUDY MEDICATION INTERVIEW

9. Did your child take study medication today? ..... Y N

FUP9

10. Sometimes doses of medication are missed. How often did your child miss a dose during the past week?

    Never ..... A
    1-2 times ..... B
    3-4 times C
    > 4 times ..... D
    Don't know ..... E
    Medication was temporarily discontinued ..... F

FUP10

11. Overall, during the past two months, how often did your child take the study medication?

    Takes medication every day ..... A → **Go to Item 14**
    Takes medication almost every day ..... B → **Go to Item 14**
    Takes medication approximately 75-90% of the time C
    Takes medication approximately 50-74% of the time ..... D
    Takes medication approximately 25-49% of the time ..... E
    Seldom takes medication (occasionally but less than 25%) ..... F
    Does not take study medication ..... G

FUP11

12. What is the primary reason that you did not give your child study medication every day or almost every day?

    Forgetfulness ..... A
    Medication was misplaced ..... B
    Child experienced side effects C
    Child refuses to take medication ..... D
    Parent felt child did not need the medication ..... E
    Medication was temporarily discontinued ..... F
    Other reason ..... G
    Specify: _____

FUP12

13. **[PC]** If the child is not taking study medication, but should, can the parent/guardian be persuaded to resume giving the medication?

    Yes, parent/guardian to resume giving medication ..... Y
    No, parent/guardian will not give medication ..... N

FUP13

14. Overall, how satisfied or dissatisfied are you with the medication your child is receiving *(read responses)*?

    Very satisfied ..... A
    Satisfied ..... B
    Indifferent C
    Dissatisfied ..... D
    Very dissatisfied ..... E
    Does not take study medication ..... F

FUP14

15. Based on your child's response, how would you rate the taste of the medication *(read responses)*?

    Very pleasant ..... A
    Pleasant ..... B
    Neither pleasant nor unpleasant C
    Unpleasant ..... D
    Very unpleasant ..... E
    Does not take study medication ..... F

FUP15

E. MEDICATION DISPENSING

16. a. **[PC]** Is medication being <u>returned</u> at this contact?

    Yes ..... Y → **Complete MRF**
    No ..... N

FUPB16A

b. **[PC]** Is medication being <u>dispensed</u> at this contact?

    Yes ..... Y → **Complete MDD**
    No ..... N

FUP16

F. INTERIM VOIDING HISTORY

17. What is the status of your child's toilet-training for urine during the day (that is, out of diapers and pull-ups, wearing underwear)?
    Note: *See DMS Follow-Up Summary report.*

    Trained since last study contact ..... T
    Not trained ..... N → **Go to 19**
    Previously trained ..... P → **Go to 19**

FUP17

18. How old was your child when he/she began urinating in the toilet or potty by him/herself during the day? (months) ..... ☐☐

FUP18

G. INTERIM BOWEL HISTORY

19. What is the status of your child's toilet-training for bowel movements? **Note:** *See DMS Follow-Up Summary report*.

    Trained since last study contact ..... T
    Not trained ..... N → **Go to 22**
    Previously trained ..... P → **Go to 22**

    FUP19

20. How old was your child when he/she began defecating in the toilet or potty by him/herself? (months) ..... | | FUP20

21. Since toilet/potty training, has your child had a history of soiling his/her underwear with stool? ..... Y N FUP21

22. During the last 2 months, how many bowel movements did your child have per week on average? ..... | | FUP22

H. ADMINISTRATIVE INFORMATION

23. **[PC]** Date of data collection (mm/dd/yyyy): ..... | |/| |/| | | | | FUP23

24. **[PC]** Method of data collection *(circle one)*:

    Computer C
    Paper ..... P

    FUP24

25. **[PC]** Interviewer's or Examiner's initials: ..... | | | BLIND_STAFF_ID

PROTOCOL SCHEDULED FOLLOW-UP CONTACT FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:								FORM CODE: FUP VERSION: A 7/2/07	Contact Occasion			SEQ #		

Participant Name: _____

Instructions: *This form will be completed at each protocol scheduled telephone or clinic follow-up contact.*

A. CONTACT INFORMATION

1. **[PC]** Type of contact *(circle one)*:

   Regularly scheduled protocol clinic visit ..... A → **Go to Item 3**
   Regularly scheduled protocol phone contact ..... B → **Go to Item 3**
   Protocol phone contact replacing protocol clinic visit ..... C → **Go to Item 3**
   Protocol clinic visit replacing protocol phone contact ..... D → **Go to Item 3**
   Missed protocol scheduled contact ..... E

   FUP1

2. **[PC]** Indicate the main reason the contact was missed *(circle one):*

   Participant refused ..... A → **Go to Item 23**
   Participant incapacitated ..... B → **Go to Item 23**
   Participant withdrew consent ..... C → **Complete ICT** → **Go to Item 23**
   Participant location unknown ..... D → **Go to Item 23**
   Oversight ..... E → **Go to Item 23**

   Participant died ..... F → **Complete AEF, MCA, MCN** → **Go to Item 23**

   Unknown ..... G → **Go to Item 23**

   FUP2

B. ADVERSE EVENTS / SIDE EFFECTS and MEDICAL CARE HISTORY

3. **[PC]** Since the last protocol study contact on (mm/dd/yyyy), has the child had any new health problems that fit the study definition of an adverse event? ..... Y → **Complete AEF for each** N

   Note: *Question parent/guardian, review parent diary, and review Follow-up Summary Report.*

   FUPA3

4. **[PC]** Since the last study contact, has the child received medical care for any reason? ..... Y N → **Go to Item 7**

   Note: *Question parent/guardian, review parent diary, and review Follow-up Summary Report.*

   FUP4

5. **[PC]** How many times has the child received medical care since the last study contact? ..... ☐☐ → **Complete MCN & MCA for each**

   FUP5

6. **[PC]** Record the MCID numbers (or affix labels) associated with medical care visits reported in item 5 above. Items 6a2 – 6j2 (column #2) are indicators of a required associated MCN form. This field is automatically pre-filled as 'Y' upon data entry in the DMS for each MCID number listed. If after assigning an MCID number, it is eventually determined that a medical visit did not actually occur, the indicator in column #2 should be set to 'N' so an MCN form is no longer expected.

Note: Space has been provided for notes, to help you keep track of MCID numbers. (Not data entered.)

	1. MCID Number	2. (Y/N)	Notes (not data entered):
a1.	BLIND_MCID6A1	a2.	FUP6A2
b1.	BLIND_MCID6B1	b2.	FUP6B2
c1.	BLIND_MCID6C1	c2.	FUP6C2
d1.	BLIND_MCID6D1	d2.	FUP6D2
e1.	BLIND_MCID6E1	e2.	FUP6E2
f1.	BLIND_MCID6F1	f2.	FUP6F2
g1.	BLIND_MCID6G1	g2.	FUP6G2
h1.	BLIND_MCID6H1	h2.	FUP6H2
i1.	BLIND_MCID6I1	i2.	FUP6I2
j1.	BLIND_MCID6J1	j2.	FUP6J2

7. Since our last study contact, has your child been treated with any prescription or over-the-counter medications? ..... Y → **Complete CMF** N FUP7

C. STUDY MEDICATION STATUS

8. **[PC]** What is the child's current status of study medication use at this contact?

On study medication ..... A
Temporarily discontinue medication today ..... B → **Complete DDF**
Medication was temporarily discontinued at a previous contact ... C → **Go to Item 16**
Permanently discontinue medication today ..... D → **Complete DDF**
Medication was permanently discontinued at a previous contact . E → **Go to Item 17**

FUP8

D. STUDY MEDICATION INTERVIEW

9. Did your child take study medication today? ..... Y N FUP9

10. Sometimes doses of medication are missed. How often did your child miss a dose during the past week?

- Never ..... A
- 1-2 times ..... B
- 3-4 times C
- > 4 times ..... D
- Don't know ..... E
- Medication was temporarily discontinued ..... F

FUP10

11. Overall, during the past two months, how often did your child take the study medication?

- Takes medication every day ..... A → **Go to Item 14**
- Takes medication almost every day ..... B → **Go to Item 14**
- Takes medication approximately 75-90% of the time C
- Takes medication approximately 50-74% of the time ..... D
- Takes medication approximately 25-49% of the time ..... E
- Seldom takes medication (occasionally but less than 25%) ..... F
- Does not take study medication ..... G

FUP11

12. What is the primary reason that you did not give your child study medication every day or almost every day?

- Forgetfulness ..... A
- Medication was misplaced ..... B
- Child experienced side effects C
- Child refuses to take medication ..... D
- Parent felt child did not need the medication ..... E
- Medication was temporarily discontinued ..... F
- Other reason ..... G
  - Specify: _____

FUP12

13. **[PC]** If the child is not taking study medication, but should, can the parent/guardian be persuaded to resume giving the medication?

- Yes, parent/guardian to resume giving medication ..... Y
- No, parent/guardian will not give medication ..... N

FUP13

14. Overall, how satisfied or dissatisfied are you with the medication your child is receiving *(read responses)*?

- Very satisfied ..... A
- Satisfied ..... B
- Indifferent C
- Dissatisfied ..... D
- Very dissatisfied ..... E

FUP14

15. Based on your child's response, how would you rate the taste of the medication *(read responses)*?

- Very pleasant ..... A
- Pleasant ..... B
- Neither pleasant nor unpleasant C

FUP15

Unpleasant ..... D
Very unpleasant ..... E

E. MEDICATION DISPENSING

16. **[PC]** Is medication being dispensed at this contact?

Yes ..... Y → **Complete MDD**
No ..... N

FUP16

F. INTERIM VOIDING HISTORY

17. What is the status of your child's toilet-training for urine during the day (that is, out of diapers and pull-ups, wearing underwear)?
Note: *See DMS Follow-Up Summary report.*

Trained since last study contact ..... T
Not trained ..... N → **Go to 19**
Previously trained ..... P → **Go to 19**

FUP17

18. How old was your child when he/she began urinating in the toilet or potty by him/herself during the day? (months) ..... ☐☐

FUP18

G. INTERIM BOWEL HISTORY

19. What is the status of your child's toilet-training for bowel movements? **Note***: See DMS Follow-Up Summary report*.

Trained since last study contact ..... T
Not trained ..... N → **Go to 22**
Previously trained ..... P → **Go to 22**

FUP19

20. How old was your child when he/she began defecating in the toilet or potty by him/herself? (months) ..... ☐☐

FUP20

21. Since toilet/potty training, has your child had a history of soiling his/her underwear with stool? ..... Y N

FUP21

22. During the last 2 months, how many bowel movements did your child have per week on average? ..... ☐☐

FUP22

H. ADMINISTRATIVE INFORMATION

23. **[PC]** Date of data collection (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐

FUP23

24. **[PC]** Method of data collection *(circle one)*:

Computer C
Paper ..... P

FUP24

25. **[PC]** Interviewer's or Examiner's initials: ..... ☐☐☐

BLIND_STAFF_ID

INFORMED CONSENT TRACKING FORM

RMUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: ICT
VERSION: B 3/18/10

Contact Occasion | | | SEQ # | | |

Participant Name: _____

Instructions: *This form should be completed by project staff after the initial study informed consent is signed, and, at all contact occasions when a request is made to modify consent or withdraw from the study.*

A. CONSENT STATUS

1. Timing of consent *(circle one)*:
   - Initial study consent I
   - Modification of consent ..... M

ICT1

2. Type of consent or modification *(circle one)*:
   - Full consent ..... F → Go to Item 14
   - Partial consent ..... P
   - Partial withdrawal of consent ..... D
   - Full withdrawal of consent ..... W → Go to Item 14
   - If consent withdrawn, specify reason: _____

ICT2

B. SPECIMEN CONSENT

3. Restrictions on stored (repository archived) serum *(circle one)*:
   - Yes, do not use/storage of archived serum ..... Y
   - No restrictions, consented to use/store archived serum ..... N → Go to Item 5

ICT3

4. a. Is there a <u>date</u> restriction on use/storage of serum? ..... Y N → Go to Item 5
   b. If yes, specify date by by which specimens must be used (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐

ICT4A ICT4B

5. Restrictions on use/storage (genetics repository) of DNA *(circle one)*:
   - Yes, do not use/storage of archived DNA ..... Y
   - No restrictions, consented to use/store archived DNA ..... N → Go to Item 7

ICT5

6. a. Is there a <u>date</u> restriction on use/storage of DNA? ..... Y N → Go to Item 7
   b. If yes, specify date by by which specimens must be used (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐

ICT6A ICT6B

7. Restrictions on stored (repository archived) urine *(circle one)*:
   - Yes, do not use/store archived urine ..... Y
   - No restrictions, consented to use/storage of archived urine ..... N → Go to Item 9

ICT7

ID NUMBER:							

FORM CODE: ICT
VERSION: B 3/18/10

Contact Occasion | | | SEQ # | |

8. a. Is there a <u>date</u> restriction on use/storage of urine? ..... Y N → Go to Item 9 ICT8A

   b. If yes, specify date by which specimens must be used (mm/dd/yyyy): ..... __/__/____ ICT8B

C. MEDICAL RECORDS AND DATA USE CONSENT

9. a. Permission to access medical records *(circle one)*:
   Yes, full access ..... Y
   No access ..... N
   Partial access ..... P
   If partial access, please specify: _____ ICT9

   b. Permission to use data for future research studies *(circle one)*:
   Yes, future use of data ..... Y
   No future use of data ..... N
   Partial data may be used ..... P
   If partial data allowed, please specify: _____ ICTB9B

10. Permission to contact informants *(circle one)*:
    Yes, full contact of informants ..... Y
    No contact ..... N
    Limited contact ..... P
    If limited, please specify: _____ ICT10

11. Permission to release results to participant's physician *(circle one)*:
    Yes, release results as applicable ..... Y
    No release of results ..... N
    Partial release of results ..... P
    If partial release, please specify: _____ ICT11

12. Permission to contact parent/guardian in the future for imminent research studies *(circle one)*:
    Yes, future contact ..... Y
    No future contact ..... N
    Limited contact ..... P
    If limited, please specify: _____ ICTB12

13. Any other restrictions not specified in items 3 to 12? ..... Y N ICT12
    If yes, specify restrictions: _____

D. ADMINISTRATIVE INFORMATION

14. Date of consent or modified consent (mm/dd/yyyy): ..... | | / | | / | | | | | ICT13

15. Method of data collection *(circle one)*:

Computer C
Paper ..... P

ICT14

16. Recorder's initials: ..... | | | BLIND_STAFF_ID

INFORMED CONSENT TRACKING FORM

RMUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: ICT
VERSION: A 6/27/07

Contact Occasion | | | SEQ # | | |

Participant Name: _____

Instructions: *This form should be completed by project staff after the initial study informed consent is signed, and, at all contact occasions when a request is made to modify consent or withdraw from the study.*

A. CONSENT STATUS

1. Timing of consent *(circle one)*:
   - Initial study consent I
   - Modification of consent ..... M

   ICT1

2. Type of consent or modification *(circle one)*:
   - Full consent ..... F → Go to Item 13
   - Partial consent ..... P
   - Partial withdrawal of consent ..... D
   - Full withdrawal of consent ..... W → Go to Item 13

   ICT2

   If consent withdrawn, specify reason: _____

B. SPECIMEN CONSENT

3. Restrictions on stored (archived) blood *(circle one)*:
   - Yes, do not use/storage of archived blood ..... Y
   - No restrictions, consented to use/store archived blood ..... N → Go to Item 5

   ICT3

4. a. Is there a <u>date</u> restriction on use/storage of blood? ..... Y N → Go to Item 5 ICT4A
   b. If yes, specify date by by which specimens must be used (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ICT4B

5. Restrictions on use/storage of DNA *(circle one)*:
   - Yes, do not use/storage of archived DNA ..... Y
   - No restrictions, consented to use/store archived DNA ..... N → Go to Item 7

   ICT5

6. a. Is there a <u>date</u> restriction on use/storage of DNA? ..... Y N → Go to Item 7 ICT6A
   b. If yes, specify date by by which specimens must be used (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ ICT6B

7. Restrictions on stored (archived) urine *(circle one)*:
   - Yes, do not use/store archived urine ..... Y
   - No restrictions, consented to use/storage of archived urine ..... N → Go to Item 9

   ICT7

8. a. Is there a date restriction on use/storage of urine? ..... Y N → Go to Item 9 ICT8A

   b. If yes, specify date by which specimens must be used (mm/dd/yyyy): ..... | | / | | / | | | | ICT8B

C. MEDICAL RECORDS CONSENT

9. Permission to access medical records *(circle one)*:
   - Yes, full access ..... Y
   - No access ..... N
   - Partial access ..... P
   - If partial access, please specify: _____

   ICT9

10. Permission to contact informants *(circle one)*:
   - Yes, full contact of informants ..... Y
   - No contact ..... N
   - Limited contact ..... P
   - If limited, please specify: _____

   ICT10

11. Permission to release results to participant's physician *(circle one)*:
   - Yes, release results as applicable ..... Y
   - No release of results ..... N
   - Partial release of results ..... P
   - If partial release, please specify: _____

   ICT11

12. Any other restrictions not specified in items 3 to 11?..... Y N ICT12
   If yes, specify restrictions: _____

D. ADMINISTRATIVE INFORMATION

13. Date of consent or modified consent (mm/dd/yyyy): ..... | | / | | / | | | | ICT13

14. Method of data collection *(circle one)*:
   - Computer C
   - Paper ..... P

   ICT14

15. Recorder's initials: ..... | | | BLIND_STAFF_ID

LIA Questionnaire

ID NUMBER:								FORM CODE: LIQ VERSION: A 8/31/06	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *This is a self-administered questionnaire to be completed by the child's parent or guardian at baseline, 12 month, and end-of-study visits.*

A. Parent/Guardian Response:

1. Here are some statements that parents have made to describe their children. Please **circle one letter for each item a through n** that best describes your child. Please consider the previous 2 weeks as you answer. Did he/she:

		Never or rarely	Some of the time	Almost always	
a.	Eat well	N	S	A	LIQA1A
b.	Sleep well	N	S	A	LIQA1B
c.	Seem contented and cheerful	N	S	A	LIQA1C
d.	Act moody	N	S	A	LIQA1D
e.	Communicate what he/she wanted	N	S	A	LIQA1E
f.	Seem to feel sick and tired	N	S	A	LIQA1F
g.	Occupy him / herself	N	S	A	LIQA1G
h.	Seem lively and energetic	N	S	A	LIQA1H
i.	Seem unusually irritable	N	S	A	LIQA1I
j.	Sleep through the night	N	S	A	LIQA1J
k.	Respond to your attention	N	S	A	LIQA1K
l.	Seem unusually difficult	N	S	A	LIQA1L
m.	React to things by crying	N	S	A	LIQA1M
n.	Seem interested in what was going on around him/her	N	S	A	LIQA1N

2. How would you rate your child's health over the last 2 weeks? *(Circle **one** number.)* LIQA2

0 ----- **1** ----- **2** ----- **3** ----- **4** ----- **5** ----- **6** ----- **7** ----- **8** ----- **9** ----- **10**

Worst imaginable health — Perfect health

3. How worried are you about your child's vesicoureteral reflux/VUR? *(Circle **one** number.)* LIQA3

0 ----- **1** ----- **2** ----- **3** ----- **4** ----- **5** ----- **6** ----- **7** ----- **8** ----- **9** ----- **10**

Not worried — Very worried

ID NUMBER:								FORM CODE: LIQ VERSION: A 8/31/06	Contact Occasion		SEQ #	

4. How difficult has it been for you to give your child medication every day? *(Circle **one** number.)* LIQA4

0 ----- **1** ----- **2** ----- **3** ----- **4** ----- **5** ----- **6** ----- **7** ----- **8** ----- **9** ----- **10**

Not difficult — Very difficult

5. How much financial burden has your child's vesicoureteral reflux/VUR been for your family? *(Circle **one** number.)*

0 ----- **1** ----- **2** ----- **3** ----- **4** ----- **5** ----- **6** ----- **7** ----- **8** ----- **9** ----- **10** LIQA5

Not a burden — Huge burden

6. How bothersome were the urinary tract infection symptoms for your child? *(Circle **one** number.)* LIQA6

0 ----- **1** ----- **2** ----- **3** ----- **4** ----- **5** ----- **6** ----- **7** ----- **8** ----- **9** ----- **10**

Not bothersome — Very bothersome

7. How would you rate your child's health during the urinary tract infection? *(Circle **one** number.)* LIQA7

0 ----- **1** ----- **2** ----- **3** ----- **4** ----- **5** ----- **6** ----- **7** ----- **8** ----- **9** ----- **10**

Worst imaginable health — Perfect health

8. How much discomfort did your child experience with the ultrasound? *(Circle **one** number.)* LIQA8

0 ----- **1** ----- **2** ----- **3** ----- **4** ----- **5** ----- **6** ----- **7** ----- **8** ----- **9** ----- **10**

No discomfort — Worst discomfort

9. How much discomfort did your child experience with the voiding cystourethrogram (VCUG)? *(Circle **one** number.)*

0 ----- **1** ----- **2** ----- **3** ----- **4** ----- **5** ----- **6** ----- **7** ----- **8** ----- **9** ----- **10** LIQA9

No discomfort — Worst discomfort

10. If your child has had a DMSA, how much discomfort did he/she experience with the DMSA? *(Circle **one** number.)*

0 ----- **1** ----- **2** ----- **3** ----- **4** ----- **5** ----- **6** ----- **7** ----- **8** ----- **9** ----- **10** **99** LIQA10

No discomfort — Worst discomfort — Not Applicable

Thank you!

B. Administrative Use Only

11. Date of Form (mm/dd/yyyy) ..... LIQA11 ☐☐/☐☐/☐☐☐☐

12. Reviewer's initials: ..... BLIND_STAFF_ID ☐☐☐

MEDICAL CARE ABSTRACTION FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER: | | | | | | | |

FORM CODE: MCA
VERSION: C 01/21/10

Contact Occasion | |

SEQ # | |

Participant Name: _____

Instructions: *Complete this form based on medical records / chart review on all medical care reported and documented initially on an MCN form including visits with fever, symptoms associated with UTI, VUR treatment, urine collection, or any hospitalization or emergency room visit.*

A. TRACKING / ADMINISTRATIVE

1. Record/label MCID Number: ..... | | | | | | | | BLIND_MCID1
   NOTE: This # should match the MCID from the notification form (MCN).

2. Date of medical care visit (mm/dd/yyyy):..... | | / | | / | | | | MCA3
   Note: Any follow-up visits to this medical care visit would require a separate MCN and MCA with a different MCID.

3. Is this a follow-up visit to a previously reported medical visit?..... Y N → **Go to Item 6** MCA4

4. Date of previously reported medical visit ..... | | / | | / | | | | MCA5

5. MCID Number associated with the previously reported visit:..... | | | | | | | | BLIND_MCID6

6. Status of Medical Records Abstraction:
   - Obtained access to chart ..... O
   - Pending access to chart ..... P → **Go to Item 33** MCA2
   - No possibility of ever accessing chart ..... N → **Go to Item 33**

B. HOSPITALIZATION OR ER VISIT

MCAB7

7a. Was this a hospitalization or an ER visit? ..... Y→ **Complete AEF** N → **Go to Item 12**

b. Specify if the participant was hospitalized or visited the emergency room *(circle one)*:
   Emergency room visit.....E
   Hospitalization.....H
   Other.....O
   Specify If other: _____ MCAC7B

8. Date of discharge (nonfatal cases) or death (mm/dd/yyyy): ..... | | / | | / | | | | MCA8

9. What was the disposition of the patient on discharge?
   - Discharged to home ..... H → **Go to Item 12**
   - Admitted to Hospital from ER..... E → **Go to Item 12**
   - Transferred to another hospital..... T → **Go to Item 12**
   - Transferred to another medical care facility (e.g. rehab)..... M → **Go to Item 12**
   - Deceased ..... D

MCA11

10. Are any causes of death given on the discharge summary? ..... Y N → **Go to Item 12** MCA12

11. Causes of death on the discharge summary:
    a. MCA13A _____
    b. MCA13B _____
    c. MCA13C _____
    d. MCA13D _____
    e. MCA13E _____
    f. MCA13F _____

C. REASON FOR MEDICAL CARE / DIAGNOSIS (for all medical care abstractions including hospitalizations)

12. Did this medical visit include a work-up for suspected UTI? ..... Y N → **Go to Item 14** MCAB12

13. Date of first urine collection for suspected UTI work-up: ..... __/__/____ MCAB13

14. Are there ICD diagnosis codes listed in the medical record? ..... Y N → **Go to Item 17** MCAB14

15. List the hospital discharge ICD codes exactly as they appear on the front sheet of the discharge summary. If visit is not a hospitalization, list any diagnosis codes provided in the medical record:

    a. MCA14A
    b. MCA14B
    c. MCA14C
    d. MCA14D
    e. MCA14E
    f. MCA14F
    g. MCA14G
    h. MCA14H
    i. MCA14I
    j. MCA14J
    k. MCA14K
    l. MCA14L
    m. MCA14M
    n. MCA14N

All ICD codes and text were evaluated by a Nosologist, please use diag_niddk1 variable "ICD_CODE" in place of MCA14A-MCA14N and MCA16A-MCA16N

16. Coding System:
    ICD-9 ..... A
    ICD-10 ..... B MCA15

17. Medical diagnosis or discharge diagnosis (**Text descriptors**, not ICD CODES). Do not split a single diagnosis across two or more response items:
    a. MCA16A _____
    b. MCA16B _____
    c. MCA16C _____

d. MCA16D _____

e. MCA16E _____

f. MCA16F _____

g. MCAC17G _____

h. MCAC17H _____

i. MCAC17I _____

j. MCAC17J _____

k. MCAC17K _____

l. MCAC17L _____

m. MCAC17M _____

n. MCAC17N _____

D. SYMPTOMS

18. Do the medical records mention either a patient complaint or a medical finding for any of the symptoms listed below (see item 19 for listing of symptoms)?..... Y N→ **If N go to 22** MCAB18

19. Please indicate which of the symptoms listed below were documented as having occurred (Y), documented as not having occurred (N), were not mentioned anywhere in the medical records (U), or do not apply (X) as either a patient complaint or medical finding. For each symptom that has occurred, please record the number of days the symptom has occurred up to and including the visit, and, indicate if the symptom occurred within 24hr of the medical visit or UTI workup reported on this form. *(**Note:** if N, U, or X is selected in column 1 and 2, then skip columns 3 and 4.)*

	1. Documented Patient Complaint	2. Documented Medical Finding	3. Duration of symptom (days)	4. Occur within 24 hours of medical visit or UTI workup reported on this form?
a. Suprapubic, abdominal, or flank pain / tenderness	MCAB19A1 Y N U	MCAB19A2 Y N U	MCAB19A3 ___	MCAB19A4 Y N U
b. Urinary urgency, frequency, hesitancy	MCAB19B1 Y N U	MCAB19B2 Y N U	MCAB19B3 ___	MCAB19B4 Y N U
c. Dysuria	MCAB19C1 Y N U	MCAB19C2 Y N U	MCAB19C3 ___	MCAB19C4 Y N U
d. Foul smelling urine	MCAB19D1 Y N U	MCAB19D2 Y N U	MCAB19D3 ___	MCAB19D4 Y N U
e. Failure to thrive (<= 4 months old)	MCAB19E1 Y N U X	MCAB19E2 Y N U X	MCAB19E3 ___	MCAB19E4 Y N U X
f Dehydration (<= 4 months old)	MCAB19F1 Y N U X	MCAB19F2 Y N U X	MCAB19F3 ___	MCAB19F4 Y N U X

ID NUMBER:								FORM CODE: MCA VERSION: C 01/21/10	Contact Occasion		SEQ #	

	MCAB19G1 1. Documented Patient Complaint	MCAB19G2 2. Documented Medical Finding	MCAB19G3 3. Duration of symptom (days)	MCAB19G4 4. Occur within 24 hours of medical visit or UTI workup reported on this form?
g. Hypothermia (<= 4 months old)	Y N U X	Y N U X		Y N U X

20. What date does the medical record indicate that the first symptom associated with this medical care visit began (mm/dd/yyyy)? ..... ☐☐/☐☐/☐☐☐☐ MCAB20

21. Were any medications given to the child for symptoms within 24 hours prior to the medical visit or work-up for suspected UTI (Y = yes, N = no, U = not documented)? ..... Y N U MCAB21

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the next CMF form.

E. FEVER

22. Do the medical records mention any fever associated with this event, either a patient complaint or a medical finding? ..... Y N→ **If N go to 26** MCAB22

23. a. Was a temperature taken during the medical visit? ..... Y N→ **If N go to 24** MCA19

b. What was the highest temperature recorded during the medical visit: ..... ☐☐☐.☐ MCA20A

c. Units of measurement during the medical visit *(circle one)*:

˚F ..... F
˚C ..... C MCA20B

d. Recorded temperature measurement route during the medical visit *(circle one)*:

Oral ..... O
Axillary ..... A
Tympanic ..... T
Rectal ..... R
Temporal ..... F
Unknown ..... U

MCAB23D

24. a. Does the medical record indicate that the child had a fever of at least 100.4˚ F or 38˚ C at any time prior to the medical visit (Y=yes, N=no, U=not documented) ..... Y N U → **If N or U go to 26**

MCAB24A

b. Highest temperature measured prior to medical visit: ..... ☐☐☐.☐ MCA25A

c. Units of measurement prior to medical visit *(circle one)*:

˚F ..... F
˚C C

MCA25B

d. Temperature measurement route prior to medical visit *(circle one)*:

Oral ..... O
Axillary ..... A
Tympanic ..... T
Rectal ..... R
Temporal ..... F
Unknown ..... U

MCAB24D

e. Date of highest fever prior to medical visit (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCAB24E

25. a. Does the medical record indicate that the child was having a fever of at least 100.4˚ F or 38˚ C within 24 hrs prior to the medical visit or UTI workup reported on this form (Y=yes, N=no, U=not documented) ..... Y N U → **If N or U go to 26** MCAB25A

b. Highest temperature measured within 24 hrs prior to the medical visit or UTI workup reported on this form: ..... ☐☐☐.☐ MCAB25B

c. Units of measurement within 24 hrs prior to the medical visit or UTI workup reported on this form *(circle one)*:

˚F ..... F
˚C C

MCAB25C

d. Temperature measurement route within 24 hrs prior to the medical visit or UTI workup reported on this form *(circle one)*:

Oral ..... O
Axillary ..... A
Tympanic ..... T
Rectal ..... R
Temporal ..... F
Unknown ..... U

MCAB25D

e. Date of highest fever within 24 hrs prior to the medical visit or UTI workup reported on this form (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCAB25E

26. Were any antipyretics given to the child within 24 hours prior to the medical visit or work-up for suspected UTI (Y=yes, N=no, U=not documented)? ..... Y N U MCAB26

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the CMF.

F. WEIGHT

27. Was a weight measurement recorded? ..... Y N → **Go to item 30** MCA30

28. a. Weight: ..... ☐☐☐.☐ MCA31A
    b. Weight units *(circle one)*:
    Kilograms ..... K
    Pounds ..... P MCA31B

29. Date of measured weight (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCA32

G. URINALYSIS

30. Was a urinalysis or urine culture performed during the medical care visit? ..... Y N → **Go to item 32** MCA33

31. How many urinalysis or urine culture reports are there associated with this hospital admission or medical care visit? ..... ☐☐ → **Complete USR for each** MCA34

H. MEDICAL PROCEDURES / IMAGES:

32. Were any of the following medical procedures noted in the chart review?

a. **Urethral catheterization** (not for urine specimen collection) ..... Y N → **Go to item 32d** MCA35A

b. If yes, date of catheterization: (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCA35B

c. If yes, number of days catheterized ..... ☐☐ MCA35C

d. **Renal and/or bladder ultrasound** ..... Y N → **Go to item 32f** MCA35D

e. If yes, date of Ultrasound: (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCA35E

f. **VCUG**: ..... Y N → **Go to item 32h** MCA35F

g. If yes, date of VCUG: (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCA35G

h. **DMSA** ..... Y N → **Go to item 32j** MCA35H

i. If yes, date of DMSA: (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCA35I

j. **Procedure to correct VUR** ..... Y N → **Go to item 33** MCAC32J

k. If yes, date of procedure: (mm/dd/yyyy): ..... | | / | | / | | | | MCAC32K

l. Name of procedure: _____ MCAC32L

I. ADMINISTRATIVE INFORMATION

33. Date of data collection (mm/dd/yyyy): ..... | | / | | / | | | | MCA36

34. Method of data collection *(circle one)*:

Computer C
Paper ..... P

MCA37

35. Recorder's initials: ..... | | | BLIND_STAFF_ID

MEDICAL CARE ABSTRACTION FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER: | | | | | | | |

FORM CODE: MCA
VERSION: B 2/22/08

Contact Occasion | |

SEQ # | |

Participant Name: _____

Instructions: *Complete this form based on medical records / chart review on all medical care reported and documented initially on an MCN form including well child visits, and RIVUR clinic sick visits.*

A. TRACKING / ADMINISTRATIVE

1. Record/label MCID Number: ..... | | | | | | | | BLIND_MCID1
   NOTE: This # should match the MCID from the notification form (MCN).

2. Date of medical care visit (mm/dd/yyyy): ..... | |/| |/| | | | | MCA3
   Note: Any follow-up visits to this medical care visit would require a separate MCN and MCA with a different MCID.

3. Is this a follow-up visit to a previously reported medical visit? ..... Y N → **Go to Item 6** MCA4

4. Date of previously reported medical visit? ..... | |/| |/| | | | | MCA5

5. MCID Number associated with the previously reported visit: ..... | | | | | | | | BLIND_MCID6

6. Status of Medical Records Abstraction:
   - Obtained access to chart ..... O
   - Pending access to chart ..... P → **Go to Item 33** MCA2
   - No possibility of ever accessing chart ..... N → **Go to Item 33**

B. HOSPITALIZATION OR ER VISIT

7. Was this a hospitalization or an ER visit? ..... Y N → **Go to Item 12** MCAB7

8. Date of discharge (nonfatal cases) or death (mm/dd/yyyy): ..... | |/| |/| | | | | MCA8

9. What was the disposition of the patient on discharge?
   - Discharged to home ..... H → **Go to Item 12**
   - Admitted to Hospital from ER ..... E → **Go to Item 12**
   - Transferred to another hospital ..... T → **Go to Item 12**
   - Transferred to another medical care facility (e.g. rehab) ..... M → **Go to Item 12**
   - Deceased ..... D

   MCA11

10. Are any causes of death given on the discharge summary? ..... Y N → **Go to Item 12** MCA12

11. Causes of death on the discharge summary:
    a. MCA13A _____
    b. MCA13B _____
    c. MCA13C _____
    d. MCA13D _____
    e. MCA13E _____
    f. MCA13F _____

C. REASON FOR MEDICAL CARE / DIAGNOSIS (for all medical care abstractions including hospitalizations)

12. Did this medical visit include a work-up for suspected UTI? ..... Y N → **Go to Item 14** MCAB12

13. Date of first urine collection for suspected UTI work-up: ..... __/__/____ MCAB13

14. Are there ICD diagnosis codes listed in the medical record? ..... Y N → **Go to Item 17** MCAB14

15. List the hospital discharge ICD codes exactly as they appear on the front sheet of the discharge summary. If visit is not a hospitalization, list any diagnosis codes provided in the medical record:

a.	MCA14A	h.	MCA14H
b.	MCA14B	i.	MCA14I
c.	MCA14C	j.	MCA14J
d.	MCA14D	k.	MCA14K
e.	MCA14E	l.	MCA14L
f.	MCA14F	m.	MCA14M
g.	MCA14G	n.	MCA14N

16. Coding System:
    ICD-9 ..... A
    ICD-10 ..... B MCA15

17. Medical diagnosis or discharge diagnosis (**Text descriptors**, not ICD CODES). Do not split a single diagnosis across two or more response items:
    a. MCA16A _____
    b. MCA16B _____
    c. MCA16C _____
    d. MCA16D _____

e. MCA16E _____

f. MCA16F _____

D. SYMPTOMS

18. Do the medical records mention either a patient complaint or a medical finding for any of the symptoms listed below (see item 19 for listing of symptoms) ..... Y N→ **If N go to 22** MCAB18

19. Please indicate which of the symptoms listed below were documented as having occurred (Y), documented as not having occurred (N), were not mentioned anywhere in the medical records (U), or do not apply (X) as either a patient complaint or medical finding. For each symptom that has occurred, please record the number of days the symptom has occurred up to and including the visit, and, indicate if the symptom occurred within 24hr of the medical visit or UTI workup reported on this form.

	1. Documented Patient Complaint	2. Documented Medical Finding	3. Duration of symptom (days)	4. Occur within 24 hours of medical visit or UTI workup reported on this form?
a. Suprapubic, abdominal, or flank pain / tenderness	MCAB19A1 Y N U	MCAB19A2 Y N U	MCAB19A3	MCAB19A4 Y N U
b. Urinary urgency, frequency, hesitancy	MCAB19B1 Y N U	MCAB19B2 Y N U	MCAB19B3	MCAB19B4 Y N U
c. Dysuria	MCAB19C1 Y N U	MCAB19C2 Y N U	MCAB19C3	MCAB19C4 Y N U
d. Foul smelling urine	MCAB19D1 Y N U	MCAB19D2 Y N U	MCAB19D3	MCAB19D4 Y N U
e. Failure to thrive (<= 4 months old)	MCAB19E1 Y N U X	MCAB19E2 Y N U X	MCAB19E3	MCAB19E4 Y N U X
f Dehydration (<= 4 months old)	MCAB19F1 Y N U X	MCAB19F2 Y N U X	MCAB19F3	MCAB19F4 Y N U X
g. Hypothermia (<= 4 months old)	MCAB19G1 Y N U X	MCAB19G2 Y N U X	MCAB19G3	MCAB19G4 Y N U X

20. What date does the medical record indicate that the first symptom associated with this medical care visit began (mm/dd/yyyy)? ..... | | | / | | | / | | | | | MCAB20

21. Were any medications given to the child for symptoms within 24 hours prior to the medical visit or work-up for suspected UTI (Y = yes, N = no, U = not documented)? ..... Y N U MCAB21

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the next CMF form.

E. FEVER

22. Do the medical records mention any fever associated with this event, either a patient complaint or a medical finding Y..... N→ **If N go to 26** MCAB22

23. a. Was a temperature taken during the medical visit?..... Y N→ **If N go to 24** MCA19

b. What was the highest temperature recorded during the medical visit: ..... | | | | . | | MCA20A

c. Units of measurement during the medical visit *(circle one)*:

˚F ..... F MCA20B
˚C C

d. Recorded temperature measurement route during the medical visit *(circle one)*:

Oral ..... O
Axillary ..... A
Tympanic ..... T MCAB23D
Rectal ..... R
Unknown ..... U

24. a. Does the medical record indicate that the child had a fever of at least 100.4˚ F or 38˚ C at any time prior to the medical visit (Y=yes, N=no, U=not documented) ..... Y N U → **If N or U go to 26** MCAB24A

b. Highest temperature measured prior to medical visit: ..... | | | | . | | MCA25A

c. Units of measurement prior to medical visit *(circle one)*:

˚F ..... F MCA25B
˚C C

d. Temperature measurement route prior to medical visit *(circle one)*:

Oral ..... O
Axillary ..... A
Tympanic ..... T MCAB24D
Rectal ..... R
Unknown ..... U

e. Date of highest fever prior to medical visit (mm/dd/yyyy): ..... | | / | | / | | | | MCAB24E

25. a. Does the medical record indicate that the child was having a fever of at least 100.4˚ F or 38˚ C within 24 hrs prior to the medical visit or UTI workup reported on this form (Y=yes, N=no, U=not documented) ..... Y N U → **If N or U go to 26** MCAB25A

b. Highest temperature measured within 24 hrs prior to the medical visit or UTI workup reported on this form: ..... | | | | . | | MCAB25B

c. Units of measurement within 24 hrs prior to the medical visit or UTI workup reported on this form *(circle one)*:

˚F ..... F
˚C C
MCAB25C

d. Temperature measurement route within 24 hrs prior to the medical visit or UTI workup reported on this form *(circle one)*:

Oral ..... O
Axillary ..... A
Tympanic ..... T
Rectal ..... R
Unknown ..... U
MCAB25D

e. Date of highest fever within 24 hrs prior to the medical visit or UTI workup reported on this form (mm/dd/yyyy): ..... | | / | | / | | | | MCAB25E

26. Were any antipyretics given to the child within 24 hours prior to the medical visit or work-up for suspected UTI (Y=yes, N=no, U=not documented)? ..... Y N U MCAB26

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the CMF.

F. WEIGHT

27. Was a weight measurement recorded? ..... Y N → **Go to item 30** MCA30

28. a. Weight: ..... | | | . | MCA31A

b. Weight units *(circle one)*:

Kilograms ..... K
Pounds ..... P
MCA31B

29. Date of measured weight (mm/dd/yyyy): ..... | | / | | / | | | | MCA32

G. URINALYSIS

30. Was a urinalysis or urine culture performed during the medical care visit? ..... Y N → **Go to item 32** MCA33

31. How many urinalysis or urine culture reports are there associated with this hospital admission or medical care visit? ..... | | → **Complete USR for each** MCA34

H. MEDICAL PROCEDURES / IMAGES:

32. Were any of the following medical procedures noted in the chart review?

a. **Urethral catheterization** (not for urine specimen collection) ..... Y N → **Go to item 32d** MCA35A

b. If yes, date of catheterization: (mm/dd/yyyy): ..... | |/| |/| | | | | MCA35B

c. If yes, number of days catheterized ..... | | MCA35C

d. **Renal and/or bladder ultrasound** ..... Y N → **Go to item 32f** MCA35D

e. If yes, date of Ultrasound: (mm/dd/yyyy): ..... | |/| |/| | | | | MCA35E

f. **VCUG**: ..... Y N → **Go to item 32h** MCA35F

g. If yes, date of VCUG: (mm/dd/yyyy): ..... | |/| |/| | | | | MCA35G

h. **DMSA** ..... Y N → **Go to item 33** MCA35H

i. If yes, date of DMSA: (mm/dd/yyyy): ..... | |/| |/| | | | | MCA35I

I. ADMINISTRATIVE INFORMATION

33. Date of data collection (mm/dd/yyyy): ..... | |/| |/| | | | | MCA36

34. Method of data collection *(circle one)*:

Computer C
Paper ..... P MCA37

35. Recorder's initials: ..... | | | BLIND_STAFF_ID

MEDICAL CARE ABSTRACTION FORM

Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER: | | | | | | | |

FORM CODE: MCA
VERSION: A 3/30/07

Contact Occasion | |

SEQ # | |

Participant Name: _____

Instructions: *Complete this form based on medical records / chart review on all medical care reported and documented initially on an MCN form, including well child visits, and RIVUR clinic sick visits.*

A. TRACKING / ADMINISTRATIVE

1. Record/label MCID Number: ..... | | | | | | | | BLIND_MCID1
   NOTE: This # should match the MCID from the notification form (MCN).

2. Status of Medical Records Abstraction:
   - Obtained access to chart ..... O
   - Pending access to chart ..... P → **Go to Item 36** MCA2
   - No possibility of ever accessing chart ..... N → **Go to Item 36**

3. Date of medical care visit (mm/dd/yyyy): ..... | | / | | / | | | | MCA3
   Note: Any follow-up visits to this medical care visit would require a separate MCN and MCA with a different MCID.

4. Is this a follow-up visit to a previously reported medical visit? ..... Y N → **Go to Item 7** MCA4

5. Date of previously reported medical visit? ..... | | / | | / | | | | MCA5

6. MCID Number associated with the previously reported visit: ..... | | | | | | | | BLIND_MCID6

7. Type of Medical Visit from this abstraction:
   - RIVUR study clinic ..... A → **Go to Item 14**
   - Primary care physician ..... B → **Go to Item 14** MCAA7
   - Outpatient clinic ..... C → **Go to Item 14**
   - ER visit (no hospital admission) ..... D → **Go to Item 14**
   - Hospitalization ..... E

B. HOSPITALIZATION

8. Date of discharge (nonfatal cases) or death (mm/dd/yyyy): ..... | | / | | / | | | | MCA8

9. Was this an unscheduled emergency admission? ..... Y → **Go to Item 11** N MCAA9

10. Was this an admission for a scheduled procedure? ..... Y N MCAA10

Participant Name: _____

11. What was the disposition of the patient on discharge?

Deceased ..... D
Transferred to another hospital ..... T → **Go to Item 14**
Transferred to another medical care facility (e.g. rehab) ..... M → **Go to Item 14**
Discharged to home ..... H → **Go to Item 14**

MCA11

12. Are any causes of death given on the discharge summary? ..... Y N → **Go to Item 14**

MCA12

13. Causes of death on the discharge summary:

a. MCA13A _____
b. MCA13B _____
c. MCA13C _____
d. MCA13D _____
e. MCA13E _____
f. MCA13F _____

C. REASON FOR MEDICAL CARE / DIAGNOSIS (for all medical care abstractions including hospitalizations)

14. List the hospital discharge diagnosis codes exactly as they appear on the front sheet of the discharge summary. If visit is not a hospitalization, list any diagnosis codes provided in the medical record (if none appear then leave Item blank):

a.	MCA14A	h.	MCA14H
b.	MCA14B	i.	MCA14I
c.	MCA14C	j.	MCA14J
d.	MCA14D	k.	MCA14K
e.	MCA14E	l.	MCA14L
f.	MCA14F	m.	MCA14M
g.	MCA14G	n.	MCA14N

15. Coding System:

ICD-9 ..... A
ICD-10 ..... B
No codes entered in item 14 C

MCA15

ID NUMBER:								FORM CODE: MCA VERSION: A 3/30/07	Contact Occasion		SEQ #	

Participant Name: _____

16. Medical diagnosis or discharge diagnosis (**Text descriptors**, not ICD CODES). Do not split a single diagnosis across two or more response items:

a. MCA16A _____

b. MCA16B _____

c. MCA16C _____

d. MCA16D _____

e. MCA16E _____

f. MCA16F _____

D. SYMPTOMS

17. Were any of the following symptoms documented anywhere among the participant Complaints or Medical findings? Note: Respond to both, Y=yes, N=no, X=does not apply.

		1. Patient Complaints			2. Medical Findings			
a.	Fever	Y	N	MCAA17A1	Y	N		MCAA17A2
b.	Suprapubic, abdominal, or flank pain or tenderness	Y	N	MCAA17B1	Y	N		MCAA17B2
c.	Urinary urgency, frequency, hesitancy	Y	N	MCAA17C1	Y	N		MCAA17C2
d.	Dysuria	Y	N	MCAA17D1	Y	N		MCAA17D2
e.	Foul smelling urine	Y	N	MCAA17E1	Y	N		MCAA17E2
f.	Failure to thrive (<= 4 months old)	Y	N	MCAA17F1	Y	N	X	MCAA17F2
g	Dehydration (<= 4 months old)	Y	N	MCAA17G1	Y	N	X	MCAA17G2
h.	Hypothermia (<= 4 months old)	Y	N	MCAA17H1	Y	N	X	MCAA17H2

18. Indicate any other symptoms/complaints/medical findings as described on hospital or medical care chart:

a. MCAA18A _____

b. MCAA18B _____

c. MCAA18C _____

d. MCAA18D _____

e. MCAA18E _____

f. MCAA18F _____

ID NUMBER:								FORM CODE: MCA VERSION: A 3/30/07	Contact Occasion		SEQ #	

Participant Name: _____

E. TEMPERATURE and WEIGHT

19. Was a temperature recorded during the medical visit? ..... Y N → **Go to 24** MCA19

20. a. Highest temperature measured during medical care: ..... ☐☐☐.☐ MCA20A

b. Units *(circle one)*:

˚F ..... F
˚C ..... C MCA20B

21. Date of highest temperature (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCAA21

22. Time of highest temperature (24 hr): ..... ☐☐:☐☐ MCAA22

23. Temperature measurement route *(circle one)*:

Oral ..... O
Axillary ..... A
Tympanic ..... T
Rectal ..... R
Unknown ..... U
MCAA23

24. Was the child reported as having a fever prior to the medical visit? .... Y N → **Go to 30** MCAA24

25. a. Highest temperature measured prior to medical visit: ..... ☐☐☐.☐ MCA25A

b. Units *(circle one)*:

˚F ..... F
˚C ..... C MCA25B

26. Date of highest temperature (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCAA26

27. Time of highest temperature (24 hr): ..... ☐☐:☐☐ MCAA27

28. Temperature measurement route *(circle one)*:

Oral ..... O
Axillary ..... A
Tympanic ..... T
Rectal ..... R
Unknown ..... U
MCAA28

Participant Name: _____

29. Duration of fever prior to treatment (hrs): ..... | | | | MCAA29

30. Was a weight measurement recorded? ..... Y N → **Go to 33** MCA30

31. a. Weight: ..... | | | | . | | MCA31A
    b. Weight units *(circle one)*:
    Kilograms ..... K
    Pounds ..... P MCA31B

32. Date of measured weight (mm/dd/yyyy): ..... | | / | | / | | | | MCA32

F. URINALYSIS

33. Was a urinalysis performed during the medical care visit? ..... Y N → **Go to 35** MCA33

34. How many urinalysis/urine culture reports are there associated with this hospital admission or medical care visit? ..... | | → **Complete USR for each** MCA34

Note: Complete a USR for each urinalysis/urine culture, noting MCID associated with this form. If urinalysis collected at home and in medical office, report only the urinalysis result collected during the medical visit.

G. MEDICAL PROCEDURES / IMAGES:

35. Were any of the following medical procedures noted in the chart review?

a. Urethral catheterization ..... Y N → **Go to 35d** MCA35A

b. If yes, date of catheterization: (mm/dd/yyyy): ..... | | / | | / | | | | MCA35B

c. If yes, number of days catheterized ..... | | MCA35C

d. Renal and bladder ultrasound ..... Y N → **Go to 35f** MCA35D

e. If yes, date of Ultrasound: (mm/dd/yyyy): ..... | | / | | / | | | | MCA35E

f. VCUG: ..... Y N → **Go to 35h** MCA35F

g. If yes, date of VCUG: (mm/dd/yyyy): ..... | | / | | / | | | | MCA35G

h. DMSA ..... Y N → **Go to 36** MCA35H

i. If yes, date of DMSA: (mm/dd/yyyy): ..... | | / | | / | | | | MCA35I

Participant Name: _____

H. ADMINISTRATIVE INFORMATION

36. Date of data collection (mm/dd/yyyy): ..... |_|_|/|_|_|/|_|_|_|_| MCA36

37. Method of data collection *(circle one)*:

Computer C

Paper..... P

MCA37

38. Recorder's initials: ..... |_|_|_| BLIND_STAFF_ID

MEDICAL CARE NOTIFICATION FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: MCN
VERSION: D 02/23/10

Contact Occasion ☐☐ SEQ # ☐☐

Participant Name: _____

Instructions: *Complete this form for all medical care reported/received since the last study contact, including in-clinic RIVUR sick visits. Each MCN form will also have a corresponding MCA form once medical records have been received. Forms are linked with an assigned MCID number.*

A. MEDICAL CARE INFORMATION

1. **[PC]** Assigned MCID number: ..... ☐☐☐☐☐☐☐ BLIND_MCID

2. Date of medical care visit (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCN2

   Provider name: _____ **[no data entry]**

   Provider address/contact information: _____ **[no data entry]**

   _____

   _____

3. a. **[PC]** Location of Medical Visit *(select one)*: MCNC3 MCN3A

   Private Physician Office ..... A → **Go to item 3c**

   The RIVUR Clinic ..... B→ **Go to item 3c**

   Specialty clinic at RIVUR center ..... C→ **Go to item 3c**

   Other specialty clinic not affiliated with RIVUR center ..... D→ **Go to item 3c**

   Hospitalization or ER visit at RIVUR-affiliated Hospital ..... E→ **Complete AEF**

   Hospitalization or ER visit at Hospital not affiliated with RIVUR .... F→ **Complete AEF**

   Other location ..... G→ **Record, Go to item 3c**

   If other, please specify: _____

   b. **[PC]** Specify if the participant was hospitalized or visited the emergency room *(circle one)*: MCND3B

   Emergency room visit.....E
   Hospitalization.....H
   Other.....O

   If other, please specify: _____

   c. **[PC]** Is the family providing information about the medical care visit? ..... Y N → **Answer items 8, 23-25** MCND3C

4. Was urine collected at this medical visit? ..... Y N → **Go to item 6** MCN4

5. Were you informed that a urinary tract infection was/is suspected or diagnosed during this medical visit? ..... Y N MCN5

6. Was the child well at the visit (displaying NO symptoms, NO fever, and no medication was prescribed)? ..... Y→ **Go to item 20** N MCN6

7. During this visit, did your child get referred to another physician or specialist? ..... Y N MCN7

   (**Note:** if 'Y', record MD name: _____
   this will require another MCN)

8. **[PC]** Does the illness or reason for sick visit fit the definition for an adverse event? ..... Y→**Complete AEF** N MCN8

B. FEVER

9. Did your child have a fever during his/her illness? ..... Y N → **Go to 15** MCN9

10. a. Highest temperature reported: ..... ☐☐☐.☐ MCN10A

    b. Units *(circle one)*:

    ˚F ..... F
    ˚C ..... C MCN10B

11. Date of highest temperature (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCN11

12. Time of highest temperature (24 hr): ..... ☐☐☐☐ MCN12

13. Temperature measurement route *(circle one)*: MCN13

    Oral ..... O
    Axillary ..... A
    Tympanic ..... T
    Rectal ..... R
    Temporal ..... F
    Unknown ..... U

14 a. Date fever started? ..... ☐☐/☐☐/☐☐☐☐ MCNB14A

    b. Duration of fever (hrs): ..... ☐☐☐ MCN14

15. Were any antipyretics given to the child within 24 hours prior to the medical visit or work-up for suspected UTI (Y=yes, N=no, U=not documented)? ..... Y N U MCNC15

    If Yes, list medications: _____

    Note: If Yes, remember to also list medication(s) on the CMF.

ID NUMBER:								FORM CODE: MCN VERSION: D 02/23/10	Contact Occasion		SEQ #		

C. SYMPTOMS

16. Has your child experienced any of the following symptoms (see item 17 for listing of symptoms)..... Y N→ **If N go to 20** MCNC16

17. **[PC]** Please indicate which of the symptoms listed below were documented as having occurred (Y), documented as not having occurred (N), were not mentioned anywhere in the medical records (U), or do not apply (X). For each symptom that has occurred, please record the number of days the symptom has occurred up to and including the visit, and indicate if the symptom occurred within 24hr of the medical visit or UTI workup reported on this form. *(**Note:** if N, U, or X selected in column 1, then skip columns 2 and 3.)*

	1. Did symptom occur?				2. Duration of symptom (days):	3. Occur within 24 hours of medical visit?			
a. Suprapubic, abdominal, or flank pain / tenderness	Y	N	U	MCN15A	MCNC17A2	Y	N	X	MCNC17A3
b. Urinary urgency, frequency, hesitancy	Y	N	U	MCN15B	MCNC17B2	Y	N	X	MCNC17B3
c. Dysuria	Y	N	U	MCN15C	MCNC17C2	Y	N	X	MCNC17C3
d. Foul smelling urine	Y	N	U	MCN15D	MCNC17D2	Y	N	X	MCNC17D3
e. Failure to thrive (<= 4 months old)	Y	N	U	X MCN15E	MCNC17E2	Y	N	X	MCNC17E3
f Dehydration (<= 4 months old)	Y	N	U	X MCN15F	MCNC17F2	Y	N	X	MCNC17F3
g. Hypothermia (<= 4 months old)	Y	N	U	X MCN15G	MCNC17G2	Y	N	X	MCNC17G3

18. Date symptoms started: ..... ☐☐/☐☐/☐☐☐☐ MCNB16A

19. Did you give your child any medications for symptoms within 24 hours prior to the medical visit or work-up for suspected UTI (Y = yes, N = no, U = not documented)? ..... Y N U MCNC19

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the next CMF form.

D. STUDY MEDICATION

20 a. Was study medication temporarily discontinued during this event? Y N →**Go to Item 21** MCN16

b. How many days was study medication discontinued? ..... ☐☐ MCN17

E. RESOURCE UTILIZATION

Note to Coordinator: If this form is being completed at the time of an event, questions 21 and 22 will need to be completed as a follow-up.

21. a. Did a parent or caregiver miss work due to this illness/event?..... Y N →**Go to Item 22** MCN18A

b. Total number of days work missed by all caregivers: ..... | | MCN18B

22. a. Did alternative child care arrangements have to be made during this illness/event?..... Y N → **Go to Item 23** MCN19A

b. Total number of days alternate care arrangements needed: ..... | | MCN19B

F. ADMINSTRATIVE INFORMATION

23. **[PC]** Date of form (mm/dd/yyyy):..... | | / | | / | | | | MCN20

24. **[PC]** Method of data collection *(circle one)*:
Computer C
Paper..... P
MCN21

25. **[PC]** Interviewer's or Examiner's initials: ..... | | | BLIND_STAFF_ID

MEDICAL CARE NOTIFICATION FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:								FORM CODE: MCN VERSION: C 2/13/08	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *Complete this form for all medical care reported/received since the last study contact, including in-clinic RIVUR sick visits. Each MCN form will also have a corresponding MCA form once medical records have been received. Forms are linked with an assigned MCID number.*

A. MEDICAL CARE INFORMATION

1. **[PC]** Assigned MCID number: ..... ☐☐☐☐☐☐☐ MCN1

2. Date of medical care visit (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCN2

Provider name: _____ **[no data entry]**

Provider address/contact information: _____ **[no data entry]**

_____

_____

3a. **[PC]** Location of Medical Visit *(select one)*: MCNC3A

- Private Physician Office ..... A
- The RIVUR Clinic ..... B
- Specialty clinic at RIVUR center C
- Other specialty clinic not affiliated with RIVUR center ..... D
- Hospitalization or ER visit at RIVUR-affiliated Hospital ..... E
- Hospitalization or ER visit at Hospital not affiliated with RIVUR ..... F
- Other location ..... G

If other, please specify: _____

4. Was urine collected at this medical visit? ..... Y N → **Go to item 6** MCN4

5. Were you informed that a urinary tract infection was/is suspected or diagnosed during this medical visit? ..... Y N MCN5

6 Was this a well-child visit (with no current symptoms, no specimens, and no medication prescribed)? ..... Y→ **Go to item 20** N MCN6

7. During this visit, did your child get referred to another physician or specialist? ..... Y N MCN7

(**Note:** if 'Y', record MD name: _____
this will require another MCN)

8. **[PC]** Does the illness or reason for sick visit fit the definition for an adverse event? ..... Y→**Complete AEF** N MCN8

B. FEVER

9. Did your child have a fever during his/her illness? ..... Y N → **Go to 15** MCN9

10. a. Highest temperature reported: ..... ☐☐☐.☐ MCN10A

b. Units *(circle one)*:

˚F ..... F
˚C C

MCN10B

11. Date of highest temperature (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCN11

12. Time of highest temperature (24 hr): ..... ☐☐☐☐ MCN12

13. Temperature measurement route *(circle one)*: MCN13

Oral ..... O
Axillary ..... A
Tympanic ..... T
Rectal ..... R
Unknown ..... U

14 a. Date fever started? ..... ☐☐/☐☐/☐☐☐☐ MCNB14A

b. Duration of fever (hrs): ..... ☐☐☐ MCN14

15. Were any antipyretics given to the child within 24 hours prior to the medical visit or work-up for suspected UTI (Y=yes, N=no, U=not documented)? ..... Y N U MCNC15

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the CMF.

C. SYMPTOMS

16. Has your child experienced any of the following symptoms (see item 17 for listing of symptoms) ..... Y N→ **If N go to 20** MCNC16

17. **[PC]** Please indicate which of the symptoms listed below were documented as having occurred (Y), documented as not having occurred (N), were not mentioned anywhere in the medical records (U), or do not apply (X). For each symptom that has occurred, please record the number of days the symptom has occurred up to and including the visit, and indicate if the symptom occurred within 24hr of the medical visit or UTI workup reported on this form.

	1. Did symptom occur?				2. Duration of symptom (days):	3. Occur within 24 hours of medical visit?			
a. Suprapubic, abdominal, or flank pain / tenderness	Y	N	U	MCN15A	MCNC17A2	Y	N	X	MCNC17A3
b. Urinary urgency, frequency, hesitancy	Y	N	U	MCN15B	MCNC17B2	Y	N	X	MCNC17B3
c. Dysuria	Y	N	U	MCN15C	MCNC17C2	Y	N	X	MCNC17C3
d. Foul smelling urine	Y	N	U	MCN15D	MCNC17D2	Y	N	X	MCNC17D3
e. Failure to thrive (<= 4 months old)	Y	N	U	X MCN15E	MCNC17E2	Y	N	X	MCNC17E3
f Dehydration (<= 4 months old)	Y	N	U	X MCN15F	MCNC17F2	Y	N	X	MCNC17F3
g. Hypothermia (<= 4 months old)	Y	N	U	X MCN15G	MCNC17G2	Y	N	X	MCNC17G3

18. Date symptoms started: ..... | | | / | | | / | | | | | MCNB16A

19. Did you give your child any medications for symptoms within 24 hours prior to the medical visit or work-up for suspected UTI (Y = yes, N = no, U = not documented)? ..... Y N U MCNC19

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the next CMF form.

D. STUDY MEDICATION

20 a. Was study medication temporarily discontinued during this event? Y N → **Go to Item 21** MCN16

b. How many days was study medication discontinued? ..... | | MCN17

E. RESOURCE UTILIZATION

Note to Coordinator: If this form is being completed at the time of an event, questions 18 and 19 will need to be completed as a follow-up.

21. a. Did a parent or caregiver miss work due to this illness/event? ..... Y N → **Go to Item 22** MCN18A

b. Total number of days work missed by all caregivers: ..... | | MCN18B

22. a. Did alternative child care arrangements have to be made during this illness/event? ..... Y N → **Go to Item 23** MCN19A

b. Total number of days alternate care arrangements needed: ..... | | MCN19B

F. ADMINSTRATIVE INFORMATION

23. **[PC]** Date of form (mm/dd/yyyy):..... | | / | | / | | | | | MCN20

24. **[PC]** Method of data collection *(circle one)*:

Computer C
Paper..... P

MCN21

25. **[PC]** Interviewer's or Examiner's initials: ..... | | | BLIND_STAFF_ID

MEDICAL CARE NOTIFICATION FORM

Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:								FORM CODE: MCN VERSION: B 8/13/07	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *Complete this form for all medical care reported/received since the last study contact, including in-clinic RIVUR sick visits. Each MCN form will also have a corresponding MCA form once medical records have been received. Forms are linked with an assigned MCID number.*

A. MEDICAL CARE INFORMATION

1. **[PC]** Assigned MCID number: ..... ☐☐☐☐☐☐☐ MCN1

2. Date of medical care visit (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCN2

Provider name: _____ **[no data entry]**

Provider address/contact information: _____ **[no data entry]**

_____

_____

3a. **[PC]** Provider of care *(circle one)*: MCN3A

RIVUR Clinic ..... A
Other clinic or health care center ..... B
A private doctor's office C
Hospital Outpatient Department ..... D
Emergency room in a hospital ..... E
Hospital ..... F
Other location ..... G

3b. If other, please specify: _____ MCN3B

4. Was urine collected at this medical visit? ..... Y N → **Go to 6** MCN4

5. Were you informed that a urinary tract infection was/is suspected or diagnosed during this medical visit? ..... Y N MCN5

6 Was this a well-child visit (with no current symptoms, no specimens, and no medication prescribed)? ..... Y→ **Go to 20** N MCN6

7. During this visit, did your child get referred to another physician or specialist? ..... Y N MCN7

(**Note:** if 'Y', record MD name: _____
this will require another MCN)

8. **[PC]** Does the illness or reason for sick visit fit the definition for an adverse event? ..... Y→**Complete AEF** N MCN8

B. HISTORY OF FEVER

9. Did your child have a fever during his/her illness? ..... Y N → **Go to 15** MCN9

10. a. Highest temperature reported: ..... | | | | . | | MCN10A

b. Units *(circle one)*:

˚F ..... F
˚C C

MCN10B

11. Date of highest temperature (mm/dd/yyyy): ..... | | / | | / | | | | MCN11

12. Time of highest temperature (24 hr): ..... | | | | MCN12

13. Temperature measurement route *(circle one)*: MCN13

Oral ..... O
Axillary ..... A
Tympanic ..... T
Rectal ..... R
Unknown ..... U

MCNB14A

14 a. Date fever started? ..... | | / | | / | | | |

b. Duration of fever (hrs): ..... | | | MCN14

C. HISTORY OF SYMPTOMS

15. Did the child have any of the following symptoms?	Yes	No	Unknown	Not Apply	
a. Suprapubic, abdominal, or flank pain or tenderness	Y	N	U		MCN15A
b. Urinary urgency, frequency, hesitancy	Y	N	U		MCN15B
c. Dysuria	Y	N	U		MCN15C
d. Foul smelling urine	Y	N	U		MCN15D
e. Failure to thrive (<= 4 months old)	Y	N	U	X	MCN15E
f Dehydration (<= 4 months old)	Y	N	U	X	MCN15F
g. Hypothermia (<= 4 months old)	Y	N	U	X	MCN15G

16 a. Date symptoms started: ..... | | / | | / | | | | MCNB16A

b. Duration of symptoms (days): ..... | | MCNB16B

D. STUDY MEDICATION

17 a. Was study medication temporarily discontinued during this event? Y N MCN16

. b. How many days was study medication discontinued? ..... | | MCN17

E. RESOURCE UTILIZATION

Note to Coordinator: If this form is being completed at the time of an event, questions 18 and 19 will need to be completed as a follow-up.

18. a. Did a parent or caregiver miss work due to this illness/event? ..... Y N → **Go to Item 19** MCN18A

b. Total number of days work missed by all caregivers: ..... | | MCN18B

19. a. Did alternative child care arrangements have to be made during this illness/event? ..... Y N → **Go to Item 20** MCN19A

b. Total number of days alternate care arrangements needed: ..... | | MCN19B

F. ADMINSTRATIVE INFORMATION

20. **[PC]** Date of form (mm/dd/yyyy): ..... | |/| |/| | | | | MCN20

21. **[PC]** Method of data collection *(circle one)*:
Computer C
Paper ..... P
MCN21

22. **[PC]** Interviewer's or Examiner's initials: ..... | | | BLIND_STAFF_ID

MEDICAL CARE NOTIFICATION FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: MCN
VERSION: A 11/17/06

Contact Occasion ☐☐ SEQ # ☐☐

Participant Name: _____

Instructions: *Complete this form for all medical care reported/received since the last study contact, including in-clinic RIVUR sick visits. Each MCN form will also have a corresponding MCA form once medical records have been received. Forms are linked with an assigned MCID number.*

A. MEDICAL CARE INFORMATION

1. **[PC]** Assigned MCID number: ..... ☐☐☐☐☐☐☐ MCN1

2. Date of medical care visit (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ MCN2

   Provider name: _____ **[no data entry]**

   Provider address/contact information: _____ **[no data entry]**

   _____

   _____

3a. **[PC]** Provider of care *(circle one)*: MCN3A

- RIVUR Clinic ..... A
- Other clinic or health care center ..... B
- A private doctor's office C
- Hospital Outpatient Department ..... D
- Emergency room in a hospital ..... E
- Hospital ..... F
- Other location ..... G

3b. If other, please specify: _____ MCN3B

4. Was urine collected at this medical visit? ..... Y N → **Go to 6** MCN4

5. Were you informed that a urinary tract infection was/is suspected or diagnosed during this medical visit? ..... Y N MCN5

6 Was this a well-child visit? ..... Y→ **Go to 20** N MCN6

7. During this visit, did your child get referred to another physician or specialist? ..... Y N MCN7

   (**Note:** if 'Y', record MD name: _____
   this will require another MCN)

8. **[PC]** Does the illness or reason for sick visit fit the definition for an adverse event? ..... Y→**Complete AEF** N MCN8

B. HISTORY OF FEVER

9. Did the child have a fever? ..... Y N → **Go to 15** MCN9

10. a. Highest temperature reported?: ..... | | | | . | | MCN10A

b. Units *(circle one)*:

˚F ..... F
˚C C
MCN10B

11. Date of highest temperature (mm/dd/yyyy): ..... | | / | | / | | | | MCN11

12. Time of highest temperature (24 hr): ..... | | | | MCN12

13. Temperature measurement route *(circle one)*: MCN13

Oral ..... O
Axillary ..... A
Tympanic ..... T
Rectal ..... R
Unknown ..... U

14. Duration of fever (hrs): ..... | | | MCN14

C. HISTORY OF SYMPTOMS

15. Did the child have any of the following symptoms?	Yes	No	Unknown	Not Apply	
a. Suprapubic, abdominal, or flank pain or tenderness	Y	N	U		MCN15A
b. Urinary urgency, frequency, hesitancy	Y	N	U		MCN15B
c. Dysuria	Y	N	U		MCN15C
d. Foul smelling urine	Y	N	U		MCN15D
e. Failure to thrive (<= 4 months old)	Y	N	U	X	MCN15E
f Dehydration (<= 4 months old)	Y	N	U	X	MCN15F
g. Hypothermia (<= 4 months old)	Y	N	U	X	MCN15G

D. STUDY MEDICATION

16. Was study medication temporarily discontinued during this event? .... Y N MCN16

17. How many days was study medication discontinued? ..... | | MCN17

E. RESOURCE UTILIZATION

Note to Coordinator: If this form is being completed at the time of an event, questions 18 and 19 will need to be completed as a follow-up.

18. a. Did a parent or caregiver miss work due to this illness/event?..... Y N → **Go to Item 19** MCN18A

    b. Total number of days work missed by all caregivers: ..... | | MCN18B

19. a. Did alternative child care arrangements have to be made during this illness/event?..... Y N → **Go to Item 20** MCN19A

    b. Total number of days alternate care arrangements needed: ..... | | MCN19B

F. ADMINSTRATIVE INFORMATION

20. **[PC]** Date of form (mm/dd/yyyy):..... | |/| |/| | | | | MCN20

21. **[PC]** Method of data collection *(circle one)*:
    Computer C
    Paper..... P
    MCN21

22. **[PC]** Interviewer's or Examiner's initials: ..... | | | BLIND_STAFF_ID

MEDICATION DISPENSING AND DOSING FORM

RMUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: MDD
VERSION: B 05/11/10

Contact Occasion [ ][ ] SEQ # [ ][ ]

Participant Name: _____

Instructions: *This form is to be completed any time that study drug is dispensed to patient.*

A. TIMING OF MEDICATION DISPENSING

1. **[PC]** Why is medication being dispensed today?

Unscheduled contact ..... U

Protocol-scheduled clinic visit (randomization or follow-up) ..... S → **Go to Item 9**

MDD1

B. UNSCHEDULED CONTACT

2. How many months supply of medication is needed before the next clinic follow-up visit? ..... [ ] MDD2

3. **[PC]** What type of visit is occurring today (*circle one)?*

Telephone ..... T

Clinic ..... C → **Go to Item 9**

MDD3

C. TELEPHONE CONTACT

NOTE: The dose should remain constant for 6 months at most. If more than 6 months will elapse between the last measured weight and the next clinic visit, then adjust the child's weight by either asking the parents for the last known weight of the child and/or estimate the child's weight from the 2000 CDC Growth Curves (Advance Data No. 314 Dec 4, 2000).

4. **[PC]** a. What is the child's last known weight? ..... [ ][ ][ ].[ ] MDD4A

b. Units *(circle one)*: Kilograms ..... K
Pounds ..... P

MDD4B

5. **[PC]** What is the date this weight was measured? ..... [ ][ ]/[ ][ ]/[ ][ ][ ][ ] MDD5

6. **[PC]** Is the time between the last weight measurement and the next clinic visit going to exceed 6 months? ..... Y N → **Go to Item 10**

MDD6

7. a. What is the child's current weight? ..... [ ][ ][ ].[ ] MDD7A

b. Units *(circle one)*: Kilograms ..... K
Pounds ..... P

MDD7B

8. **[PC]** Where was this weight measured (*circle one*)?

Parent measured ..... P → **Go to Item 10**

Estimated from CDC Growth Curve ..... G → **Go to Item 10**

MDD8

ID NUMBER:								FORM CODE: MDD VERSION: B 05/11/10	Contact Occasion		SEQ #	

D. CLINIC CONTACT

9. **[PC]** a. What was the child's weight measured today? ..... ___.___ MDD9A

b. Units *(circle one)*: Kilograms ..... K
Pounds ..... P MDD9B

E. DISPENSING

Instruction: Entry of a 'Y' into the DMS for Item 10 will automatically run the medication dispensing and dosing program, providing you with the bottle numbers to dispense, and the dosing instructions appropriate for the child's weight.

10. Are you ready for medication bottle numbers and dosing?..... Y N MDD10

11. **[Provided by DMS]** Dose (mL/day): ..... ___.___ MDD11

12. **[Provided by DMS]** How many bottles are being dispensed? ..... ___ MDD12

13. **[Provided by DMS]** Bottles to Distribute: .....

a. ______ MDD13A
b. ______ MDD13B
c. ______ MDD13C
d. ______ MDD13D
e. ______ MDD13E
f. ______ MDD13F
g. ______ MDDB13G
h. ______ MDDB13H
i. ______ MDDB13I

F. ADMINSTRATIVE INFORMATION

14. Date of drug distribution (mm/dd/yyyy): ..... __/__/____ MDD14

15. Method of data collection *(circle one)*:
Computer C
Paper..... P MDD15

16. Recorders initials: ..... ___ BLIND_STAFF_ID

MEDICATION DISPENSING AND DOSING FORM

RMUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: MDD
VERSION: A 06/29/07

Contact Occasion [ ][ ] SEQ # [ ][ ]

Participant Name: _____

Instructions: *This form is to be completed any time that study drug is dispensed to patient.*

A. TIMING OF MEDICATION DISPENSING

1. **[PC]** Why is medication being dispensed today?

Unscheduled contact ..... U

Protocol-scheduled clinic visit (randomization or follow-up) ..... S → **Go to Item 9**

MDD1

B. UNSCHEDULED CONTACT

2. How many months supply of medication is needed before the next clinic follow-up visit? ..... [ ] MDD2

3. **[PC]** What type of visit is occurring today (*circle one)?*

Telephone ..... T

Clinic ..... C → **Go to Item 9**

MDD3

C. TELEPHONE CONTACT

NOTE: The dose should remain constant for 6 months at most. If more than 6 months will elapse between the last measured weight and the next clinic visit, then adjust the child's weight by either asking the parents for the last known weight of the child and/or estimate the child's weight from the 2000 CDC Growth Curves (Advance Data No. 314 Dec 4, 2000).

4. **[PC]** a. What is the child's last known weight? ..... [ ][ ][ ].[ ] MDD4A

b. Units *(circle one)*: Kilograms ..... K
Pounds ..... P

MDD4B

5. **[PC]** What is the date this weight was measured? ..... [ ][ ]/[ ][ ]/[ ][ ][ ][ ] MDD5

6. **[PC]** Is the time between the last weight measurement and the next clinic visit going to exceed 6 months? ..... Y N → **Go to Item 10** MDD6

7. a. What is the child's current weight? ..... [ ][ ][ ].[ ] MDD7A

b. Units *(circle one)*: Kilograms ..... K
Pounds ..... P

MDD7B

8. **[PC]** Where was this weight measured (*circle one*)?

Parent measured ..... P → **Go to Item 10**

Estimated from CDC Growth Curve ..... G → **Go to Item 10**

MDD8

ID NUMBER:							

FORM CODE: MDD
VERSION: A 06/29/07

Contact Occasion | | SEQ # | |

D. CLINIC CONTACT

9. **[PC]** a. What was the child's weight measured today? ..... ___.___ MDD9A

b. Units *(circle one)*: Kilograms ..... K
Pounds ..... P MDD9B

E. DISPENSING

Instruction: Entry of a 'Y' into the DMS for Item 10 will automatically run the medication dispensing and dosing program, providing you with the bottle numbers to dispense, and the dosing instructions appropriate for the child's weight.

10. Are you ready for medication bottle numbers and dosing?..... Y N MDD10

11. **[Provided by DMS]** Dose (mL/day): ..... ___.___ MDD11

12. **[Provided by DMS]** How many bottles are being dispensed? ..... ___ MDD12

13. **[Provided by DMS]** Bottles to Distribute: .....
a. ______ MDD13A
b. ______ MDD13B
c. ______ MDD13C
d. ______ MDD13D
e. ______ MDD13E
f. ______ MDD13F

F. ADMINSTRATIVE INFORMATION

14. Date of drug distribution (mm/dd/yyyy): ..... __/__/____ MDD14

15. Method of data collection *(circle one)*:
Computer C
Paper..... P MDD15

16. Recorders initials: ..... ___ BLIND_STAFF_ID

MEDICATION RETURN FORM

Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER: | | | | | | | |

FORM CODE: MRF
VERSION: A 01/08/07

Contact Occasion | |

SEQ # | |

Participant Name: _____

Instructions: *This form is to be completed any time that study drug is returned from the participant or to report lost bottles.*

A. ADMINSTRATIVE INFORMATION

1. Date of drug return (mm/dd/yyyy): ..... | | / | | / | | | | | MRFA1

2. Method of data collection *(circle one)*:
   - Computer C
   - Paper ..... P

   MRFA2

3. Recorders initials: ..... | | | BLIND_STAFF_ID

B. MEDICATION BOTTLE LOST OR RETURNED

4. Have you lost any bottles of medication? ..... Y N→**Go to Item 5** MRFA4

   a. If 'Y', how many bottles have been lost? ..... | | MRFA4A

5. How many bottles were returned? ..... | | MRFA5

6. Returned Bottles

	1. Bottle Number		2. Sealed		3. Weight (grams)	
a. Bottle 1:		MRFA6A1	Y→**Next line** N	MRFA6A2		MRFA6A3
b. Bottle 2:		MRFA6B1	Y→**Next line** N	MRFA6B2		MRFA6B3
c. Bottle 3:		MRFA6C1	Y→**Next line** N	MRFA6C2		MRFA6C3
d. Bottle 4:		MRFA6D1	Y→**Next line** N	MRFA6D2		MRFA6D3
e. Bottle 5:		MRFA6E1	Y→**Next line** N	MRFA6E2		MRFA6E3
f. Bottle 6:		MRFA6F1	Y→**Next line** N	MRFA6F2		MRFA6F3
g. Bottle 7:		MRFA6G1	Y→**Next line** N	MRFA6G2		MRFA6G3
h. Bottle 8:		MRFA6H1	Y→**Next line** N	MRFA6H2		MRFA6H3
i. Bottle 9:		MRFA6I1	Y→**Next line** N	MRFA6I2		MRFA6I3
j. Bottle 10:		MRFA6J1	Y→**Next line** N	MRFA6J2		MRFA6J3
k. Bottle 11:		MRFA6K1	Y→**Next line** N	MRFA6K2		MRFA6K3

ID NUMBER:							

FORM CODE: MRF
VERSION: A 01/08/07

Contact Occasion | | | SEQ # | |

l. Bottle 12: ..... | | | | | MRFA6L1 | Y→**Next line** | MRFA6L2 | N | | | | MRFA6L3 .

m. Bottle 13: ..... | | | | | MRFA6M1 | Y→**Next line** | MRFA6M2 | N | | | | MRFA6M3 .

n. Bottle 14: ..... | | | | | MRFA6N1 | Y→**Exit form** | MRFA6N2 | N | | | | MRFA6N3 .

12 or bottles were never distributed to a participant, therefor variables MRFAL1, MRFAL2, MRFAL3, MRFAM1, MRFAM2, MRFAM3, MRFAN1, MRFAN2, MRFAN3 are not included in the closed NIDDK dataset

PHYSICAL EXAM FORM

ID NUMBER: | | | | | | | |

FORM CODE: PEF
VERSION: B 09/18/12

Contact Occasion | | |

SEQ # | |

Participant Name: _____

Instructions: *This form should be completed at baseline and during all protocol-scheduled clinic follow-up visits.*

A. PHYSICAL EXAM

1. Has your child been circumcised? *(Circle one):* PEF1
   - Male, circumcised C
   - Male, uncircumcised ..... U → **Go to Item 4**
   - Male, circumcision reported at earlier contact occasion ..... R → **Go to Item 4**
   - Female ..... F → **Go to Item 4**

2. Date of circumcision (mm/dd/yyyy): ..... | | / | | / | | | | | PEF2

3. How old was the child when he was circumcised (months)? ..... | | PEF3

4. a. Temperature: ..... | | | . | PEF4A
   b. Units *(circle one)*:
   - ˚F ..... F PEF4B
   - ˚C C

5. Temperature measurement route *(circle one)*: PEF5
   - Oral ..... O
   - Axillary ..... A
   - Tympanic ..... T
   - Rectal ..... R
   - Temporal ..... F
   - Unknown ..... U

6. Is the child showing any of the following during the abdominal examination today?
   - a. Suprapubic pain or tenderness ..... Y N PEF6A
   - b. Abdominal pain or tenderness ..... Y N PEF6B
   - c. Flank pain or tenderness ..... Y N PEF6C

7. Is the child experiencing dysuria today? ..... Y N PEF7

8. Does the child have foul-smelling urine today? ..... Y N PEF8

9. a. Systolic blood pressure (mm Hg): ..... | | | PEF9A
   b. Diastolic blood pressure (mm Hg): ..... | | | PEF9B

10. a. Weight: ..... | | | | . | | PEF10A

b. Weight units *(circle one)*:
Kilograms ..... K
Pounds ..... P
PEF10B

11. a. Length / Height: ..... | | | | . | | PEF11A

b. Units *(circle one)*:
Centimeters C
Inches I
PEF11B

B. ADMINISTRATIVE INFORMATION

12. Date of physical exam (mm/dd/yyyy): ..... | | / | | / | | | | PEF12

13. Method of data collection *(circle one)*:
Computer C
Paper ..... P
PEF13

14. Examiner's initials: ..... | | | BLIND_EXAM_ID

15. Recorder's initials: ..... | | | BLIND_STAFF_ID

PHYSICAL EXAM FORM

RMUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: PEF
VERSION: A 03/30/07

Contact Occasion | | | SEQ # | | |

Participant Name: _____

Instructions: *This form should be completed at baseline and during all protocol-scheduled clinic follow-up visits.*

A. PHYSICAL EXAM

1. Has your child been circumcised? *(Circle one):*
   - Male, circumcised C
   - Male, uncircumcised ..... U → **Go to Item 4** PEF1
   - Male, circumcision reported at earlier contact occasion ..... R → **Go to Item 4**
   - Female ..... F → **Go to Item 4**

2. Date of circumcision (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ PEF2

3. How old was the child when he was circumcised (months)? ..... ☐☐ PEF3

4. a. Temperature: ..... ☐☐☐.☐ PEF4A

   b. Units *(circle one)*:
   - ˚F ..... F
   - ˚C C

   PEF4B

5. Temperature measurement route *(circle one)*:
   - Oral ..... O
   - Axillary ..... A
   - Tympanic ..... T
   - Rectal ..... R

   PEF5

6. Is the child showing any of the following during the abdominal examination today?
   - a. Suprapubic pain or tenderness ..... Y N PEF6A
   - b. Abdominal pain or tenderness ..... Y N PEF6B
   - c. Flank pain or tenderness ..... Y N PEF6C

7. Is the child experiencing dysuria today? ..... Y N PEF7

8. Does the child have foul-smelling urine today? ..... Y N PEF8

9. a. Systolic blood pressure (mm Hg): ..... ☐☐☐ PEF9A

   b. Diastolic blood pressure (mm Hg): ..... ☐☐☐ PEF9B

10. a. Weight: ..... ☐☐☐.☐ PEF10A

b. Weight units *(circle one)*:
Kilograms ..... K
Pounds ..... P
PEF10B

11. a. Length / Height: ..... | | | | . | |
PEF11A

b. Units *(circle one)*:
Centimeters C
Inches I
PEF11B

B. ADMINISTRATIVE INFORMATION

12. Date of physical exam (mm/dd/yyyy): ..... | | / | | / | | | | |
PEF12

13. Method of data collection *(circle one)*:
Computer C
Paper ..... P
PEF13

14. Examiner's initials: ..... | | |
PEF14

15. Recorder's initials: ..... | | |
PEF15

Participant Screening Log

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

SiteID:			0	0	0	0	0

FORM CODE: PSL
VERSION: B 06/20/08

Contact Occasion: ____

SEQ #: ____

Instructions:
- *Record final eligibility disposition of all children who were considered and screened for the RIVUR study.*
- *Include children with (any) UTI for whom some effort occurred to assess eligibility.*
- *Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.*

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7b. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11b. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	PSL7A-B	PSL8	PSL9	PSL10	PSL11A-B	__ __/__ __ /20 PSL12 __ __
02						__ __				__ __	__ __/__ __ /20 __ __
03						__ __				__ __	__ __/__ __ /20 __ __
04						__ __				__ __	__ __/__ __ /20 __ __
05						__ __				__ __	__ __/__ __ /20 __ __
06						__ __				__ __	__ __/__ __ /20 __ __
07						__ __				__ __	__ __/__ __ /20 __ __
08						__ __				__ __	__ __/__ __ /20 __ __
09						__ __				__ __	__ __/__ __ /20 __ __
10						__ __				__ __	__ __/__ __ /20 __ __

Entry Codes

2. Referral Source:
A = ED
B = Labs
C = PCP
D = Inpatient
E = Urology
F = Radiology
G = Other (notelog)

4. Race codes
A = Black or AA
B = White
C = Asian
D = Hawaiian/Pacific Islander
E = Am. Indian/Alaska Native
F = Other or Mixed (notelog)
G = Unknown/Refused

5. Ethnicity codes
A = Hispanic / Latino
B = Not Hispanic / Latino
C = Unknown/Refused

7. If not Protocol UTI, why?
A = Not 1st or 2nd UTI
B = Timing
C = Bagged Spec
D = No UA Or Uricult done
E = No pyuria
F = Ins. growth
G = Mult. Org.
H = No fever/Sx
I = Other (notelog)

8. VCUG Result
A = Not Done
B = No result
C = No VUR
D = Timing
E = Grade 1-IV
F = Grade V

9. Other Exclusions
A = None
B = Sulfatrim allergy
C = Prematurity
D = Anomaly/Syndromes
E = Chronic condition
F= Renal dis./injury
G = Can't follow
H = Other (add notelog)

11. If not Enrolled, why?
A= Ineligible
B = Refused
C=Refused - Wants bx
D = Refused - doesn't Want abx
E = Refuse DMSA
F = Other (add notelog)

Participant Screening Log

SiteID:			0	0	0	0	0

FORM CODE: PSL
VERSION: B 06/20/08

Contact Occasion | | |

SEQ # | |

Instructions:
- *Record final eligibility disposition of all children who were considered and screened for the RIVUR study.*
- *Include children with (any) UTI for whom some effort occurred to assess eligibility.*
- *Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.*

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7b. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11b. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	PSL7A-B	PSL8	PSL9	PSL10	PSL11A-B	__ __PSL12/20 __ __
12						__ __				__ __	__ __/__ __ /20 __ __
13						__ __				__ __	__ __/__ __ /20 __ __
14						__ __				__ __	__ __/__ __ /20 __ __
15						__ __				__ __	__ __/__ __ /20 __ __
16						__ __				__ __	__ __/__ __ /20 __ __
17						__ __				__ __	__ __/__ __ /20 __ __
18						__ __				__ __	__ __/__ __ /20 __ __
19						__ __				__ __	__ __/__ __ /20 __ __
20						__ __				__ __	__ __/__ __ /20 __ __

Entry Codes

2. Referral Source:
A = ED
B = Labs
C = PCP
D = Inpatient
E = Urology
F = Radiology
G = Other (notelog)

4. Race codes
A = Black or AA
B = White
C = Asian
D = Hawaiian/Pacific Islander
E = Am. Indian/Alaska Native
F = Other or Mixed (notelog)
G = Unknown/Refused

5. Ethnicity codes
A = Hispanic / Latino
B = Not Hispanic / Latino
C = Unknown/Refused

7. If not Protocol UTI, why? 8.
A = Not 1st or 2nd UTI
B = Timing
C = Bagged Spec
D = No UA Or Uricult done
E = No pyuria
F = Ins. growth
G = Mult. Org.
H = No fever/Sx
I = Other (notelog)

VCUG Result
A = Not Done
B = No result
C = No VUR
D = Timing
E = Grade 1-IV
F = Grade V

9. Other Exclusions
A = None
B = Sulfatrim allergy
C = Prematurity
D = Anomaly/Syndromes
E = Chronic condition
F= Renal dis./injury
G = Can't follow
H = Other (add notelog)

11. If not Enrolled, why?
A= Ineligible
B = Refused
C=Refused - Wants bx
D = Refused - doesn't Want abx
E = Refuse DMSA
F = Other (add notelog)

Participant Screening Log

SiteID:			0	0	0	0	0

FORM CODE: PSL
VERSION: B 06/20/08

Contact Occasion: ____

SEQ #: ____

Instructions:
- *Record final eligibility disposition of all children who were considered and screened for the RIVUR study.*
- *Include children with (any) UTI for whom some effort occurred to assess eligibility.*
- *Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.*

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7b. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11b. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	PSL7A-B	PSL8	PSL9	PSL10	PSL11A-B	__ __/__PSL12__ __
22						__ __				__ __	__ __/__ __ /20 __ __
23						__ __				__ __	__ __/__ __ /20 __ __
24						__ __				__ __	__ __/__ __ /20 __ __
25						__ __				__ __	__ __/__ __ /20 __ __
26						__ __				__ __	__ __/__ __ /20 __ __
27						__ __				__ __	__ __/__ __ /20 __ __
28						__ __				__ __	__ __/__ __ /20 __ __
29						__ __				__ __	__ __/__ __ /20 __ __
30						__ __				__ __	__ __/__ __ /20 __ __

Entry Codes

2. Referral Source:
A = ED
B = Labs
C = PCP
D = Inpatient
E = Urology
F = Radiology
G = Other (notelog)

4. Race codes
A = Black or AA
B = White
C = Asian
D = Hawaiian/Pacific Islander
E = Am. Indian/Alaska Native
F = Other or Mixed (notelog)
G = Unknown/Refused

5. Ethnicity codes
A = Hispanic / Latino
B = Not Hispanic / Latino
C = Unknown/Refused

7. If not Protocol UTI, why? 8.
A = Not 1st or 2nd UTI
B = Timing
C = Bagged Spec
D = No UA Or Uricult done
E = No pyuria
F = Ins. growth
G = Mult. Org.
H = No fever/Sx
I = Other (notelog)

VCUG Result
A = Not Done
B = No result
C = No VUR
D = Timing
E = Grade 1-IV
F = Grade V

9. Other Exclusions
A = None
B = Sulfatrim allergy
C = Prematurity
D = Anomaly/Syndromes
E = Chronic condition
F= Renal dis./injury
G = Can't follow
H = Other (add notelog)

11. If not Enrolled, why?
A= Ineligible
B = Refused
C=Refused - Wants bx
D = Refused - doesn't Want abx
E = Refuse DMSA
F = Other (add notelog)

Participant Screening Log

SiteID:			0	0	0	0	0

FORM CODE: PSL
VERSION: A 11/29/07

Contact Occasion: ____

SEQ #: ____

Instructions:
- *Record final eligibility disposition of all children who were considered and screened for the RIVUR study.*
- *Include children with (any) UTI for whom some effort occurred to assess eligibility.*
- *Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.*

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7e. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11e. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	__ PSL7A-E __	PSL8	PSL9	PSL10	__ PSL11A-E __	__ __ PSL12 '20 __ __
02						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
03						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
04						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
05						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
06						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
07						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
08						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
09						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
10						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __

Entry Codes

Referral Source:
1 = ED
2 = Labs
3 = PCP
4 = Inpatient
5 = Urology
6 = Radiology
7 = Other (notelog)

Race codes
1 = Black or AA
2 = White
3 = Asian
4 = Hawaiian/Pacific Islander
5 = Am. Indian/Alaska Native
6 = Other or Mixed (notelog)
7 = Unknown/Refused

Ethnicity codes
1 = Hispanic / Latino
2 = Not Hispanic / Latino
3 = Unknown/Refused

If not Protocol UTI, why?
1 = Not 1st UTI
2 = Timing
3 = Bagged
4 = No UA
5 = No pyuria
6 = Ins. growth
7 = Mult. Org.
8 = No fever/Sx
9 = Uricult
10 = Other (notelog)

VCUG Result
1 = Not Done
2 = No result
3 = No VUR
4 = Timing
5 = Grade 1-IV
6 = Grade V

Other Exclusions
1 = None
2 = Sulfatrim allergy
3 = Prematurity
4 = Anomaly/Syndromes
5 = Chronic condition
6 = Renal dis./injury
7 = Other (add notelog)

If not Enrolled, why?
1= Ineligible
2 = Wants abx
3 = Doesn't want abx
4 = Refuse DMSA
5 = Can't Follow
6 = Other (add notelog)

Participant Screening Log

SiteID:			0	0	0	0	0

FORM CODE: PSL
VERSION: A 11/29/07

Contact Occasion: ____

SEQ #: ____

Instructions:
- *Record final eligibility disposition of all children who were considered and screened for the RIVUR study.*
- *Include children with (any) UTI for whom some effort occurred to assess eligibility.*
- *Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.*

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7e. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11e. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	__ __ __ __ __ PSL7A-E	PSL8	PSL9	PSL10	__ __ __ __ __ PSL11A-E	__ __/__ __ /20 __ __ PSL12
12						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
13						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
14						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
15						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
16						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
17						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
18						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
19						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __
20						__ __ __ __ __				__ __ __ __ __	__ __/__ __ /20 __ __

Entry Codes

Referral Source:
1 = ED
2 = Labs
3 = PCP
4 = Inpatient
5 = Urology
6 = Radiology
7 = Other (notelog)

Race codes
1 = Black or AA
2 = White
3 = Asian
4 = Hawaiian/Pacific Islander
5 = Am. Indian/Alaska Native
6 = Other or Mixed (notelog)
7 = Unknown/Refused

Ethnicity codes
1 = Hispanic / Latino
2 = Not Hispanic / Latino
3 = Unknown/Refused

If not Protocol UTI, why?
1 = Not 1st UTI
2 = Timing
3 = Bagged
4 = No UA
5 = No pyuria
6 = Ins. growth
7 = Mult. Org.
8 = No fever/Sx
9 = Uricult
10 = Other (notelog)

VCUG Result
1 = Not Done
2 = No result
3 = No VUR
4 = Timing
5 = Grade 1-IV
6 = Grade V

Other Exclusions
1 = None
2 = Sulfatrim allergy
3 = Prematurity
4 = Anomaly/Syndromes
5 = Chronic condition
6 = Renal dis./injury
7 = Other (add notelog)

If not Enrolled, why?
1= Ineligible
2 = Wants abx
3 = Doesn't want abx
4 = Refuse DMSA
5 = Can't Follow
6 = Other (add notelog)

Participant Screening Log

SiteID:			0	0	0	0	0

FORM CODE: PSL
VERSION: A 11/29/07

Contact Occasion | | | SEQ # | |

Instructions:
- *Record final eligibility disposition of all children who were considered and screened for the RIVUR study.*
- *Include children with (any) UTI for whom some effort occurred to assess eligibility.*
- *Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.*

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7e. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11e. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	PSL7A-E	PSL8	PSL9	PSL10	PSL11A-E	PSL12 /20
22											/20
23											/20
24											/20
25											/20
26											/20
27											/20
28											/20
29											/20
30											/20

Entry Codes

Referral Source:
1 = ED
2 = Labs
3 = PCP
4 = Inpatient
5 = Urology
6 = Radiology
7 = Other (notelog)

Race codes
1 = Black or AA
2 = White
3 = Asian
4 = Hawaiian/Pacific Islander
5 = Am. Indian/Alaska Native
6 = Other or Mixed (notelog)
7 = Unknown/Refused

Ethnicity codes
1 = Hispanic / Latino
2 = Not Hispanic / Latino
3 = Unknown/Refused

If not Protocol UTI, why?
1 = Not 1st UTI
2 = Timing
3 = Bagged
4 = No UA
5 = No pyuria
6 = Ins. growth
7 = Mult. Org.
8 = No fever/Sx
9 = Uricult
10 = Other (notelog)

VCUG Result
1 = Not Done
2 = No result
3 = No VUR
4 = Timing
5 = Grade 1-IV
6 = Grade V

Other Exclusions
1 = None
2 = Sulfatrim allergy
3 = Prematurity
4 = Anomaly/Syndromes
5 = Chronic condition
6 = Renal dis./injury
7 = Other (add notelog)

If not Enrolled, why?
1= Ineligible
2 = Wants abx
3 = Doesn't want abx
4 = Refuse DMSA
5 = Can't Follow
6 = Other (add notelog)

RIVUR
Randomized Intervention for Children with Vesicoureteral Reflux

Dear Parent, thank you for your participation in the RIVUR study. We have been trying to contact you, but have not been able to reach you. We would appreciate your help by answering the 10 questions below about your child's health and mailing them back as soon as possible. Thank you!

0. Date form mailed to participant RFFA0

00. Staff member who mailed questionnaire BLIND_STAFF_ID

1. Today's Date: _____ RFFA1

2. Please circle who is completing this form *(circle one)*: **Mother** **Father** **Legal guardian** **Other**_____ RFFA2

3. Date of your child's last RIVUR contact was _____ RFFA3.

4. Since your child's last RIVUR contact, do you feel your child has had any side effects that are possibly due to taking the study medication? **No** **Yes** RFFA4

   If yes, please describe the side effects:

5. Since the last RIVUR study contact, has your child had urine collected for medical testing? **No** **Yes** RFFA5

6. Since the last RIVUR study contact, has your child **received medical care** for :

a.	fever	**No** **Yes**	RFFA6A
b.	rash	**No** **Yes**	RFFA6B
c.	abdominal or lower back pain	**No** **Yes**	RFFA6C
d.	diarrhea or loose stools	**No** **Yes**	RFFA6D
e.	urinary urgency, painful urination, or foul-smelling urine	**No** **Yes**	RFFA6E
f.	urinary tract infection	**No** **Yes**	RFFA6F

7. Since the last RIVUR contact how many times has your child received medical care **for any of the reasons listed above**? _RFFA7

8. If your child did receive medical care please fill out the form below

Date of medical care	**Reason**	**Medical Care Provider Name or Place of Treatment**
RFFA8A1 _____	RFFA8A2 _____	RFFA8A3 _____
RFFA8B1 _____	RFFA8B2 _____	RFFA8B3 _____
RFFA8C1 _____	RFFA8C2 _____	RFFA8C3 _____

9. Sometimes medication is missed. How often did your child miss a dose of the RIVUR medication during the past week (seven days)? *(circle one)* RFFA9
   Never
   1-2 times
   3-4 times
   > 4 times
   Don't know

10. Is your child out of study medication? **No** **Yes** RFFA10

Thank You!! _____**(RIVUR Study Coordinator)**

For office use only:

ID NUMBER:								Contact Occasion		SEQ #		

Form Code: RFF
Version: A 08/30/10

Rectal Swab Results Form

ID NUMBER: | | | | | | | |

FORM CODE: RSR
VERSION: C 2/19/08

Contact Occasion | |

SEQ # | |

Versions A and B of this form were never used

Participant Name: _____

Line Number | |

Instructions: *Central lab completes this form at baseline, end of study, and as needed in case of treatment failure (as determined by the Endpoints Committee).*

A. E COLI (LACTOSE POSITIVE AND INDOLE POSITIVE COLONIES ON MACONKEY AGAR)

1. a. Date rectal swab was received in central lab (mm/dd/yyyy): ..... | | / | | / | | | | | RSRC1A

   b. Date rectal swab planted by central lab personnel (mm/dd/yyyy): .. | | / | | / | | | | | RSRC1B

2. E Coli growth: RSRC2
   - Present ..... P
   - Absent ..... A → **Go to Item 11**

3. Density of E coli growth: RSRC3
   - 1+ ..... A
   - 2+ ..... B
   - 3+ C
   - 4+ ..... D

4. E coli growth on TMP-SMZ agar: RSRC4
   - Present ..... P
   - Absent ..... A

5. E coli growth on Ceftazidime agar: RSRC5
   - Present ..... P
   - Absent ..... A

6. E coli growth on Ciprofloxacin agar: RSRC6
   - Present ..... P
   - Absent ..... A → **If Items 4-6 all A, go to Item 11**

Instruction: *For items 7-9, please record (a.) the data type (see options below) and (b.) the E coli sensitivity:*

(a.) Data Type:
- = (equal to) ..... A
- > (greater than) ..... B
- ≥ (greater than or equal to) C
- < (less than) ..... D
- ≤ (less than or equal to) ..... E

RSR7CA RSRC7B

7. E coli sensitivities: TMP-SMZ E-test ..... a. | | b. | | | | . | | |

ID NUMBER:							

FORM CODE: RSR
VERSION: C 2/19/08

Contact Occasion | | SEQ # | |

Participant Name: _____ Line Number | |

RSRC8A RSRC8B

8. E coli sensitivities: Ceftazidime E-test ..... a. | | b. | | | | . | | | |

RSRC9A RSRC9B

9. E coli sensitivities: Ciprofloxacin E-test ..... a. | | b. | | | | . | | | |

10. ESBL production as determined by double disk synergy test:

Positive ..... P
Negative ..... N

RSRC10

B. ADMINISTRATIVE INFORMATION

11. Date of data collection (mm/dd/yyyy): ..... | | / | | / | | | | | RSRC11

12. Method of data collection *(circle one)*:

Computer C
Paper ..... P

RSRC12

13. Recorder's initials: ..... | | | BLIND_STAFF_ID

RIVUR
Randomized Intervention for Children with Vesicoureteral Reflux

Specimen Collection Form

ID NUMBER:							

FORM CODE: SCF
VERSION: A 04/11/07

Contact Occasion [ ][ ] SEQ # [ ][ ]

Participant Name: _____

Instructions: *Complete this form for collection of all protocol specified specimens, including blood, urine, and rectal swabs. If collection is for a QC specimen, record the QC ID provided by the DCC in the form header above.*

A. QC SPECIMEN

1. Is this a QC specimen collection? ..... Y N → **Go to Item 3** SCFA1
2. Record or attach the participant ID label ..... [ ][ ][ ][ ][ ][ ][ ] SCFA2

B. BLOOD SPECIMEN

3. Were blood specimens collected? ..... Y N → **Go to Item 9** SCFA3
   If no, specify reason_____
4. Date of blood specimen collection (mm/dd/yyyy): ..... [ ][ ]/[ ][ ]/[ ][ ][ ][ ] SCFA4
5. Time of blood draw *(24 hr clock)*: ..... [ ][ ]:[ ][ ] SCFA5
6. Total volume of blood drawn (mL): ..... [ ][ ].[ ] SCFA6
7. Phlebotomist initials: ..... [ ][ ][ ] BLIND_STAFF_ID7
8. Indicate blood specimens collected:
   a. Local lab CBC ..... Y N SCFA8A
      If no, specify reason_____
   b. Local lab metabolic/electrolyte analytes ..... Y N SCFA8B
      If no, specify reason_____
   c. Central lab serum ..... Y N → **Go to Item 8d** SCFA8C
      If no, specify reason _____
      c1. Ship date of central lab serum specimen (mm/dd/yyyy): ..... [ ][ ]/[ ][ ]/[ ][ ][ ][ ] SCFA8C1
   d. Repository blood collection: ..... Y N → **Go to Item 9** SCFA8D
      If no, specify reason _____
      d1. Repository whole blood specimen ..... Y N → **Go to Item 8d4** SCFA8D1
      If no, specify reason _____
      d2. Volume of repository whole blood (mL) ..... [ ].[ ] SCFA8D2
      d3. Ship date of repository blood specimen (mm/dd/yyyy): ..... [ ][ ]/[ ][ ]/[ ][ ][ ][ ] SCFA8D3

d4. Repository serum specimen ..... Y N → **Go to Item 9** SCFA8D4
If no, specify reason _____

d5. Volume of repository serum specimen (mL) ..... | | . | | SCFA8D5

d6. Ship date of repository serum specimen (mm/dd/yyyy): ..... | | / | | / | | | | SCFA8D6

C. URINE SPECIMEN

9. Was urine collected? ..... Y N → **Go to Item 15** SCFA9
If no, specify reason _____

10. Date of urine specimen collection (mm/dd/yyyy): ..... | | / | | / | | | | SCFA10

11. Method of urine collection:

Catheterization ..... A
Suprapubic aspiration ..... B
Clean Voided C
Bag collected ..... D

SCFA11

Note: bag-collected specimen may only be used if dipstick is negative for pyuria.

12. Indicate urine specimens collected:

a. Local lab urine culture ..... Y N SCFA12A

b. Repository urine specimen ..... Y N → **Go to Item 15** SCFA12B
If no, specify reason _____

13. Volume of urine specimen for repository (mL): ..... | | . | | SCFA13

14. Urine repository specimen shipping date (mm/dd/yyyy): ..... | | / | | / | | | | SCFA14

D. RECTAL SWAB SPECIMEN

15. Was a rectal swab collected? ..... Y N → **Go to Item 18** SCFA15
If no, specify reason _____

16. Date of rectal swab specimen collection (mm/dd/yyyy): ..... | | / | | / | | | | SCFA16

17. Rectal swab specimen shipping date (mm/dd/yyyy): ..... | | / | | / | | | | SCFA17

E. ADMINISTRATIVE INFORMATION

18. Date of data collection (mm/dd/yyyy): ..... | | / | | / | | | | SCFA18

19. Method of data collection *(circle one)*:

Computer C
Paper ..... P

SCFA19

20. Recorder's initials: ..... | | | BLIND_STAFF_ID20

TREATMENT FAILURE FORM

RIVUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:							

FORM CODE: TFF
VERSION: A 07/21/09

Contact Occasion | | | SEQ # | |

Instructions: *This form is to be completed by DCC research staff and should be used to identify RIVUR participant treatment failures. Record relevant details, particularly DSMB responses or actions, in Comments (#6).*

1. a. Date identified as treatment failure by DCC staff (mm/dd/yyyy): ..... __/__/____ TFFA1A

   b. Staff's initials who identified treatment failure: ..... ___ TFFA1B TFFA1B will not be included in the NIDDK closed datasets

2. a. Date site notified (mm/dd/yyyy): ..... __/__/____ TFFA2A

   b. Staff's initials who notified site of treatment failure: ..... ___ TFFA2B TFFA2B will not be included in the NIDDK closed datasets

3. a. Date DSMB notified (mm/dd/yyyy): ..... __/__/____ TFFA3A

   b. Staff's initials who notified DSMB of treatment failure: ..... ___ TFFA3B TFFA3B will not be included in the NIDDK closed datasets

4. Type of Treatment Failure:

   a. New or Worsening Scarring on Follow-up DMSA..... Y N TFFA4A
   b. New or Worsening Scarring on post-$_F$UTI Interim DMSA on Participant with severe baseline scarring ..... Y N TFFA4B
   c. 2 Febrile UTI ..... Y N TFFA4C
   d. 4 Symptomatic OR 1 Febrile + 3 Symptomatic..... Y N TFFA4D

5. Date of data entry (mm/dd/yyyy): ..... __/__/____ TFFA5

6. Comments: ..... Y N TFFA6 TFFA6 will not be included in the NIDDK closed datasets

   _____

   _____

   _____

7. SC Request Number of Treatment Failure Report to DSMB ..... ______ TFFA7 TFFA7 will not be included in the NIDDK closed datasets

8. Recorder's initials: ..... ___ BLIND_STAFF_ID

ULTRASOUND RESULTS FORM

RMUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER: | | | | | | | |

FORM CODE: URF
VERSION: C 05/08/07

Contact Occasion | |

SEQ # | |

Instructions: *This form should be completed by the reference radiologist. Affix the participant ID label above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

A. IMAGING RESULTS

1. Date of ultrasound (mm/dd/yyyy): ..... | | / | | / | | | | | UR_1

2. Right kidney:
   a. Length (cm): ..... | | . | UR_2A
   b. Width (cm): ..... | . | UR_2B
   c. Duplication:
      Yes ..... Y
      No ..... N UR_2C
      Unevaluated ..... U
   d. Hydronephrosis: ..... Y N → **Go to Q3** UR_2D
   e. SFU hydronephrosis grade ..... | UR_2E
   f. Renal pelvis A-P diameter (cm): | . | UR_2F

3. Left kidney:
   a. Length (cm): ..... | | . | UR_3A
   b. Width (cm): ..... | . | UR_3B
   c. Duplication:
      Yes ..... Y
      No ..... N UR_3C
      Unevaluated ..... U
   d. Hydronephrosis: ..... Y N → **Go to** UR_3D
   e. SFU hydronephrosis grade ..... | UR_3E
   f. Renal pelvis A-P diameter (cm): | . | UR_3F

4. Right Ureter:
   a. Dilated: ..... Y N UR_4A
   b. Proximal: ..... Y N UR_4B
   c. Distal: ..... Y N UR_4C

5. Left Ureter:
   a. Dilated: ..... Y N UR_5A
   b. Proximal: ..... Y N UR_5B
   c. Distal: ..... Y N UR_5C

6. Bladder post-void volume assessed? ..... Y N → **Go to Q8** UR_6

7. Post void residual (circle one):
   None, bladder is empty, post void ..... A
   Small, nearly empty, post void ..... B
   Moderate, volume less, still distended post void .... C UR_7
   Large, volume similar pre and post void ..... D
   Not assessed, no comparable pre/post images ..... E

8. Bladder wall qualitatively thickened: ..... Y N UR_8

9. Bladder wall (posterior) measured? ..... Y N → **Go to Q11** UR_9

10. Bladder wall (posterior) measurement (mm): ..... | | . | UR_10

11. Bladder diverticulum: ..... Y N U UR_11

12. Bladder masses: ..... Y N U UR_12

13. Comments: ..... Y N UR_13

Specify: _____

_____

_____

14. Quality of film:

Adequate ..... A UR_14
Inadequate I

B. ADMINISTRATIVE INFORMATION

15. Date of reading (mm/dd/yyyy): ..... | |/| |/| | | | | UR_15

16. Method of data collection *(circle one)*:

Computer ..... C UR_16
Paper ..... P

17. Radiologist's initials: ..... | | | BLIND_STAFF_ID

URINE SPECIMEN RESULTS FORM

Version A of this form was used for pilot study

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: E 02/18/13

Contact Occasion | | |

SEQ # | | |

Line Number | | |

Participant Name: _____

Instructions: *Complete this form from medical records abstraction to report on all urinalysis results at baseline and end-of-study, or at any time during the study when urinalysis or urine culture is performed. Increment the line number above if multiple urinalyses are performed during one event.*

A. DIPSTICK RESULTS

1. Was a urine dipstick performed? ..... Y N → **Go to Item 6** USR1

2. Date of urine sample collection for dipstick (mm/dd/yyyy): ..... | | / | | / | | | | | USR2

3. Method of urine collection for dipstick *(circle one)*:
   - Catheterization ..... A
   - Suprapubic aspiration ..... B
   - Clean voided C
   - Bag collected ..... D
   - Unknown ..... E

   USR3

4. Are the dipstick results based on urine collected at home? ..... Y N USR4

5. Dipstick results:
   a. Leukocyte esterase *(circle one)*:
      - Negative ..... A
      - Trace ..... B
      - Small (+) C
      - Moderate (++) ..... D
      - Large (+++) ..... E

      USR5A

   b. Nitrite *(circle one)*:
      - Negative ..... N
      - Positive ..... P

      USR5B

B. MICROSCOPY RESULTS

6. a. Are urine microscopy results available?
   - Yes ..... Y
   - No, urine microscopy not performed ..... N → **Go to Item 8**
   - No, other reason ..... O
     - If other, please specify: _____ → **Go to Item 8**

   USR6A

   b. Date of urine sample collection for microscopy (mm/dd/yyyy): ..... | | / | | / | | | | | USR6B

c. Method of urine collection for microscopy *(circle one)*:

Catheterization ..... A
Suprapubic aspiration ..... B
Clean voided C
Bag collected ..... D
Unknown ..... E

USR6C

d. Are the microscopy results based on urine collected at home? .... Y N

USR6D

7. Urine microscopy results:

a. WBC *(Enter count. Use 999.999 for values ≥ 999.999)*: ..... | | | | . | | | |

USR7A

b. Reporting units for WBC microscopy *(circle one)*:

WBC/mm^3 ..... A
WBC/hpf ..... B

USR7B

C. URINE CULTURE RESULTS

8. Are urine culture results available?

USR8

Yes ..... Y
No, urine culture not performed ..... N → **Go to Item 40**
No, sample contaminated ..... C → **Do Items 9-11, then go to Item 40**
No, other reason ..... O
If other, please specify: _____ → **Go to Item 40**

9. Date of urine sample collection for culture (*mm/dd/yyyy):* ..... | | / | | / | | | | |

USR9

10. Method of urine collection for urine culture *(circle one)*:

Catheterization ..... A
Suprapubic aspiration ..... B
Clean voided C
Bag collected ..... D
Unknown ..... E

USR10

11. Is the urine culture report based on urine collected at home? ..... Y N

USR11

12. How many different organisms were isolated on culture? *(Describe type and colony count in Q13-Q16.)*..... | → **If 0, Go to Item 40**

USR12

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: E 02/18/13

Contact Occasion | | SEQ # | |

Participant Name: _____

Line Number | |

Instructions: *For each organism isolated on culture, please record the (a.) organism from coded list, (b.) the data type (see options below) (c.) the colony count (CFU/ML) of isolated organism (do **not** enter commas in the colony count) and (d) species (if there are more than 3 species please specify in a notelog):*

(b.) Data Type:

= (equal to) ..... A → **Skip field c2 in items 13-16**
> (greater than) ..... B → **Skip field c2 in items 13-16**
≥ (greater than or equal to) ..... C → **Skip field c2 in items 13-16**
< (less than) ..... D → **Skip field c2 in items 13-16**
≤ (less than or equal to) ..... E → **Skip field c2 in items 13-16**
Range ..... F

Organism (code from list)	Data Type	Colony Count		Species (code from list)		
13. a.	b.	c1.	- c2.	d1.	d2.	d3.
USRORG13A01	USR13B	USR13C1	USR13C2	USRD13D1	USRD13D2	USRD13D3
14. a.	b.	c1.	- c2.	d1.	d2.	d3.
USRORG14A01	USR14B	USR14C1	USR14C2	USRD14D1	USRD14D2	USRD14D3
15. a.	b.	c1.	- c2.	d1.	d2.	d3.
USRORG15A01	USR15B	USR15C1	USR15C2	USRD15D1	USRD15D2	USRD15D3
16. a.	b.	c1.	- c2.	d1.	d2.	d3.
USRORG16A01	USR16B	USR16C1	USR16C2	USRD16D1	USRD16D2	USRD16D3

D. DRUG SENSITIVITY RESULTS

17. How many different antimicrobials were tested for sensitivity?

(Describe sensitivity item 18-item 39.) ..... | | USR17

a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
	Sensitivity of each isolated organism *(S=sensitive, I=intermediate, R=resistant, N=not tested)*:			
18. USR18A	USR18B S I R N	USR18C S I R N	USR18D S I R N	USR18E S I R N
19. USR19A	USR19B S I R N	USR19C S I R N	USR19D S I R N	USR19E S I R N
20. USR20A	USR20 S I R N	USR20C S I R N	USR20D S I R N	USR20E S I R N
21. USR21A	USR21 S I R N	USR21C S I R N	USR21D S I R N	USR21E S I R N
22. USR22A	USR22B S I R N	USR22C S I R N	USR22D S I R N	USR22E S I R N
23. USR23A	USR23B S I R N	USR23C S I R N	USR23D S I R N	USR23E S I R N

ID NUMBER:								FORM CODE: USR VERSION: E 02/18/13	Contact Occasion			SEQ #		

Participant Name: _____ Line Number | |

Sensitivity of each isolated organism

(S=sensitive, I=intermediate, R=resistant, N=not tested):

	a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
24.	USR24A	USR24B S I R N	USR24C S I R N	USR24D S I R N	USR24E S I R N
25.	USR25A	USR25B S I R N	USR25C S I R N	USR25D S I R N	USR25E S I R N
26.	USR26A	USR26B S I R N	USR26C S I R N	USR26D S I R N	USR26E S I R N
27.	USR27A	USR27B S I R N	USR27C S I R N	USR27D S I R N	USR27E S I R N
28.	USR28A	USR28B S I R N	USR28C S I R N	USR28D S I R N	USR28E S I R N
29.	USR29A	USR29B S I R N	USR29C S I R N	USR29D S I R N	USR29E S I R N
30.	USR30A	USR30B S I R N	USR30C S I R N	USR30D S I R N	USR30E S I R N
31.	USR31A	USR31B S I R N	USR31C S I R N	USR31D S I R N	USR31E S I R N
32.	USR32A	USR32B S I R N	USR32C S I R N	USR32D S I R N	USR32E S I R N
33.	USR33A	USR33B S I R N	USR33C S I R N	USR33D S I R N	USR33E S I R N
34.	USR34A	USR34B S I R N	USR34C S I R N	USR34D S I R N	USR34E S I R N
35.	USR35A	USR35B S I R N	USR35C S I R N	USR35D S I R N	USR35E S I R N
36.	USR36A	USR36B S I R N	USR36C S I R N	USR36D S I R N	USR36E S I R N
37.	USR37A	USR37B S I R N	USR37C S I R N	USR37D S I R N	USR37E S I R N
38.	USR38A	USR38B S I R N	USR38C S I R N	USR38D S I R N	USR38E S I R N
39.	USR39A	USR39B S I R N	USR39C S I R N	USR39D S I R N	USR39E S I R N

E. UTI TREATMENT

40. Was UTI treatment prescribed? ..... Y N → **Go to Item 46** USR40

41. How many different antimicrobials were prescribed to treat the UTI?

*(Describe in item 42-item 45, and update the **CMF**.)* USR41

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: E 02/18/13

Contact Occasion | | SEQ # | |

Participant Name: _____

Line Number | |

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
42.	a. USR42A	b. USR42B	c. USR42C	d. Y N U USR42D
43.	a. USR43A	b. USR43B	c. USR43C	d. Y N U USR43D
44.	a. USR44A	b. USR44B	c. USR44C	d. Y N U USR44D
45.	a. USR45A	b. USR45B	c. USR45C	d. Y N U USR45D

F. URINE CHEMISTRY RESULTS

46. Are urine chemistry results available? USR46

- Yes ..... Y
- No, urine chemistry not performed ..... N → **Go to Item 54**
- No, sample inadequate ..... I → **Do Item 47, then go to Item 54**
- No, other reason ..... O
  - If other, please specify: _____ → **Go to Item 54**

47. Date of urine sample collection for chemistry (*mm/dd/yyyy):* ..... | | | / | | / | | | | | USR47

48. a. Method of urine collection for chemistry *(circle one)*:

- Catheterization ..... A
- Suprapubic aspiration ..... B
- Clean voided C
- Bag collected ..... D
- Unknown ..... E

USR48A

b. Are the urine chemistry results based on urine collected at home? ..... Y N USR48B

49. Creatinine

a. Value | | | . | CREATININE01

b. Data Type *(circle one)*:

- = (equal to) ..... A
- > (greater than) ..... B
- ≥ (greater than or equal to) C
- < (less than) ..... D
- ≤ (less than) ..... E

DT_CRE01

Participant Name: _____

c. Units *(circle one)*:

mg/dL ..... A
mg/L ..... B
mcg/mL C
mcg/mg ..... D
mg/g ..... E
Other ..... F

Variable removed, all are in mg/dL

If other, please specify: _____

d. Reference range

USRC49D1 d1. | | | . | | - d2. | | | . | | USRC49D2

50. Did the laboratory provide results for microalbumin? ..... Y N → **Go to Item 52** USRC50

51. Microalbumin

a. Value | | | . | | ALBUMIN01

b. Data Type *(circle one)*:

= (equal to) ..... A
> (greater than) ..... B
≥ (greater than or equal to) C
< (less than) ..... D
≤ (less than) ..... E

DT_ALB01

c. Units *(circle one)*:

mg/dL ..... A
mg/L ..... B
mcg/mL C
mcg/mg ..... D
mg/g ..... E
Other ..... F

Variable removed, all are in mg/dL

If other, please specify: _____

d. Reference range

USRC51D1 d1. | | | . | | - d2. | | | . | | USRC51D2

52. Did the laboratory provide results for the microalbumin/creatinine ratio? .....Y N → **Go to Item 54** USRC52

Participant Name: _____

53. Microalbumin/Creatinine Ratio

a. Value |_|_|_|.|_| ACR01

b. Data Type *(circle one)*:

= (equal to) ..... A
> (greater than) ..... B
≥ (greater than or equal to) C
< (less than) ..... D
≤ (less than) ..... E

DT_ACR01

c. Units *(circle one)*:

mg/dL ..... A
mg/L ..... B
mcg/mL C
mcg/mg ..... D
mg/g ..... E
Other ..... F
If other, please specify: _____

Variable removed, all are in mg/g

d. Reference range

USRC53D1 d1. |_|_|_|.|_| - d2. |_|_|_|.|_| USRC53D2

G. ADMINISTRATIVE INFORMATION

54. Source of results:

Protocol scheduled baseline or end-of study ..... P → **Go to Item 56**
Abstracted from medical record ..... M
Routine office visit ..... O → **Go to Item 56**

USR50

55. MCID Number if results derive from abstraction of a medical care visit (from MCA form) ..... |_|_|_|_|_|_|_| BLIND_MCID

56. Date of data entry (mm/dd/yyyy): ..... |_|_|/|_|_|/|_|_|_|_| USR52

57. Method of data collection *(circle one)*:

Computer C
Paper ..... P

USR53

58. Recorder's initials: ..... |_|_|_| BLIND_STAFF_ID

URINE SPECIMEN RESULTS FORM

RMUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: D 07/27/12

Contact Occasion | | |

SEQ # | | |

Line Number | | |

Participant Name: _____

Instructions: *Complete this form from medical records abstraction to report on all urinalysis results at baseline and end-of-study, or at any time during the study when urinalysis or urine culture is performed. Increment the line number above if multiple urinalyses are performed during one event.*

A. DIPSTICK RESULTS

1. Was a urine dipstick performed? ..... Y N → **Go to Item 6** USR1

2. Date of urine sample collection for dipstick (mm/dd/yyyy): ..... | | / | | / | | | | | USR2

3. Method of urine collection for dipstick *(circle one)*:
   - Catheterization ..... A
   - Suprapubic aspiration ..... B
   - Clean voided C
   - Bag collected ..... D
   - Unknown ..... E

   USR3

4. Are the dipstick results based on urine collected at home? ..... Y N USR4

5. Dipstick results:
   a. Leukocyte esterase *(circle one)*:
      - Negative ..... A
      - Trace ..... B
      - Small (+) C
      - Moderate (++) ..... D
      - Large (+++) ..... E

      USR5A

   b. Nitrite *(circle one)*:
      - Negative ..... N
      - Positive ..... P

      USR5B

B. MICROSCOPY RESULTS

6. a. Are urine microscopy results available?
   - Yes ..... Y
   - No, urine microscopy not performed ..... N → **Go to Item 8**
   - No, other reason ..... O
     - If other, please specify: _____ → **Go to Item 8**

   USR6A

   b. Date of urine sample collection for microscopy (mm/dd/yyyy): ..... | | / | | / | | | | | USR6B

c. Method of urine collection for microscopy *(circle one)*:

Catheterization ..... A
Suprapubic aspiration ..... B
Clean voided C
Bag collected ..... D
Unknown ..... E

USR6C

d. Are the microscopy results based on urine collected at home? .... Y N

USR6D

7. Urine microscopy results:

a. WBC *(Enter count. Use 999.999 for values ≥ 999.999)*: ..... | | | | . | | | |

USR7A

b. Reporting units for WBC microscopy *(circle one)*:

WBC/mm^3 ..... A
WBC/hpf ..... B

USR7B

C. URINE CULTURE RESULTS

8. Are urine culture results available?

USR8

Yes ..... Y
No, urine culture not performed ..... N → **Go to Item 40**
No, sample contaminated ..... C → **Do Items 9-11, then go to Item 40**
No, other reason ..... O
If other, please specify: _____ → **Go to Item 40**

9. Date of urine sample collection for culture (*mm/dd/yyyy):* ..... | | / | | / | | | | |

USR9

10. Method of urine collection for urine culture *(circle one)*:

Catheterization ..... A
Suprapubic aspiration ..... B
Clean voided C
Bag collected ..... D
Unknown ..... E

USR10

11. Is the urine culture report based on urine collected at home? ..... Y N

USR11

12. How many different organisms were isolated on culture? *(Describe type and colony count in Q13-Q16.)* ..... | → **If 0, Go to Item 40**

USR12

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: D 07/27/12

Contact Occasion | | |

SEQ # | | |

Line Number | | |

Participant Name: _____

Instructions: *For each organism isolated on culture, please record the (a.) organism from coded list, (b.) the data type (see options below) (c.) the colony count (CFU/ML) of isolated organism (do **not** enter commas in the colony count) and (d) species (if there are more than 3 species please specify in a notelog):*

(b.) Data Type:

= (equal to) ..... A → **Skip field c2 in items 13-16**
> (greater than) ..... B → **Skip field c2 in items 13-16**
≥ (greater than or equal to) ..... C → **Skip field c2 in items 13-16**
< (less than) ..... D → **Skip field c2 in items 13-16**
≤ (less than or equal to) ..... E → **Skip field c2 in items 13-16**
Range ..... F

	Organism (code from list)	Data Type	Colony Count		Species (code from list)		
13.	a. USR13A	b. USR13B	c1. USR13C1	- c2. USR13C2	d1. USRD13D1	d2. USRD13D2	d3. USRD13D3
14.	a. USR14A	b. USR14B	c1. USR14C1	- c2. USR14C2	d1. USRD14D1	d2. USRD14D2	d3. USRD14D3
15.	a. USR15A	b. USR15B	c1. USR15C1	- c2. USR15C2	d1. USRD15D1	d2. USRD15D2	d3. USRD15D3
16.	a. USR16A	b. USR16B	c1. USR16C1	- c2. USR16C2	d1. USRD16D1	d2. USRD16D2	d3. USRD16D3

D. DRUG SENSITIVITY RESULTS

17. How many different antimicrobials were tested for sensitivity?

(Describe sensitivity item 18-item 39.) ..... | | USR17

	a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
		Sensitivity of each isolated organism *(S=sensitive, I=intermediate, R=resistant, N=not tested)*:			
18.	USR18A	S I R N USR18B	S I R N USR18C	S I R N USR18D	S I R N USR18E
19.	USR19A	S I R N USR19B	S I R N USR19C	S I R N USR19D	S I R N USR19E
20.	USR20A	S I R N USR20B	S I R N USR20C	S I R N USR20D	S I R N USR20E
21.	USR21A	S I R N USR21B	S I R N USR21C	S I R N USR21D	S I R N USR21E
22.	USR22A	S I R N USR22B	S I R N USR22C	S I R N USR22D	S I R N USR22E
23.	USR23A	S I R N USR23B	S I R N USR23C	S I R N USR23D	S I R N USR23E

ID NUMBER:								FORM CODE: USR VERSION: D 07/27/12	Contact Occasion		SEQ #	

Participant Name: _____ Line Number

Sensitivity of each isolated organism
(S=sensitive, I=intermediate, R=resistant, N=not tested):

	a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
24.	USR24A	USR24B S I R N	USR24C S I R N	USR24D S I R N	USR24E S I R N
25.	USR25A	USR25B S I R N	USR25C S I R N	USR25D S I R N	USR25E S I R N
26.	USR26A	USR26B S I R N	USR26C S I R N	USR26D S I R N	USR26E S I R N
27.	USR27A	USR27B S I R N	USR27C S I R N	USR27D S I R N	USR27E S I R N
28.	USR28A	USR28B S I R N	USR28C S I R N	USR28D S I R N	USR28E S I R N
29.	USR29A	USR29B S I R N	USR29C S I R N	USR29D S I R N	USR29E S I R N
30.	USR30A	USR30B S I R N	USR30C S I R N	USR30D S I R N	USR30E S I R N
31.	USR31A	USR31B S I R N	USR31C S I R N	USR31D S I R N	USR31E S I R N
32.	USR32A	USR32B S I R N	USR32C S I R N	USR32D S I R N	USR32E S I R N
33.	USR33A	USR33B S I R N	USR33C S I R N	USR33D S I R N	USR33E S I R N
34.	USR34A	USR34B S I R N	USR34C S I R N	USR34D S I R N	USR34E S I R N
35.	USR35A	USR35B S I R N	USR35C S I R N	USR35D S I R N	USR35E S I R N
36.	USR36A	USR36B S I R N	USR36C S I R N	USR36D S I R N	USR36E S I R N
37.	USR37A	USR37B S I R N	USR37C S I R N	USR37D S I R N	USR37E S I R N
38.	USR38A	USR38B S I R N	USR38C S I R N	USR38D S I R N	USR38E S I R N
39.	USR39A	USR39B S I R N	USR39C S I R N	USR39D S I R N	USR39E S I R N

E. UTI TREATMENT

40. Was UTI treatment prescribed? ..... Y N → **Go to Item 46** USR40

41. How many different antimicrobials were prescribed to treat the UTI?
*(Describe in item 42-item 45, and update the **CMF**.)* ..... ☐ USR41

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: D 07/27/12

Contact Occasion | | |

SEQ # | | |

Line Number | | |

Participant Name: _____

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
42.	a. USR42A	b. USR42B	c. USR42C	d. Y N U USR42D
43.	a. USR43A	b. USR43B	c. USR43C	d. Y N U USR43D
44.	a. USR44A	b. USR44B	c. USR44C	d. Y N U USR44D
45.	a. USR45A	b. USR45B	c. USR45C	d. Y N U USR45D

F. URINE CHEMISTRY RESULTS

46. Are urine chemistry results available? USR46

- Yes ..... Y
- No, urine chemistry not performed ..... N → **Go to Item 54**
- No, sample inadequate ..... I → **Do Item 47, then go to Item 54**
- No, other reason ..... O
  - If other, please specify: _____ → **Go to Item 54**

47. Date of urine sample collection for chemistry (*mm/dd/yyyy):* ..... | | | / | | | / | | | | | USR47

48. a. Method of urine collection for chemistry *(circle one)*:

- Catheterization ..... A
- Suprapubic aspiration ..... B
- Clean voided C
- Bag collected ..... D
- Unknown ..... E

USR48A

b. Are the urine chemistry results based on urine collected at home? ..... Y N USR48B

49. Creatinine

a. Value | | | | . | | USRC49A

b. Data Type *(circle one)*:

- = (equal to) ..... A
- > (greater than) ..... B
- ≥ (greater than or equal to) C
- < (less than) ..... D
- ≤ (less than) ..... E

USRC49B

Participant Name: _____

c. Units *(circle one)*:

mg/dL ..... A
mg/L ..... B
mcg/mL C
mcg/mg ..... D
mg/g ..... E
Other ..... F
If other, please specify: _____

USRC49C

d. Reference range

USRC49D1 d1. | | | . | | - d2. | | | . | | USRC49D2

50. Did the laboratory provide results for microalbumin? ..... Y N → **Go to Item 52** USRC50

51. Microalbumin

a. Value | | | . | | USRC51A

b. Data Type *(circle one)*:

= (equal to) ..... A
> (greater than) ..... B
≥ (greater than or equal to) C
< (less than) ..... D
≤ (less than) ..... E

USRC51B

c. Units *(circle one)*:

mg/dL ..... A
mg/L ..... B
mcg/mL C
mcg/mg ..... D
mg/g ..... E
Other ..... F
If other, please specify: _____

USRC51C

d. Reference range

USRC51D1 d1. | | | . | | - d2. | | | . | | USRC51D2

52. Did the laboratory provide results for the microalbumin/creatinine ratio? .....Y N → **Go to Item 54** USRC52

53. Microalbumin/Creatinine Ratio

a. Value | | | | . | | USRC53A

b. Data Type *(circle one)*:

= (equal to) ..... A
> (greater than) ..... B
≥ (greater than or equal to) C
< (less than) ..... D
≤ (less than) ..... E

USRC53B

c. Units *(circle one)*:

mg/dL ..... A
mg/L ..... B
mcg/mL C
mcg/mg ..... D
mg/g ..... E
Other ..... F
If other, please specify: _____

USRC53C

d. Reference range

USRC53D1 d1. | | | . | | - d2. | | | . | | USRC53D2

G. ADMINISTRATIVE INFORMATION

54. Source of results:

Protocol scheduled baseline or end-of study ..... P → **Go to Item 56**
Abstracted from medical record ..... M
Routine office visit ..... O → **Go to Item 56**

USR50

55. MCID Number if results derive from abstraction of a medical care visit (from MCA form) ..... | | | | | | | | BLIND_MCID

56. Date of data entry (mm/dd/yyyy): ..... | | / | | / | | | | | USR52

57. Method of data collection *(circle one)*:

Computer C
Paper ..... P

USR53

58. Recorder's initials: ..... | | | BLIND_STAFF_ID

URINE SPECIMEN RESULTS FORM

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: C 04/05/11

Contact Occasion | | |

SEQ # | | |

Line Number | | |

Participant Name: _____

Instructions: *Complete this form from medical records abstraction to report on all urinalysis results at baseline and end-of-study, or at any time during the study when urinalysis or urine culture is performed. Increment the line number above if multiple urinalyses are performed during one event.*

A. DIPSTICK RESULTS

1. Was a urine dipstick performed? ..... Y N → **Go to Item 6** USR1

2. Date of urine sample collection for dipstick (mm/dd/yyyy): ..... | | / | | / | | | | | USR2

3. Method of urine collection for dipstick *(circle one)*:
   - Catheterization ..... A
   - Suprapubic aspiration ..... B
   - Clean voided C
   - Bag collected ..... D
   - Unknown ..... E

   USR3

4. Are the dipstick results based on urine collected at home? ..... Y N USR4

5. Dipstick results:
   a. Leukocyte esterase *(circle one)*:
      - Negative ..... A
      - Trace ..... B
      - Small (+) C
      - Moderate (++) ..... D
      - Large (+++) ..... E

      USR5A

   b. Nitrite *(circle one)*:
      - Negative ..... N
      - Positive ..... P

      USR5B

B. MICROSCOPY RESULTS

6. a. Are urine microscopy results available?
   - Yes ..... Y
   - No, urine microscopy not performed ..... N → **Go to Item 8**
   - No, other reason ..... O

     If other, please specify: _____ → **Go to Item 8**

     USR6A

   b. Date of urine sample collection for microscopy (mm/dd/yyyy): ..... | | / | | / | | | | | USR6B

Participant Name: _____

c. Method of urine collection for microscopy *(circle one)*:

Catheterization	A
Suprapubic aspiration	B
Clean voided	C
Bag collected	D
Unknown	E

USR6C

d. Are the microscopy results based on urine collected at home? .... Y N USR6D

7. Urine microscopy results:

a. WBC *(Enter count. Use 999.999 for values ≥ 999.999)*: ..... | | | | . | | | USR7A

b. Reporting units for WBC microscopy *(circle one)*:

WBC/mm^3	A
WBC/hpf	B

USR7B

C. URINE CULTURE RESULTS

8. Are urine culture results available? USR8

Yes	Y	
No, urine culture not performed	N	→ **Go to Item 40**
No, sample contaminated	C	→ **Do Items 9-11, then go to Item 40**
No, other reason	O	
If other, please specify: _____		→ **Go to Item 40**

9. Date of urine sample collection for culture (*mm/dd/yyyy):* ..... | | / | | / | | | | | USR9

10. Method of urine collection for urine culture *(circle one)*:

Catheterization	A
Suprapubic aspiration	B
Clean voided	C
Bag collected	D
Unknown	E

USR10

11. Is the urine culture report based on urine collected at home? ..... Y N USR11

12. How many different organisms were isolated on culture? *(Describe type and colony count in Q13-Q16.)*..... | → **If 0, Go to Item 40** USR12

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: C 04/05/11

Contact Occasion | |

SEQ # | |

Line Number | |

Participant Name: _____

Instruction: *For each organism isolated on culture, please record the (a.) organism from coded list, (b.) the data type (see options below) and (c.) the colony count (CFU/ML) of isolated organism:*

(b.) Data Type:

= (equal to) ..... A → **Skip field c2 in items 13-16**
> (greater than)..... B → **Skip field c2 in items 13-16**
≥ (greater than or equal to)..... C → **Skip field c2 in items 13-16**
< (less than)..... D → **Skip field c2 in items 13-16**
≤ (less than or equal to)..... E → **Skip field c2 in items 13-16**
Range ..... F

	Organism (code from list)		Data Type		Colony Count:	
13.	a.	USR13A	b. USR13B	c1. USR13C1		c2. USR13C2
14.	a.	USR14A	b. USR14B	c1. USR14C1		c2. USR14C2
15.	a.	USR15A	b. USR15B	c1. USR15C1		c2. USR15C2
16.	a.	USR16A	b. USR16B	c1. USR16C1		c2. USR16C2

D. DRUG SENSITIVITY RESULTS

17. How many different antimicrobials were tested for sensitivity?

(Describe sensitivity item 18-item 39.) ..... | | USR17

Sensitivity of each isolated organism
(S=sensitive, I=intermediate, R=resistant, N=not tested):

	a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
18.	USR18A	S I R N USR18B	S I R N USR18C	S I R N USR18D	S I R N USR18E
19.	USR19A	S I R N USR19B	S I R N USR19C	S I R N USR19D	S I R N USR19E
20.	USR20A	S I R N USR20B	S I R N USR20C	S I R N USR20D	S I R N USR20E
21.	USR21A	S I R N USR21B	S I R N USR21C	S I R N USR21D	S I R N USR21E
22.	USR22A	S I R N USR22B	S I R N USR22C	S I R N USR22D	S I R N USR22E
23.	USR23A	S I R N USR23B	S I R N USR23C	S I R N USR23D	S I R N USR23E
24.	USR24A	S I R N USR24B	S I R N USR24C	S I R N USR24D	S I R N USR24E
25.	USR25A	S I R N USR25B	S I R N USR25C	S I R N USR25D	S I R N USR25E

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: C 04/05/11

Contact Occasion | |

SEQ # | |

Line Number | |

Participant Name: _____

Sensitivity of each isolated organism
(S=sensitive, I=intermediate, R=resistant, N=not tested):

	a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
26.	USR26A	USR26B S I R N	USR26C S I R N	USR26D S I R N	USR26E S I R N
27.	USR27A	USR27B S I R N	USR27C S I R N	USR27D S I R N	USR27E S I R N
28.	USR28A	USR28B S I R N	USR28C S I R N	USR28D S I R N	USR28E S I R N
29.	USR29A	USR29B S I R N	USR29C S I R N	USR29D S I R N	USR29E S I R N
30.	USR30A	USR30B S I R N	USR30C S I R N	USR30D S I R N	USR30E S I R N
31.	USR31A	USR31B S I R N	USR31C S I R N	USR31D S I R N	USR31E S I R N
32.	USR32A	USR32B S I R N	USR32C S I R N	USR32D S I R N	USR32E S I R N
33.	USR33A	USR33B S I R N	USR33C S I R N	USR33D S I R N	USR33E S I R N
34.	USR34A	USR34B S I R N	USR34C S I R N	USR34D S I R N	USR34E S I R N
35.	USR35A	USR35B S I R N	USR35C S I R N	USR35D S I R N	USR35E S I R N
36.	USR36A	USR36B S I R N	USR36C S I R N	USR36D S I R N	USR36E S I R N
38.	USR37A	USR37B S I R N	USR37C S I R N	USR37D S I R N	USR37E S I R N
39.	USR38A	USR38B S I R N	USR38C S I R N	USR38D S I R N	USR38E S I R N

E. UTI TREATMENT

40. Was UTI treatment prescribed? ..... Y N → **Go to Item 46** USR40

41. How many different antimicrobials were prescribed to treat the UTI?
*(Describe in item 42-item 45, and update the **CMF**.)* ..... | USR41

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
42.	a. USR42A	b. / / USR42B	c. USR42C	d. Y N U USR42D
43.	a. USR43A	b. / / USR43B	c. USR43C	d. Y N U USR43D
44.	a. USR44A	b. / / USR44B	c. USR44C	d. Y N U USR44D

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: C 04/05/11

Contact Occasion | | SEQ # | |

Participant Name: _____ Line Number | |

Antimicrobial *(code from list)*: | Date prescribed (mm/dd/yyyy): | Duration of treatment (days): | Pathogen sensitive to drug:

45. a. | | USR45A b. | | / | / | | | USR45B c. | | USR45C d. Y N U USR45D

F. URINE CHEMISTRY RESULTS

46. Are urine chemistry results available? USR46

Yes ..... Y

No, urine chemistry not performed ..... N → **Go to Item 54**

No, sample inadequate ..... I → **Do Item 47, then go to Item 54**

No, other reason ..... O

If other, please specify: _____ → **Go to Item 54**

47. Date of urine sample collection for chemistry *(mm/dd/yyyy)*: ..... | | / | | / | | | | | USR47

48. a. Method of urine collection for chemistry *(circle one)*:

Catheterization ..... A
Suprapubic aspiration ..... B
Clean voided C
Bag collected ..... D
Unknown ..... E

USR48A

b. Are the urine chemistry results based on urine collected at home? ..... Y N USR48B

49. Creatinine

a. Value | | | | . | | USRC49A

b. Data Type *(circle one)*:

= (equal to) ..... A
> (greater than) ..... B
≥ (greater than or equal to) C
< (less than) ..... D
≤ (less than) ..... E

USRC49B

c. Units *(circle one)*:

mg/dL ..... A
mg/L ..... B
mcg/mL C
mcg/mg ..... D
mg/g ..... E
Other ..... F

USRC49C

If other, please specify: _____

Participant Name: _____

d. Reference range

USRC49D1 d1. ___.___ - d2. ___.___ USRC49D2

50. Did the laboratory provide results for microalbumin? ..... Y N → **Go to Item 52** USRC50

51. Microalbumin

a. Value ___.___ USRC51A

b. Data Type *(circle one)*:

= (equal to) ..... A
> (greater than) ..... B
≥ (greater than or equal to) C
< (less than) ..... D
≤ (less than) ..... E

USRC51B

c. Units *(circle one)*:

mg/dL ..... A
mg/L ..... B
mcg/mL C
mcg/mg ..... D
mg/g ..... E
Other ..... F
If other, please specify: _____

USRC51C

d. Reference range

USRC51D1 d1. ___.___ - d2. ___.___ USRC51D2

52. Did the laboratory provide results for the microalbumin/creatinine ratio? .....Y N → **Go to Item 54** USRC52

53. Microalbumin/Creatinine Ratio

a. Value ___.___ USRC53A

b. Data Type *(circle one)*:

= (equal to) ..... A
> (greater than) ..... B
≥ (greater than or equal to) C
< (less than) ..... D
≤ (less than) ..... E

USRC53B

c. Units *(circle one)*:

mg/dL ..... A
mg/L ..... B
mcg/mL C
mcg/mg ..... D
mg/g ..... E
Other ..... F
If other, please specify: _____

USRC53C

d. Reference range

USRC53D1 d1. | | | . | | – d2. | | | . | | USRC53D2

G. ADMINISTRATIVE INFORMATION

54. Source of results:
Protocol scheduled baseline or end-of study ..... P → **Go to Item 56**
Abstracted from medical record ..... M
Routine office visit ..... O → **Go to Item 56**

USR50

55. MCID Number if results derive from abstraction of a medical care visit (from MCA form) ..... | | | | | | | |

BLIND_MCID

56. Date of data entry (mm/dd/yyyy): ..... | | / | | / | | | | |

USR52

57. Method of data collection *(circle one)*:
Computer C
Paper ..... P

USR53

58. Recorder's initials: ..... | | |

BLIND_STAFF_ID

URINE SPECIMEN RESULTS FORM

RMUR Randomized Intervention for Children with Vesicoureteral Reflux

ID NUMBER:								FORM CODE: USR VERSION: B 08/15/07	Contact Occasion		SEQ #	

Participant Name: _____ Line Number

Instructions: *Complete this form from medical records abstraction to report on all urinalysis results at baseline and end-of-study, or at any time during the study when urinalysis or urine culture is performed. Increment the line number above if multiple urinalyses are performed during one event.*

A. DIPSTICK RESULTS

1. Was a urine dipstick performed? ..... Y N → **Go to Item 6** USR1

2. Date of urine sample collection for dipstick (mm/dd/yyyy): ..... __/__/____ USR2

3. Method of urine collection for dipstick *(circle one)*:

Catheterization	A	
Suprapubic aspiration	B	
Clean voided	C	USR3
Bag collected	D	
Unknown	E	

4. Are the dipstick results based on urine collected at home? ..... Y N USR4

5. Dipstick results:

   a. Leukocyte esterase *(circle one)*:

Negative	A	
Trace	B	
Small (+)	C	USR5A
Moderate (++)	D	
Large (+++)	E	

   b. Nitrite *(circle one)*:

Negative	N	USR5B
Positive	P	

B. MICROSCOPY RESULTS

6. a. Are urine microscopy results available?

Yes	Y	
No, urine microscopy not performed	N → **Go to Item 8**	
No, other reason	O	USR6A
If other, please specify: _____	→ **Go to Item 8**	

USR6B

   b. Date of urine sample collection for microscopy (mm/dd/yyyy): ..... __/__/____

c. Method of urine collection for microscopy *(circle one)*:

Catheterization	A
Suprapubic aspiration	B
Clean voided	C
Bag collected	D
Unknown	E

USR6C

d. Are the microscopy results based on urine collected at home? .... Y N USR6D

7. Urine microscopy results:

a. WBC *(Enter count. Use 999.999 for values ≥ 999.999)*: ..... |_|_|_|.|_|_|_| USR7A

b. Reporting units for WBC microscopy *(circle one)*:

WBC/mm^3	A
WBC/hpf	B

USR7B

C. URINE CULTURE RESULTS

8. Are urine culture results available? USR8

Yes	Y	
No, urine culture not performed	N	→ **Go to Item 40**
No, sample contaminated	C	→ **Do Items 9-11, then go to Item 40**
No, other reason	O	
If other, please specify: _____		→ **Go to Item 40**

9. Date of urine sample collection for culture (*mm/dd/yyyy):* ..... |_|_|/|_|_|/|_|_|_|_| USR9

10. Method of urine collection for urine culture *(circle one)*:

Catheterization	A
Suprapubic aspiration	B
Clean voided	C
Bag collected	D
Unknown	E

USR10

11. Is the urine culture report based on urine collected at home? ..... Y N USR11

12. How many different organisms were isolated on culture? *(Describe type and colony count in Q13-Q16.)*..... |_| → **If 0, Go to Item 40** USR12

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: B 08/15/07

Contact Occasion | | |

SEQ # | |

Line Number | |

Participant Name: _____

Instruction: *For each organism isolated on culture, please record the (a.) organism from coded list, (b.) the data type (see options below) and (c.) the colony count (CFU/ML) of isolated organism:*

(b.) Data Type:

= (equal to) ..... A → **Skip field c2 in items 13-16**
> (greater than)..... B → **Skip field c2 in items 13-16**
≥ (greater than or equal to)..... C → **Skip field c2 in items 13-16**
< (less than)..... D → **Skip field c2 in items 13-16**
≤ (less than or equal to)..... E → **Skip field c2 in items 13-16**
Range ..... F

	Organism (code from list)		Data Type		Colony Count:		
13.	a.	USR13A	b. USR13B	c1. USR13C1	–	c2.	USR13C2
14.	a.	USR14A	b. USR14B	c1. USR14C1	–	c2.	USR14C2
15.	a.	USR15A	b. USR15B	c1. USR15C1	–	c2.	USR15C2
16.	a.	USR16A	b. USR16B	c1. USR16C1	–	c2.	USR16C2

D. DRUG SENSITIVITY RESULTS

17. How many different antimicrobials were tested for sensitivity?

(Describe sensitivity item 18-item 39.) ..... | | USR17

Sensitivity of each isolated organism
(S=sensitive, I=intermediate, R=resistant, N=not tested):

	a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
18.	USR18A	S I R N USR18B	S I R N USR18C	S I R N USR18D	S I R N USR18E
19.	USR19A	S I R N USR19B	S I R N USR19C	S I R N USR19D	S I R N USR19E
20.	USR20A	S I R N USR20B	S I R N USR20C	S I R N USR20D	S I R N USR20E
21.	USR21A	S I R N USR21B	S I R N USR21C	S I R N USR21D	S I R N USR21E
22.	USR22A	S I R N USR22B	S I R N USR22C	S I R N USR22D	S I R N USR22E
23.	USR23A	S I R N USR23B	S I R N USR23C	S I R N USR23D	S I R N USR23E
24.	USR24A	S I R N USR24B	S I R N USR24C	S I R N USR24D	S I R N USR24E
25.	USR25A	S I R N USR25B	S I R N USR25C	S I R N USR25D	S I R N USR25E

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: B 08/15/07

Contact Occasion | | |

SEQ # | | |

Participant Name: _____

Line Number | | |

Sensitivity of each isolated organism
(S=sensitive, I=intermediate, R=resistant, N=not tested):

	a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
26.	USR26A	USR26B	USR26C	USR26D	USR26E
27.	USR27A	USR27B	USR27C	USR27D	USR27E
28.	USR28A	USR28B	USR28C	USR28D	USR28E
29.	USR29A	USR29B	USR29C	USR29D	USR29E
30.	USR30A	USR30B	USR30C	USR30D	USR30E
31.	USR31A	USR31B	USR31C	USR31D	USR31E
32.	USR32A	USR32B	USR32C	USR32D	USR32E
33.	USR33A	USR33B	USR33C	USR33D	USR33E
34.	USR34A	USR34B	USR34C	USR34D	USR34E
35.	USR35A	USR35B	USR35C	USR35D	USR35E
36.	USR36A	USR36B	USR36C	USR36D	USR36E
38.	USR37A	USR37B	USR37C	USR37D	USR37E
39.	USR38A	USR38B	USR38C	USR38D	USR38E

S I R N..... S I R N..... S I R N..... S I R N

E. UTI TREATMENT

40. Was UTI treatment prescribed? ..... Y N → **Go to Item 46** USR40

41. How many different antimicrobials were prescribed to treat the UTI?
*(Describe in item 42-item 45, and update the **CMF**.)* ..... | | USR41

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
42.	a. USR42A	b. USR42B	c. USR42C	d. Y N U USR42D
43.	a. USR43A	b. USR43B	c. USR43C	d. Y N U USR43D
44.	a. USR44A	b. USR44B	c. USR44C	d. Y N U USR44D

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: B 08/15/07

Contact Occasion | | SEQ # | |

Participant Name: _____

Line Number | |

Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
45. a.	b.	c.	d. Y N U
USR45A	USR45B	USR45C	USR45D

F. URINE CHEMISTRY RESULTS

46. Are urine chemistry results available? USR46

- Yes ..... Y
- No, urine chemistry not performed ..... N → **Go to Item 50**
- No, sample inadequate ..... I → **Do Item 47, then go to Item 50**
- No, other reason ..... O
  - If other, please specify: _____ → **Go to Item 50**

47. Date of urine sample collection for chemistry (*mm/dd/yyyy):* ..... | | / | | / | | | | | USR47

48. a. Method of urine collection for chemistry *(circle one)*:

- Catheterization ..... A
- Suprapubic aspiration ..... B
- Clean voided C
- Bag collected ..... D
- Unknown ..... E

USR48A

b. Are the urine chemistry results based on urine collected at home? ..... Y N USR48B

49. Urine chemistry results:

a. Creatinine (mg/dL) ..... | | | . | | USR49A

b. Microalbumin (mg/dL) ..... | | | | . | | USR49B

G. ADMINISTRATIVE INFORMATION

50. Source of results:

- Protocol scheduled baseline or end-of study ..... P → **Go to Item 52**
- Abstracted from medical record ..... M

USR50

51. MCID Number if results derive from abstraction of a medical care visit (from MCA form) ..... | | | | | | | | BLIND_MCID

ID NUMBER:							

FORM CODE: USR
VERSION: B 08/15/07

Contact Occasion | | SEQ # | |

Line Number | |

Participant Name: _____

52. Date of data entry (mm/dd/yyyy): ..... | | | / | | / | | | | | USR52

53. Method of data collection *(circle one)*:

Computer C
Paper..... P

USR53

54. Recorder's initials: ..... | | | BLIND_STAFF_ID

VCUG RESULTS FORM

Versions A and B of this form were used for pilot study

ID NUMBER:							

FORM CODE: VRF
VERSION: C 05/08/07

Contact Occasion | | | SEQ # | |

Instructions: *This form should be completed by the reference radiologist. Affix the participant ID label above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. Y, N, U indicates a Yes, No, Unknown response set.*

A. IMAGING RESULTS

1. Date of VCUG (mm/dd/yyyy): ____/____/____ VR_1

2. Voided during study: VR_2
   - Yes ..... Y
   - No ..... N
   - Unknown ..... U

3. Highest grade of reflux:

	None	I	II	III	IV	V	
a. Right ureter: VR_3A	0	1	2	3	4	5	→ **If 0, skip Q4a-d**
b. Left ureter: VR_3B	0	1	2	3	4	5	→ **If 0, skip Q5a-d**

4. Right Ureter

   a. Complete duplication: ..... Y N → **Go to Q4e** VR_4A

   b. Location of reflux *(circle one)*: VR_4B
   - Upper pole alone ..... U → **Go to Q4e**
   - Lower pole alone ..... L → **Go to Q4e**
   - Both poles ..... B

   c. Upper pole grade of reflux *(code as Q3)*: ____ VR_4C

   d. Lower pole grade of reflux *(code as Q3)*: ____ VR_4D

   e. Paraureteral diverticulum: ... Y N → **Go to Q5a** VR_4E

   f. Diameter of diverticulum *(circle one)*: VR_4F
   - < 1 cm ..... A
   - 1 - 2 cm ..... B
   - ≥ 2 cm C
   - Not measured ..... D

5. Left Ureter VR_5A

   a. Complete duplication: ..... Y N → **Go to Q5e**

   b. Location of reflux *(circle one)*: VR_5B
   - Upper pole alone ..... U → **Go to Q5e**
   - Lower pole alone ..... L → **Go to Q5e**
   - Both poles ..... B

   c. Upper pole grade of reflux *(code as Q3)*: ____ VR_5C

   d. Lower pole grade of reflux *(code as Q3)*: ____ VR_5D

   e. Paraureteral diverticulum: ... Y N → **Go to Q6** VR_5E

   f. Diameter of diverticulum *(circle one)*: VR_5F
   - < 1 cm ..... A
   - 1 - 2 cm ..... B
   - ≥ 2 cm C
   - Not measured ..... D

6. Bladder shape *(circle one)*: VR_6
   - Smooth / round ..... A
   - Triangular / elongated ..... B
   - Not reported C

7. Bladder trabeculations:..... Y N U VR_7

8. Bladder ureterocele: ..... Y N U VR_8

9. Bladder wall diverticulum:..... Y N U VR_9

10. Normal urethra:..... Y N U VR_10

11. "Spinning Top" urethra ..... Y N U VR_11

12. Osseous structures spinal dysraphism:..... Y N U VR_12

13. Comments: ..... Y N VR_13

Specify: _____

_____

_____

14. Quality of film:

Adequate..... A VR_14

Inadequate I

B. ADMINISTRATIVE INFORMATION

15. Date of VCUG reading (mm/dd/yyyy): ..... VR_15 | | | /| | | /| | | | |

16. Method of data collection *(circle one)*:

Computer ..... VR_16 C

Paper..... P

17. Radiologist's initials: ..... BLIND_STAFF_ID | | |

VCUG Sedation Form

ID NUMBER: | | | | | | | | FORM CODE: VSF
VERSION: A 02/07/07 Contact Occasion | | | SEQ # | |

Participant Name: _____

Instructions: *Complete this form for every VCUG to provide information on possible sedation.*

A. RADIOLOGICAL PROCEDURE

1. Date of VCUG procedure (mm/dd/yyyy): ..... | | / | | / | | | | | VSFA1

2. Was sedation used during the radiological procedure? VSFA2
   - Yes ..... Y
   - No ..... N → **Go to Item 9**
   - Unknown ..... U → **Go to Item 9**

B. SEDATION

	Medication Used for Sedation:		Medication Dose (mg/kg):		General Anesthesia:	
3.	Chloral hydrate	a. Y N VSFA3A	b. | | | . | VSFA3B		c. Y N U	VSFA3C
4.	Diazepam (Valium)	a. Y N VSFA4A	b. | | | . | VSFA4B		c. Y N U	VSFA4C
5.	Fentanyl	a. Y N VSFA5A	b. | | | . | VSFA5B		c. Y N U	VSFA5C
6.	Midazolam (Versed)	a. Y N VSFA6A	b. | | | . | VSFA6B		c. Y N U	VSFA6C
7.	Pentobarbital	a. Y N VSFA7A	b. | | | . | VSFA7B		c. Y N U	VSFA7C
8.	Other Drug	a. Y N VSFA8A	b. | | | . | VSFA8B		c. Y N U	VSFA8C

d. If other, specify: VSFA8D _____

C. ADMINISTRATIVE INFORMATION

9. Date of data collection (mm/dd/yyyy): ..... | | / | | / | | | | | VSFA9

10. Method of data collection *(circle one)*:
    - Computer C
    - Paper ..... P

    VSFA10

11. Recorder's initials: ..... | | | BLIND_STAFF_ID