CIT-02

STRATEGIES TO IMPROVE LONG TERM ISLET GRAFT SURVIVAL

FOR CENTRAL LABORATORY ASSESSMENTS

VERSION 6.0

AUGUST, 2011

CONFIDENTIAL

TABLE OF CONTENTS

1. CIT-02 PROTOCOL COORDINATOR INFORMATION

EVMS **Dept. of Internal Medicine** **700 W. Olney Rd** **Lewis Hall 2130** **Norfolk, VA 23507** **Attn: Norine Kuhn** **Phone: 757-446-5991** **Fax: 757-446-7339**	**Clinical Trials Statistical and Data Management Center** Traci Schwieger, M.A. Protocol Coordinator The University of Iowa 2400 University Capitol Centre Iowa City, IA 52242 phone: 319-384-4180 fax: 319-353-3960 e-mail: traci-schwieger@uiowa.edu

2. CIT-02 SPECIMEN SCHEDULE

Central Laboratory Assessments					
Assessment	Laboratory	Visit / Time-point	Volume	Collection Container	Shipping Instructions
Hemoglobin A1c (HbA1c)	University of Washington	V10,13,14,15,Y1, 16, 17, 18 19, Y2	2 mL Blood	(1) 2-mL Lavender top EDTA Vacutainer	Ship on cold pack within 24 hours of collection. Ship Monday-Thursday only.
Fasting serum glucose and c-peptide / serum creatinine	University of Washington	V04,05,06,07,08, 08a,08b,08c,09,10,10a, 10b,11,12,13,13a,13b, 14,14a,14b,15,Y1, 17, 19, Y2	2 mL Blood	(1) 3.5-mL Gold SST	Ship on dry ice in batches at least weekly. Ship Monday – Thursday only.
MMTT: Stimulated serum Glucose and c-peptide (Boost Extra, 15,30,60,90,120,150,180, 210,240,270,300 min)	University of Washington	V10,13,14,15,Y1, 17, 19, 90-min only at Y2	22 mL Total Blood 2 mL at 15,30,60, 90,120,150,180,210, 240,270, and 300 minutes each	(11) 3.5-mL Gold SST	Ship on dry ice in batches at least weekly. Ship Monday – Thursday only.
Insulin Modified FSIGT	University of Washington	V10,15,Y1	48 mL Total Blood 2 mL each at -10, -5, and -1 minutes pre-injection of glucose 2 mL each at 1, 2, 3, 4, 5, 7, 10, 12, 14, 16, 18, 20, 22, 25, 30, 40, 50, 70, 100, 140, and 180 minutes post injection of glucose	(24) 3.5-mL Gold SST	Ship on dry ice in batches at least weekly. Ship Monday – Thursday only.
Alloantibodies	University of Pennsylvania	V03,10,13,14,15,Y1, 17, 19	2 mL Blood	(1) 3-mL Red-top Vacutainer	Ship on dry ice in batches at least quarterly. Ship Monday – Thursday only.
Autoantibodies	Barbara Davis Center	V10,13,14,15,Y1, 17, 19	2 mL Blood	(1) 3-mL Red-top OR (1) 3.5 mL Gold SST	Ship on dry ice in batches at least quarterly. Ship Mon – Wed only. If collected on Thurs or Fri, freeze serum at -20°C or -70°C until Mon, Tues, or Wed. in dry ice.
TAT Complex, C3a, c-peptide	Rudbeck Laboratory	V03	10 mL Total Blood 2 mL each pre-Immunosuppression, immediately pre-tx, 15, 60,180 min post-tx	(5) 2-mL EDTA Vacutainer (lavender top)	Ship on dry ice in batches at least quarterly.

Central Laboratory Assessments					
Assessment	Laboratory	Visit / Time-point	Volume	Collection Container	Shipping Instructions
Serum to Archive	NIDDK Repository	V10,13,14,15,Y1	4 mL Blood	(1) 4-mL Gold SST	Ship in batches at least quarterly.
PBMC / Plasma to Archive	ITN Central Cell Processing Core Facility	V10,13,14,15,Y1	30 mL Blood	(3) 10-mL Na Heparin Vacutainer	Ship ambient daily.
RNA to Archive	ITN RNA Isolation Core Facility	V10,13,14,15,Y1	9 mL Blood	(3) 3-mL Tempus RNA Tube	Ship in batches quarterly on dry ice.
GFR	University of Minnesota[9]	V08,10,15,Y1, 19	10 mL Total Blood 2 mL each at 120, 150, 180, 210 and 240 minutes	(5) 2-mL Na Heparin Tube	Ship in batches weekly on dry ice. Ship Mon – Thurs.
Albumin/Creatinine Ratio	University of Minnesota	V08,10,13,14,15,Y1, 17, 19	5 mL Urine	Sterile Urine Container	Ship in batches weekly, frozen on dry ice. Ship Mon – Thurs.
LSF Peak and Trough Level (LSF Arm Only)	EVMS Lab	V03(Infusion 1), V05(Infusion 27)	2 mL Blood	(5) 2-mL EDTA Vacutainer (lavender top)	Ship on dry ice in batches at least quarterly.
Atherogenic Profile	University of Washington	Visit Y1, 19	8.5 mL Blood	(1) 8.5 mL Gold SST	Ship on dry ice in batches at least weekly. Ship Monday – Thursday only.

1

[1]LSF Arm Only; kits will be supplied by the site

3. LISOFYLLINE PEAK AND TROUGH LEVEL

Infusate Collections:

Use the body weight obtained at the time of admission (Day-2) to determine appropriate amount of LSF to be infused throughout the study.

The DCC has provided an LSF Kit which only contains labels for Specimen Tracking. Tubes and aliquots are provided by the site.

Transfer a 1.0 mL aliquot of infusion 1 for each subject to an appropriately labeled polypropylene container and store at -20º C prior to shipment to Frontage Labs.

Amount:	Date (mmddyy):	Time: (24 hr clock)

Transfer a 1.0 mL aliquot of Infusion 27 to an appropriately labeled polypropylene container and store at -20º C prior to shipment to Frontage Labs.

Amount:	Date (mmddyy):	Time: (24 hr clock)

Timing of Pharmacokinetic Profile Plasma Collections:

Dose 1:
0 hour: immediately prior to the first dose infusion (Day -1)
30 minutes: immediately before **completion** of the **first** infusion. Collect the blood sample, and stop the pump
90 minutes: after the **start** of the **first** infusion.
6 hours: after the **start** of the **first** infusion.

Collect Sample (0.75mL) in a 2.0mL purple top vacutainer tube containing liquid K3 EDTA. Place sample on ice and transfer to lab to begin processing within 2 hours.

Collection Time Protocol	Start Date (mmddyy):		
DAY	Code	Schedule	Time of Collection (24 hr clock)
		0 hour	
		30 minutes	
		90 minutes	
		6 hours	

Dose 27:
6 hours after Dose 27, i.e. immediately before the **28** dose is infused. Collect sample (0.75 mL) in a 2.0mL purple top vacutainer tube containing liquid K3 EDTA. Place sample on ice and transfer to lab to begin processing within 2 hours.

Start Date (mmddyy):			
DAY	Code	Schedule	Time of Collection (24 hr clock)
		6 hours after infusion 27 finished	

Blood Drawing Procedures:
All blood samples can be taken from the infusion line after the line has been flushed with 5 mL of normal saline **except** for the 30-minute sample at the completion of the first infusion and the 30-minutes sample at the completion of the last infusion.

Blood samples will be obtained from the arm contra lateral to the infusion site via a peripheral vein for the sample taken at the 30-minute completion of the first infusion.

Collect each sample (0.75 mL) in a 2.0 mL purple top tube Vacutainer tube containing liquid K3 EDTA.

Blood Sample Processing:
Immediately following collection, gently invert blood samples 8 times and place on ice.
Store blood samples in the refrigerator no longer than two hours before the sample is processed.
Centrifuge the samples at 3,000 rpm for 20 minutes and then aliquot the plasma into screw cap polypropylene tubes using standard laboratory technique.

Complete labels as shown below. Label each sample with the following information:

- Sample Identification number
- Patient Identification number
- Protocol number
- Date of collection
- Time of sample in relationship to dose (example: end of infusion, 30 minutes post, etc.)
- Code
- Initials of person preparing sample

Plasma samples should be stored in a -20º freezer.

Shipping Instructions:

Send all samples to Frontage Labs when the patient has completed the study. The address is:
EVMS
Dept. of Internal Medicine
700 W. Olney Rd
Lewis Hall 2130
Norfolk, VA 23507
Attn: Norine Kuhn
Phone: 757-446-5991
Fax: 757-446-7339 Transport all samples on dry ice.

Ship samples on dry ice

Ship via Federal Express, Priority for next morning delivery.

- On the day of the shipment, print the Shipping Report from the Specimen Tracking System and place a copy in the shipping box. An automatic email will be sent to: NadlerJL@EVMS.edu and KuhnNS@EVMS.edu
- If you are unable to print the Shipping Report from the Specimen Tracking System on the day of shipment, complete a Specimen Submission Form and fax a copy of the form including the airbill tracking number to the laboratory at +1-757-446-7339

Upon receipt at Frontage, samples will be inventoried and held in a secured freezer until the completion of the study when they will be analyzed.

4. CIT-02 KIT COMPONENTS

VISIT 03 **Day -2 through Day 0**	**KIT #3**	**TAT, C3a, C-Peptide** (5) 2-mL EDTA Vacutainer Tube (5) 1.8-mL Cryogenic Vial **LSF PK (Tubes and Aliq provided by site)** (5) 2-mL K3 EDTA (7) 1.8 mL Cryogenic Vials	**Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8mL cryovial
VISIT 04, 05, 06 & 07 **Days 3,7,14,21**	**KIT #5**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials	
VISIT 08 **Day 28**	**KIT #4**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials	**Albumin/Creatinine Ratio** (1) Urine Specimen Container (1) 4.0 mL Cryogenic Vial **GFR** (5) 2-mL Na Heparin Vacutainer Tubes (5) 1.8-mL Cryogenic Vials
VISIT 8a,8b,8c,09 **Days 35,42,49,56**	**KIT #5**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials	
VISIT 10 **Day 75**	**KIT #6**	***Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials ***MMTT (stimulated glucose and c-peptide)** (11) 3.5-mL Gold SST (22) 1.8-mL Cryogenic Vials **HBA1C** (1) 2-mL EDTA Vacutainer Tube **Albumin/Creatinine Ratio** (1) Urine Specimen Container (1) 4.0 mL Cryogenic Vial ***FSIGT** (24) 3.5-mL Gold SST (58) 1.8-mL Cryogenic Vials **GFR** (5) 2-mL Na Heparin Vacutainer Tubes (5) 1.8-mL Cryogenic Vials *Do not collect these samples at Day 75 for subjects with confirmed graft failure.	**Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **Autoantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **RNA to Archive (NIDDK)** (3) 3-mLTempus RNA Tube **Serum to Archive** (1) 4-mL Gold SST Vacutainer Tube (3) 1.8-mL Cryogenic Vials **PBMC and Plasma to Archive** (3) 10-mL NA Heparin Tubes

VISIT 10a,10b,11,12 **(+/- 7 day window)** **Day 90,105,120,150**	**KIT #5**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials
VISIT 13 **Day 180**	**KIT #7**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials **MMTT (stimulated glucose and c-peptide)** (11) 3.5-mL Gold SST (22) 1.8-mL Cryogenic Vials **HBA1C** (1) 2-mL EDTA Vacutainer Tube **Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **Autoantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **RNA to Archive (NIDDK)** (3) 3-mLTempus RNA Tube **Serum to Archive** (1) 4-mL Gold SST Vacutainer Tube (3) 1.8-mL Cryogenic Vials **PBMC and Plasma to Archive** (3) 10-mL Na Heparin Tubes
VISIT 13a, 13b **Days 210,240**	**KIT #5**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials
VISIT 14 **Day 270**	**KIT #7**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials **MMTT (stimulated glucose and c-peptide)** (11) 3.5-mL Gold SST (22) 1.8-mL Cryogenic Vials **HBA1C** (1) 2-mL EDTA Vacutainer Tube **Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **Autoantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **RNA to Archive (NIDDK)** (3) 3-mLTempus RNA Tube **Serum to Archive** (1) 4-mL Gold SST Vacutainer Tube (3) 1.8-mL Cryogenic Vials **PBMC and Plasma to Archive** (3) 10-mL Na Heparin Tubes
VISIT 14a, 14b **Days 300, 330**	**KIT #5**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials

VISIT 15 **Day 365**	**KIT #6**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials **MMTT (stimulated glucose and c-peptide)** (11) 3.5-mL Gold SST (22) 1.8-mL Cryogenic Vials **HBA1C** (1) 2-mL EDTA Vacutainer Tube **Albumin/Creatinine Ratio** (1) Urine Specimen Container (1) 4.0-mL Cryogenic Vial **FSIGT** (24) 3.5-mL Gold SST (58) 1.8-mL Cryogenic Vials **GFR** (5) 2-mL Na Heparin Vacutainer Tubes (5) 1.8-mL Cryogenic Vials	**Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **Autoantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **RNA to Archive (NIDDK)** (3) 3-mLTempus RNA Tube **Serum to Archive** (1) 4-mL Gold SST Vacutainer Tube (3) 1.8-mL Cryogenic Vials **PBMC and Plasma to Archive** (3) 10-mL Na Heparin Tubes
VISIT Y1 **365 days post initial transplant**	**KIT #11**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials **MMTT (stimulated glucose and c-peptide)** (11) 3.5-mL Gold SST (22) 1.8-mL Cryogenic Vials **HBA1C** (1) 2-mL EDTA Vacutainer Tube **Albumin/Creatinine Ratio** (1) Urine Specimen Container (1) 4.0-mL Cryogenic Vial **FSIGT** (24) 3.5-mL Gold SST (58) 1.8-mL Cryogenic Vials **GFR** (5) 2-mL Na Heparin Vacutainer Tubes (5) 1.8-mL Cryogenic Vials	**Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **Autoantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **RNA to Archive (NIDDK)** (3) 3-mLTempus RNA Tube **Serum to Archive** (1) 4-mL Gold SST Vacutainer Tube (3) 1.8-mL Cryogenic Vials **PBMC and Plasma to Archive** (3) 10-mL Na Heparin Tubes **Atherogenic Profile** (1) 8.5mL Gold SST (4) 1.8mL Cryogenic Vials
Visit 16 **Month 15**	**Kit #12**	**HBA1C** **(1) 2-mL EDTA Vacutainer Tube**	
VISIT 17 **Month 18**	**KIT #8**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials **MMTT (stimulated glucose and c-peptide)** (11) 3.5-mL Gold SST (22) 1.8-mL Cryogenic Vials **HBA1C** (1) 2-mL EDTA Vacutainer Tube	**Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **Autoantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials

		Albumin/Creatinine Ratio (1) Urine Specimen Container (1) 4.0-mL Cryogenic Vial	
Visit 18 Month 21	**Kit #12**	**HBA1C (1) 2-mL EDTA Vacutainer Tube**	
VISIT 19 Month 24	**KIT #9**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials **MMTT (stimulated glucose and c-peptide)** (11) 3.5-mL Gold SST (22) 1.8-mL Cryogenic Vials **HBA1C** (1) 2-mL EDTA Vacutainer Tube **Albumin/Creatinine Ratio** (1) Urine Specimen Container (1) 4.0-mL Cryogenic Vial **GFR** (5) 2-mL Na Heparin Vacutainer Tubes (5) 1.8-mL Cryogenic Vials	**Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **Autoantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **Atherogenic Profile** (1) 8.5mL Gold SST (4) 1.8mL Cryogenic Vials
VISIT Y2	**KIT #10**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials **HBA1C** (1) 2-mL EDTA Vacutainer Tube **MMTT (stimulated glucose and c-peptide)** (2) 3.5-mL Gold SST (4) 1.8-mL Cryogenic Vials	* There are two 3.5 mL Gold SST tubes for MMTT. Only one of these tubes will be filled at 90 minutes, unless it is suspected that the participant has suffered graft failure (in which case, the second tube should be filled at 60 minutes). If there is no suspicion of graft failure, one of the two 3.5 mL Gold SST tubes can be discarded.
Reduced Follow-Up (1 year post final transplant)	**KIT #50**	**90 min c-peptide post MMTT, Serum Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials **Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials	**HBA1C** (1) 2-mL EDTA Vacutainer Tube
Reduced Follow-up (Monthly and Quarterly)	**Kit #50X**	**Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials	
Suspected Graft Failure	**KIT #50Z**	**Fasting Serum Glucose, C-Peptide, Creatinine** (1) 3.5-mL Gold SST (2) 1.8-mL Cryogenic Vials **MMTT (stimulated glucose and c-peptide)** (2) 3.5-mL Gold SST (4 1.8-mL Cryogenic Vials	**Alloantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials **Autoantibody** (1) 3-mL Red-top Vacutainer Tube (1) 1.8-mL Cryogenic Vials

SEE APPENDIX 1 FOR KIT SUPPLY ORDER FORM

5. CIT-02 BLOOD VOLUME TABLE

CIT02 - MAXIMUM RESEARCH BLOOD VOLUME TABLE																				
TIME POINTS/VISITS																				
	Days				**Weeks**				**Months**											
TIMING OF STUDY PARTICIPATION	**SCRN**	**BL**	**TX 0**	**3**	**1**	**2**	**3**	**4**	**2**	**2.5** (Day 75)	**4**	**5**	**6, 7, 8**	**9, 10, 11**	**12**	1 yr post initial tx	**15**	**18**	**21**	**24**	2 yr post initial tx
VISIT	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13***	**14****	**15**	**Y1**	**16**	**17**	**18**	**19**	**Y2**
BLOOD VOLUMES																				
LOCAL LABORATORY ASSESSMENTS																				
CBC (WBC + Diff & Plat)	3	3	3		3	3	3	3	3	3	3	3	3	3	3		3	3	3	3	
Chemistry	4	4	4		4	4	4	4	4	4	4	4	4	4	4		4	4	4	4	
Lipids	4	4								4			4	4	4			4		4	
Thyroid Function	4	4													4						
Serology (1)	7	7														7					
EBV IgG	2																				
CMV IgG, CMV IgM (2)		4														4					
Coagulation (PT, PTT, INR)	5	5	5																		
Blood Type & HLA		11																			
Crossmatch		10																			
PRA		10																			
Fasting and 2 post-prandial (1-3 hrs) c-				9	9																
Sirolimus drug levels (trough)			3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
Tacrolimus drug level (trough)				3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	
LSF Levels (LSF group only on day -1			8		2																
CENTRAL LABORATORY AND METABOLIC ASSESSMENTS																					
GFR (5 timed specimens/timept, 2 ml each)	10	10						10		10					10	10				10	
EBV and CMV by PCR (3)		8								8			8								
HbA1c	2	2								2			2	2	2	2	2	2	2	2	2
Fasting glucose & c-pep / serum	4	2		2	2	2	2	2	8	2	6	2	6	6	2	2					
MMTT	2									22			22	22	22	22		22		22	2
Insulin modified FSIGT (c-pep, insulin,		48								48					48	48					

CIT02 - MAXIMUM RESEARCH BLOOD VOLUME TABLE

TIME POINTS/VISITS

	Days				Weeks				Months												
TIMING OF STUDY PARTICIPATION	**SCRN**	**BL**	**TX 0**	**3**	**1**	**2**	**3**	**4**	**2**	**2.5** (Day 75)	**4**	**5**	**6, 7, 8**	**9, 10, 11**	**12**	1 yr post initial tx	**15**	**18**	**21**	**24**	**Y2**
VISIT	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13***	**14****	**15**	**Y1**	**16**	**17**	**18**	**19**	
BLOOD VOLUMES																					
CENTRAL MECHANISTIC ASSAYS																					
Alloantibody	2	2								2			2	2	2	2		2		2	
Autoantibody		2								2			2	2	2	2		2		2	
TAT, c-peptide & C3a		2	8																		
MIAMI MECHANISTIC ASSAYS																					
Soluble Mediators(5)		2	6	6	2	2	2	2													
Granzyme B, etc.(6)		4	4	4	4	4	4	4	8	8	8	8	8	8	4	4	4	4	4	4	
Phenotype (intra and		4			4			4		4			4	4	4		4		4	4	
RNA for microarray		15								15			15	15	15		15		15	15	
T and B cell assays		60								60			60	60	60		60		60	60	
CENTRAL ARCHIVED SAMPLES																					
Serum		4								4			4	4	4	4					
PBMC / Plasma		30								30			30	30	30	30					
RNA		9								9			9	9	9	9					
TOTALS (mls)	**49.0**	**376.0**	**###**	**27.0**	**36.0**	**###**	**21.0**	**43.0**	**29.0**	**243.0**	**27.0**	**23.0**	**189.0**	**181.0**	**235.0**	**152.0**	**96.0**	**49.0**	**96.0**	**138.0**	**4.0**
BL - WK 6 TOTAL (mls)	**557.0**																				

* 13, 13a, and 13b

(1) Serology includes: HBc Ab, HBs AB, HBs Ag, HCV Ab, HIV, and HTLV I/II. Do not repeat Hepatitis B tests if HBs Ab was previously positive.

(2) Repeat test only if first test was negative

(3) The 8 ml indicated on Day 75 will be completed only on Day 90 (3 months)

(4) To be completed twice a week for first week, weekly for the first and second month, twice a month up to month 4, and monthly there after.

(5)To be completed once while on the waiting list, at day -2, on day 0 (pre transplant, 1hr and 6hrs), and days 1,2,4,7,14,21,28.

(6) To be completed once while on the waitnig list, at day -2, on day 0, and days 3,7,14,21, 28 and every 2 weeks until month 6 .

Appendix 1: KIT SUPPLY ORDER FORM

Please complete form and fax to University of Iowa @ +1-319-335-6580

Protocol #: _____

Site Name: _____ Site Number: _____

Order Date: _____ Due Date @ Site: _____

Requested By: _____ Requestor's phone: _____

Requestor's FAX: _____ Requestor's email: _____

Kit(s) #	QUANTITY
Kit(s) # _____	_____
Kit(s) # _____	_____
Kit(s) # _____	_____
Kit(s) # _____	_____

You will receive an initial supply of kits for 10 participants upon notice of your site activation. The initial supply of kits will include (1) Kit #1 through Kit# 5, per subject.

Please check your kits' expiration dates and DO NOT order more than a 6 month supply of kits.