SECTION XI

2.2 LABORATORY SPECIMEN MANAGEMENT

Blood Collection Order
Collection Kits
Fasting Blood Draw Option
Saliva Sample and Shipment
Ambient ACD Sample
Biomarkers: Plasma, Urine, Whole Blood, RNA
Cerebrospinal Fluid (CSF) Sample

Appendix XI

CSF Sample Laboratory Requisition
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NINDS Repository Electronic Inventory Spreadsheet Example
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Laboratory Information

Hours of Operation

Coriell operates from 9 AM to 5 PM Eastern Time, Monday through Friday.

Holiday Schedules

Please note that courier services may observe a different set of holidays. Please be sure to verify with your courier's schedule prior to any holiday.

Frozen samples must be shipped so that expected arrival at Coriell occurs Tuesday – Thursday (please plan accordingly as transit times may vary between sites).
Ambient samples may be shipped Monday – Friday (preferably Monday – Thursday) provided they are received at Coriell within 5 days of collection.

Weekend/holiday delivery must be arranged in advance with Coriell.
*Additional information about shipping restrictions will be provided as necessary.

Holiday Observations* 2012 – 2013 – United States

Date	Holiday
Thursday, Nov 22, 2012	Thanksgiving
Friday, Nov 23, 2012	Day after Thanksgiving
Tuesday, Dec 25, 2012	Christmas Day
Tuesday, Jan 1, 2013	New Year's Day
Monday, Jan 21, 2013	Martin Luther King Day
Monday, May 27, 2013	Memorial Day
Thursday, July 4, 2013	Independence Day
Monday, Sept 2, 2013	Labor Day
Thursday, Nov 28, 2013	Thanksgiving Day
Thursday, Nov 29, 2013	Day after Thanksgiving
Wednesday, Dec 25, 2013	Christmas Day

Biological specimens are a prime study focus with several researchers eager to analyze new components of plasma, DNA, CSF, etc.; thus we must make all efforts to continually replenish our invaluable samples so that the possibility of new discoveries can be achieved.

COLLECTION PROCEDURES

Specimen Collection Kits and Supplies

Research specimen collection kits will be provided to you by NINDS Repository at Coriell Institute for Medical Research with most of the materials needed for the urine, blood, RNA and CSF collection, as well as shipping labels and pre-filled Fedex Airway Bills to send samples back to the NINDS Repository.

The University of Iowa will provide saliva kits and waybills for shipments back to the UI. The saliva sample must be shipped with the remaining visit materials.

BLOOD COLLECTION ORDER

Blood and Plasma Sample Protocol at BASELINE/Initial 2.2 visit

1. RNA PAXgene tubes (Two, 2.5 ml)
2. 10ml Yellow-top ACD tube
3. Plastic 5ml Red Top Whole Blood
4. Plastic 6ml Green Top (Lithium Heparin) Vacutainer
5. Plastic 6ml Lavender top (K_2EDTA) Vacutainer
6. Plastic 6ml Green Top (Lithium Heparin) Vacutainer
7. Plastic 6ml Lavender top (K_2EDTA) Vacutainer

Blood and Plasma Sample Protocol at FOLLOW UP visit

1. RNA PAXgene tubes (Two, 2.5 ml)
2. Plastic 5ml Red Top Whole Blood
3. Plastic 6ml Green Top (Lithium Heparin) Vacutainer
4. Plastic 6ml Lavender top (K_2EDTA) Vacutainer
5. Plastic 6ml Green Top (Lithium Heparin) Vacutainer
6. Plastic 6ml Lavender top (K_2EDTA) Vacutainer
7. Plastic 6ml Green Top (Lithium Heparin) Vacutainer
8. Plastic 6ml Lavender top (K_2EDTA) Vacutainer

Specimen Collection Kits

Baseline Kit Components

Type of sample	Tube type	# of tubes in the kit	Tubes sent to Coriell	Tubes stay at sites
RNA	2 (2.5ml) PAXgene tubes	2	2	0
DNA	1 (8.5 ml) yellow-top ACD solution vacutainer tubes	1	1	0
Whole-blood	plastic 5ml red top whole blood	1	1	0
Plasma	plastic 6ml green top lithium heparin vacutainer	2	2	0
Plasma	plastic 6ml lavender top K_2EDTA vacutainer	2	2	0
Urine	50ml polypropylene vial	1	1	0
Urine	5ml orange screw top tube	1	1	0
Urine	Collection Cup	1	0	1

Follow-up Kit Components

Type of sample	Tube type	# of tubes in the kit	Tubes sent to Coriell	Tubes stay at sites
RNA	2 (2.5ml) PAXgene tubes	2	2	0
Whole-blood	plastic 5ml red top whole blood	1	1	0
Plasma	plastic 6ml green top lithium heparin vacutainer	3	Up to 3	0
Plasma	plastic 6ml lavender top K_2EDTA vacutainer	3	Up to 3	0
Urine	5ml orange screw top tube	1	1	0
Urine	50ml polypropylene vial	1	1	0
Urine	Collection Cup	1	0	1

CSF Kit Components

Type of sample	Tube type	# of tubes in the kit	Tubes sent to Coriell	Tubes stay at sites
Whole-blood for CSF screening	plastic 3ml lavender top K_2EDTA	1	0	1
	plastic 5ml green PST	1	0	1
	plastic 3ml light blue Na Citrate	1	0	1
CSF	2ml purple top microcentrifuge tube for routine lab testing	1	0	1
CSF	15ml conical polypropylene tube	1	N/A	N/A
CSF	2ml microcentrifuge tubes for CSF aliquoting (1.5 ml aliquot. A total of 8-10 aliquots will be obtained)	10	all	0
CSF	Cardboard Cryobox	1	1	0

Lumbar Puncture Kit Contents

Quantity	Kit Component
1	Sprotte Spinal Needle, 24G x 90 mm
1	Introducer needle, 1mm x 30mm
1	22G x 1.5 in. Needle
4	Plastic Syringes (5 ml, Luer Lock)
1	Plastic Syringe (3 ml, Luer Lock) with 25G x 5/8 in. Needle (Attached)
1	Needle stick pad
1	Adhesive bandage
1	Fenestrated Drape
2	Towels
6	Gauze Sponges
3	Sponge Applicators
1	Lidocaine HCl (1%), 5 ml
1	Povidone-Iodine Solution, 0.75 oz

Sites must supply the following phlebotomy equipment:

- Dry ice
- Gloves
- Alcohol wipes
- Butterfly needles
- Tourniquet
- Gauze Pad
- Bandage
- Microcentrifuge tube rack
- Sharps bin and lid
- Crushed Ice
- Pipettes and pipette tips

FASTING BLOOD DRAW: OPTIONAL PROCEDURE

- All participants should be informed of the option to complete a fasting blood draw prior to the day of the visit
- If the participant agrees, they must fast for a period of 12 hours. If participant forgets to fast, blood and CSF samples can still be obtained
- Blood should be drawn immediately after consenting using the 2.2 consent
- If CSF sample will be obtained, the participant should be instructed to fast after Day 1 of PREDICT-HD visit CSF samples obtained immediately in the morning of Day 2. **For participants that are unwilling to fast, or have minimal availability for a two-day visit, it is possible to do the pre-screen activities right away in the AM, followed by a late afternoon LP (pending on-site physician availability)
- Participants will need to be provided a snack and/or rest period following the blood draw to ease any discomfort or difficulties
- Coordinators should record whether a fasting blood and/or CSF procedure(s) was/were completed via the CSF Collection Laboratory form and Biomarker Sample Requisition Form

Collection of Saliva

Saliva samples will be collected for all NEW participants (at Baseline Visit) for the purpose of CAG analysis. For participants who have experienced past difficulties with DNA samples being viable, they may be asked to provide a saliva sample either at home (via mail-in kit) or at their next scheduled visit.

Participants should not eat, drink, smoke or chew gum for 30 minutes before giving their saliva sample.

An ORAGENE Discover (ORG-500) kit will be provided by the University of Iowa. These kits should arrive pre-labeled. If they are not, **please write the participant ID, Visit #, Site #, gender, initials and date on the label supplied using a permanent marker and affix to the outside of the tube**. The coordinator or participant should remove the contents of the kit, review the collection instructions and keep the kit at room temperature at all times.

HELPFUL TIPS:

**Ensure you secure a private location/room for the participant to provide their saliva sample.

**If a participant is experiencing difficulty salivating, begin a conversation about food and inquire about their favorite foods. Additionally, you could provide picture stimuli to help him/her. If needed, allow the participant to return to a private location to provide the sample.

Step 1: Participants need to refrain from talking. It is better for the participant to drop down the head and let the saliva run naturally to the front of the mouth; hold for a while and spit into the provided tube. Participants will spit into the collection tube for approximately 2-5 minutes. Should the participant cough up mucus as saliva is collected, instruct them to spit it in a sink/trash can/etc then await the next saliva collection opportunity.

Step 2: After the participant has filled the saliva to the designated fill line, the coordinator or participant should close the funnel lid (you will hear a loud click). The liquid in the lid will mix with the saliva.

Step 3: Hold the tube upright and unscrew the funnel from the tube.

Step 4: Place the small screw cap on the tube and tightly close. Shake for 5 seconds.

Step 5: Place the closed tube into the bio-specimen bag and seal.

Step 6: Place the bio-specimen bag into the padded envelope and mail to the University of Iowa with the remaining visit materials:

PREDICT-HD
The University of Iowa
200 Newton Road
1185 Westlawn
Iowa City, IA 52242
(319) 353-4523

AMBIENT LABORATORY SPECIMEN MANAGEMENT: AMBIENT YELLOW-TOP ACD TUBE

Blood Samples

- Samples may be used to produce plasma, lymphocytes and a lymphoblastoid cell line which will be stored for future medical research.
- Each site will be provided all of the necessary materials to collect the required specimens.

All bio-specimen collecting supplies except saliva collecting tubes will be shipped to you from the NINDS Repository. To order bio-specimen collection kits, please contact PREDICT Management Team at University of Iowa. Please allow at least **three-week turnaround time**.

Ambient Yellow-Top ACD Blood Sample Tube

- One (1) ACD blood sample will be collected at the Screening/Baseline visit (Visit 201) after all eligibility criteria have been verified and consent procedures completed.

- Gently invert the tube to ensure mixture of the solution in the tube and the blood.
- Using a permanent black ink marker, ACD tube must be properly labeled with the designated participant ID number, visit number, site number, visit date.
- Under 2.2, the previous barcode labels have been discontinued, thus writing essential information on the tube is important (as above). *If you still have barcodes on-site, please return to the University of Iowa with your next UI shipment.
- Coordinators must complete the designated ACD tube section on the NINDS Repository/Coriell Sample Record Shipping Form prior to shipping sample; also specify whether fasting occurred.

Retention/Destruction of Yellow-Top ACD Blood Samples

- Sample will be stored and maintained for future research at the NINDS Repository at the Coriell Institute for Medical Research indefinitely or until the sample is depleted.

Shipment of Yellow-Top ACD Blood Sample

- Blood sample should be shipped to the NINDS Repository at room temperature on the same date of draw for priority overnight delivery. **Do not freeze blood.**
- **Ambient blood samples may be shipped Monday – Friday (preferably Monday – Thursday) provided they are received at Coriell within 5 days of collection.**

- Insert the blood sample into the foam-lined ambient shipping container and ship at room temperature according to kit instructions. If sample cannot be shipped the same day as collected, hold at room temperature until shipping

can be arranged. **Sample must be received at Coriell within 5 days of being collected.**

- Holiday shipments to the US should be avoided; Holidays are listed on the Home Page of the SharePoint site and in Appendix XI. Shipping during US holidays may result in ruined samples and payment penalties.

FROZEN LABORATORY SPECIMEN MANAGEMENT: PLASMA, URINE, RNA, CSF & WHOLE BLOOD

Within the 2.0 protocol, the biosample procedures have been updated to include urine sample collection in addition to the normal yearly plasma samples. Plasma samples will be used to conduct more sophisticated analyses, such as metabolomics, proteomics, lipidomics, and mass spectroscopy. Samples will be evaluated to measure the DNA injury markers (such as 8-OH2'dG) and the RNA injury markers (such as 8OHrG). All samples will be kept indefinitely for future research in the NINDS Repository at the Coriell Institute for Medical Research. Within the 2.2 protocol amendment, the sample collection has been expanded to include the possible collection of saliva, RNA and/or CSF.

Researchers who have had their research reviewed by an Institutional Review Board will be able to request coded samples following approval by the principal investigator, the PREDICT-HD Executive Committee and NINDS.

RNA PAXgene samples

Two (2) 2.5ml RNA samples (totaling 5ml) should be obtained early in the collection process (before plasma, etc.). **Please be sure to have a designated location where both tubes can be placed UPRIGHT and stored for a period of 24 hours at room temperature prior to freezing in a -70 or -80 freezer**.

INSTRUCTIONS for PAXgene tubes:

1. Store PAXgene™ Blood RNA Tubes at room temperature 64^0F -77^0F (18°C to 25°C) before use. Write the participant #, site #, visit # and date of collection on the PAXgene RNA tubes prior to blood draw using a permanent black marker. **Label tubes prior to specimen collection.**

2. Using a blood collection set and a holder, collect blood into the first of the two PAXgene™ Blood RNA Tubes using your institution's recommended procedure for standard venipuncture technique.
The following techniques shall be used to prevent possible backflow:

a. Place donor's arm in a downward position.
b. Hold tube in a vertical position, below the donor's arm during blood collection.
c. Release tourniquet as soon as blood starts to flow into tube.
d. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

3. Allow at least 10 seconds for a complete blood draw to take place in each tube. **Ensure that the blood has stopped flowing into the tube before removing the tube from the holder.** The PAXgene™ Blood RNA Tube with its vacuum is designed to draw 2.5ml of blood into the tube. Record time of draw on Biomarker Sample Laboratory Requisition form.

4. **CRITICAL STEP:** Immediately after blood collection, gently invert/mix (180 degree turns) the PAXgene™ Blood RNA Tube 8 – 10 times.

5. REPEAT STEPS 2 TO 4 for the second PAXgene™ Blood RNA Tube to be collected.

6. **CRITICAL STEP:** Incubate the PAXgene™ Blood RNA Tubes **UPRIGHT at room temperature (18°C to 25°C) for 24 hours**. Record time and date of draw on Biomarker Requisition form.

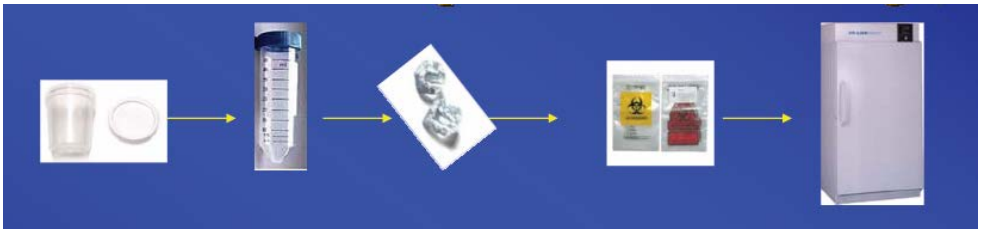
- *If blood is drawn on a Friday and you are unable to return on Saturday to place tubes in the freezer, transfer the tubes as late as possible before leaving on Friday.* ***Samples must sit at room temperature for a minimum of 2 hours.***

7. After **24 hours** at room Temperature, transfer the two PAXgene tubes to -70 or **-80°C freezer.** Keep the two **PAXgene™ Blood RNA Tubes at -80 °C** until you ship on dry ice. Both tubes are to be shipped to Coriell. Complete remainder of the Biomarker Sample Laboratory Requisition form.

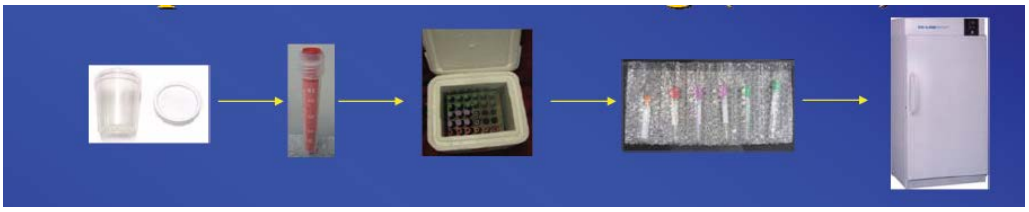
IMPORTANT: Prior to beginning bio-sample collection, be sure that your freezer block has been in the freezer for at least 2 hours or more prior to removing it from the freezer to conduct sample procedures for urine and plasma. The freezer block does not need to remain in the freezer at all times. Also note that the metal freezer block will only maintain a temperature of -70°C to -80°C for 4-5 hours at room temperature.

Urine Sample Protocol

Urine samples will be collected via clean catch method. 50ml of urine will be pipetted into a **50ml screw top polypropylene vial**, frozen on dry ice and stored at -70°C to -80°C until shipment.



An additional 5ml of urine will be pipetted into an **orange screw top tube**, flash frozen in the freezer block and transferred to the -70°C to -80°C freezer until ready for shipment. All tubes must be labeled with participant #, site #, visit # and date of collection. **Label tubes prior to specimen collection.**



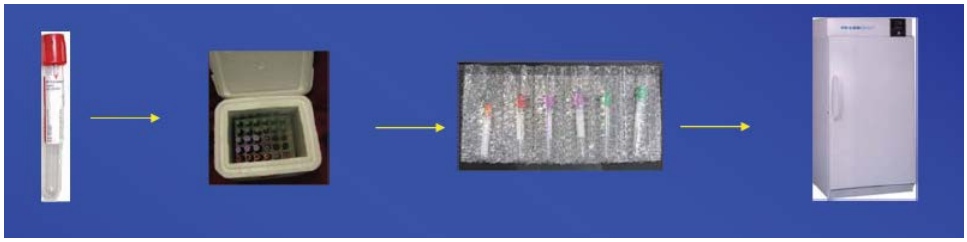
Complete the *2.2 Biomarker Sample Laboratory Requisition (see Appendix XI)* with all pertinent details relating to the urine collection (i.e. time of collection, etc). In the future, the Biomarker Sample Laboratory Requisition form will be entered via the web and/or laptop/tablet. Sites will be prepped to be able to scan and upload the form via the web. Until the site has been trained, they may continue to send the paper Biomarker Sample Laboratory Requisition form via mail.

IMPORTANT: Prior to beginning bio-sample collection, be sure that your freezer block has been in the freezer for at least 2 hours or more prior to removing it from the freezer to conduct sample procedures for urine and plasma. The freezer block does not need to remain in the freezer at all times. Also note that the metal freezer block will only maintain a temperature of -70°C to -80°C for 4-5 hours at room temperature.

Whole Blood and Plasma Samples Protocol

Red-top 5ml tube:

- Whole Blood 5 ml red top vacutainer is drawn
- Immediately place in the freezer block for flash freezing (no spinning required)
- Transfer tube to -70°C to -80°C freezer. Tube should be in a freezer box or tube pouch until ready for shipment.
- Document date, time of draw, time frozen and storage temperature on the *Biomarker Sample Laboratory Requisition* form.



Four (4) plasma tubes (Baseline) or Six (6) plasma tubes (at Follow up):

- Two 6 ml green top (Heparin) vacutainer and two 6ml lavender top (K_2EDTA) vacutainer are drawn at baseline visits. [Three tubes of each are drawn at follow-up visits.]
- Invert tubes 4 times to mix anticoagulant. (if you are drawing multiple participant samples, you may keep the tubes in an ice/water 0 °C for no longer than 40 minutes before centrifuging.
- Centrifuge TUBE 2, 3, 4 & 5 in a refrigerated centrifuge at 4°C according to the following centrifuge dependent schedule below. Note both swing rotor and slant rotor centrifuge heads are acceptable. **NOTE:** The highest time/g force is the preferred method.

g force	Time (minutes)
8000xg	20 minutes
7000xg	25 minutes
6000xg	35 minutes
<6000xg	40 minutes

- The tubes are then immediately flash frozen in the metal freezer block and maintained at -70°C to -80°C until shipment.

- Document date, time of draw, time frozen, storage temperature and spin rate on the *Biomarker Sample Laboratory Requisition* form.
- Send a copy of the *Biomarker Sample Laboratory Requisition* form to the University of Iowa with all other visit paperwork after each visit.

** Tubes 6 & 7will be processed for follow-up visits as well.

STORAGE OF PLASMA AND URINE SAMPLES

- Samples should be stored in -70°C to -80°C freezer until shipment to the NINDS Repository. Samples should be shipped within 2 weeks (US sites) and 4 weeks (international sites) after draw (See "Shipping Procedures" section).

SHIPPING PROCEDURES

NOTE: There are different guidelines for US and International Sites. Please reference Appendix XI.

Collection of Cerebrospinal Fluid (CSF)

Within the 2.2 protocol, CSF collection is an important aspect that NINDS/NIH has requested be incorporated into the PREDICT-HD study in order to examine possible biomarkers unique to CSF that are most closely associated with the disease, hopefully creating a powerful means to measure response to treatments under development now and in the future.

Site personnel will carefully review the 2.2 consent which explains the potential risks, side effects and procedures for the lumbar puncture procedure with participants. Participants, themselves, can only consent to this study component; their legal authorized guardian cannot. For participants willing to undergo a LP, the site coordinator and MD should complete all necessary pre-screen recommendations to ensure safety. For some sites, their ethics boards or MD's may request additional screening protocols; please follow their requirements as well.

Pre-screen Procedures

- ✓ Medication review: all current medications should be documented on the Concomitant Medication Log and MD should verify that the participant is not taking any anti-coagulants (such as warfarin and heparin) and/or anti-platelets (such as aspirin). Participants taking these CANNOT undergo a LP.
- ✓ Physical and Neuro exams: The site investigator, or other designated personnel, should ensure that the participant does not have any medical conditions that would preclude undergoing the procedure.

- ✓ Blood pre-screen labs: 10 ml of the blood will need to be collected and analyzed on-site prior to the LP.
  - plastic 5ml light green PST
  - plastic 3ml light blue Na Citrate
  - plastic 3ml lavender top K_2EDTA

The study coordinator will complete the top portion of the CSF Screening Blood Samples form indicating time of collection and time samples were sent to their local lab for analyses.

Necessary on-site labs include:
- Sodium (Na)
- Potassium (K)
- Chloride (Cl)
- Carbon Dioxide (CO_2)
- Blood Urea Nitrogen (BUN)
- Glucose
- Calcium (Ca)
- Creatinine (Crn)
- Bilirubin Total
- Albumin
- Total Protein
- Aspartate aminotransferase (AST)
- Alanine aminotransferase (ALT)
- Alkaline Phosphatase (ALKP)
- Uric Acid
- Prothrombin time (PT)
- Partial Thromboplastin Time (PTT)
- White Blood Cell Count (WBC)
- Red Blood Cell Count (RBC)
- Hemoglobin (Hb)
- Hematocrit (HCT)
- Platelet Count (PLT)

The study coordinator should request lab results prior to the end of the visit day, insert values into the CSF Screening Blood Samples form and provide to their MD/Site Investigator. Abnormalities in lab values may preclude participation, in particular increased PT/PTT and/or low platelets.

After all pre-screen steps are complete, the MD will decide if he/she supports participant's safety to undergo a LP. The MD MUST sign off on the CSF Screening Blood Samples form prior to the LP.

Setting up for the LP

Site coordinators will be supplied with LP kits which can be provided to the LP physician. On an over bed table, remove the contents of the LP kit from outer plastic packaging, leaving the contents wrapped in their sterile drape. Leave everything wrapped until the person performing the LP is seated, and begins examining the subject.

Feel the outside of the LP kit (still wrapped up) to determine which end contains the spongy swabs. Turn this end toward the person performing the LP and begin unwrapping the kit.

Touch only the outside of the paper wrapper**.** When you grab an edge to unfold it, touch only the folded under portions of the outside of the wrapper. Also, don't let the outside of the wrapper touch any part of the inside. If you touch any part of the inside of the paper wrapper, or if any non-sterile object or outside of the wrapper touches any part of the inside of the wrapper, throw the kit away and start over. If you are in doubt as to whether something touched the inside of the paper wrapper, throw the kit away and start over.

Maintaining the sterile field
Keep in mind that there is usually a lot of staff in the room during an LP, and a big part of assisting with the LP is keeping the field sterile, and keeping people away from it, and reminding people to be careful around it. If anybody touches the inside of the paper wrapper or any part of the contents of the kit, throw the kit away and start over. If you are in doubt as to whether someone touched the kit, throw it away and start over. Also, you are the monitor for whether the person performing the LP has broken sterility – usually by touching something not sterile with a sterile gloved hand. Feel free to be the boss of people if need be. Be assertive.

Tips for clinicians performing lumbar puncture

Optimizing patient comfort and minimizing risk of adverse events.

1. Talk the patient through the procedure -no surprises.

2. Use of a Sprotte 24g atraumatic spinal needle and careful technique are optimal for reducing post-LP headache risk. A pencil point spinal needle such as Spinocan, 22g or 24g may also be used.

3. Use adequate local anesthesia. Use the 25g 1/2" needle and inject lidocaine to raise a skin wheal. Then inject lidocaine using the pattern of a square -first the center and then to all 4 corners. If the subject is thin, do not insert the deep infiltration needle OR the spinal introducer all the way. Use only about 2/3 of their length (to prevent entering the subarachnoid space with anything other than the 24g pencil point spinal needle).

4. Increasing fluid intake immediately after LP is helpful.

5. Be sure to give post-LP care instructions verbally to subject (see below).

Detailed Lumbar Puncture Procedure

Remember, CSF is processed at Room Temperature [64^0F -77^0F (18°C to 25°C)]. Also, a portion of the CSF must be sent to your clinical lab and analyzed within 4 hours of collection.

1. Label participant ID, specimen type (CSF), Visit #, Site # and Date on the collection and aliquot tubes (per section 6.2). Prepare at least 10 aliquot tubes based on the collection of 15mls of CSF.

2. Place aliquot tubes on ice prior to procedure so they are pre-cooled. **Label all aliquot tubes prior to placing on ice.**

3. Perform lumbar puncture using the atraumatic technique.

4. Collect CSF into syringes. After the LP has begun and fluid is being collected, take the first 1-2 mls of CSF from the first syringe and place in the CSF labs tube (PURPLE TOP). **Do not freeze this sample.**

- Send at room temperature to local clinical lab for basic CSF analyses. NOTE: Sample must be analyzed within 4 hours of collection.
  - Cell count (erythrocytes first)
  - Total protein
  - Glucose

5. Collect remaining 15mLs of CSF and transfer to 15 mL conical polypropylene tubes at room temperature, mix gently by inverting 3-4 times. Record time of draw (i.e., once collection is complete) on the Lumbar Puncture data form.

6. Within 15 minutes of collection, spin the remaining CSF sample down at 2000 x g for 10 minutes at **Room Temperature** [64^0F -77^0F (18°C to 25°C)].

- Equivalent rpm for spin at 2000 x g = _____
- While centrifuging record the time of centrifuge start on the Biomarker Sample Requisition form.

7. Pipette (micropipette preferred) 1.5 ml of supernatant directly into labeled, pre-cooled 2-ml microcentrifuge tubes (clear-top, 2 ml microcentrifuge tubes). provided in the kit. This will yield, on average, 8-10 aliquot tubes per participant.

8. Freeze aliquots immediately following processing by transferring to **-80°C Freezer**. If samples cannot be immediately transferred to **-80°C Freezer**, prepare a sufficient amount of dry ice for immediate freezing. Store all samples at **-80°C Freezer** until you ship on dry ice. Complete the remainder of the Biomarker Sample Laboratory Requisition form and ensure timely entry of data.

Post-LP Care Instructions for Participants

IMMEDIATELY FOLLOWING THE SPINAL TAP:

1. You will have a 60-minute rest period during which time your vitals will be taken and you will be provided a light snack if you fasted the evening before.
2. You should continue with increased fluid intake.
3. You should not do any tiring activity for the next 24 hours. This includes things as such:
    a. Lifting
    b. Bending
    c. Housework
    d. Gardening
    e. Vigorous Exercise like jogging or bicycling
    f. Sexual activity
4. You are able to travel in a car or plane the same day of the procedure unless you experience severe side effects
5. If necessary, the study coordinator can arrange for suitable transportation service to your hotel or home if you are unable to drive for any reason.
6. You will receive a follow-up phone call within 3 days of your spinal tap to ask about any post-ST side effects. If you experience any symptoms or require further healthcare consultation, please alert your site investigator using the contact information below.

POTENTIAL SIDE EFFECTS YOU MAY EXPERIENCE:

Mild to moderate headache following lumbar puncture usually appears after 6+ hours and typically resolves within 3-4 days. 30% of individuals are likely to experience a mild to moderate headache.

- Treatment for mild to moderate headache:
    - First, always lie flat and rest. In many cases, this simple task helps relieve the headache.
    - Limit physical activity as much as possible
    - Oral fluids and caffeine are helpful. Drinking a soft drink (e.g. Mountain Dew) is preferable to coffee
    - Tylenol should be used for symptomatic relief. If you cannot tolerate Tylenol, then ibuprofen should be used. **AVOID ASPIRIN**. If they do not relieve the headache, a doctor may prescribe Tylenol with Codeine or similar analgesic.

Severe headache: 0.5% of individuals experience a severe headache.

- If you have a severe headache, severe back pain, nausea, vomiting, visual disturbances, etc. we encourage you to seek consultation from your local physician or emergency room.

Fever can be controlled using Tylenol or ibuprofen. If your fever doesn't subside within 24 hours, please call the study investigator for further assistance.

Redness at the Spinal Tap Area occurs and usually goes away with time and healing.

[**COORDINATORS: Feel free to copy and paste these post-LP instructions into a handout for participants to take home; along with the site personnel contact information.]

FOLLOW UP PHONE CALL AFTER LP

REPORTABLE EVENTS FOLLOWING CSF LP

Appendix XI

Biomarker Sample Laboratory Requisition Form
NINDS Repository Electronic Inventory Spreadsheet Examples
United States Shipping Instructions
International Site Shipping Instructions
Holiday Schedule
Cerebrospinal Fluid (CSF) Related Forms

Biomarker Sample Laboratory Requisition Form

PREDICT–HD 2.0
BIOMARKER SAMPLE LABORATORY REQUISITION
Baseline/Initial Visit

PARTICIPANT NO. ____ SITE NO. ____

VISIT NO. 2 ____ EVAL. DATE ____ (DD) ____ (MMM) ____ (YYYY)

Instructions: Complete information as indicated. Ship these biomarkers to Coriell Institute. Please retain one copy for your records and send the original to Iowa.

1. Were all biomarker samples collected on the same date (0=No, 1 =Yes)? 1. ____

1a. If **YES**, please record date of collection: 1a. ____ (DD) ____ (MMM) ____ (YYYY)

If **NO**, please complete all date fields for each sample:

SAMPLE	TUBE TYPE	DATE COLLECTED dd/mmm/yyyy	Frequency
RNA	**2.5ml Paxgene tube**	/ /	Annual
RNA	**2.5ml Paxgene tube**	/ /	Annual
DNA	**10ml Yellow Top** ACD solution vacutainer tubes	/ /	BL/Initial ONLY
Whole Blood	Plastic **5ml red top** whole blood	/ /	Annual
Plasma	Plastic **6ml green top** lithium heparin vacutainer	/ /	Annual
Plasma	Plastic **6ml lavender top** K2EDTA vacutainer	/ /	Annual
Plasma	Plastic **6ml green top** lithium heparin vacutainer	/ /	Annual
Plasma	Plastic **6ml lavender top** K2EDTA vacutainer	/ /	Annual
Urine	**5ml screw top**	/ /	Annual
Urine	**50ml conical tube**	/ /	Annual

Continued....

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PREDICT–HD 2.0
BIOMARKER SAMPLE LABORATORY REQUISITION
Follow Up Visit

PARTICIPANT NO. ☐☐☐☐ SITE NO. ☐☐☐

VISIT NO. 2☐☐ EVAL. DATE ☐☐ (DD) ☐☐☐ (MMM) ☐☐☐☐ (YYYY)

Instructions: Complete information as indicated. Ship these biomarkers to Coriell Institute. Please retain one copy for your records and send the original to Iowa.

1. Were all biomarker samples collected on the same date (0=No, 1 =Yes)? 1. ☐

1a. If **YES**, please record date of collection: 1a. ☐☐ (DD) ☐☐☐ (MMM) ☐☐☐☐ (YYYY)

If **NO**, please complete all date fields for each sample:

SAMPLE	TUBE TYPE	DATE COLLECTED dd/mmm/yyyy	Frequency
RNA	**2.5ml Paxgene tube**	/ /	Annual
RNA	**2.5ml Paxgene tube**	/ /	Annual
Whole Blood	**Plastic 5ml red top whole blood**	/ /	Annual
Plasma	**Plastic 6ml green top lithium heparin vacutainer**	/ /	Annual
Plasma	**Plastic 6ml lavender top K2EDTA vacutainer**	/ /	Annual
Plasma	**Plastic 6ml green top lithium heparin vacutainer**	/ /	Annual
Plasma	**Plastic 6ml lavender top K2EDTA vacutainer**	/ /	Annual
Plasma	**Plastic 6ml green top lithium heparin vacutainer**	/ /	Annual
Plasma	**Plastic 6ml lavender top K2EDTA vacutainer**	/ /	Annual
Urine	**5ml screw top**	/ /	Annual
Urine	**50ml conical tube**	/ /	Annual

Continued....

 Amendment 2.2 / Last Modified 1 July 2012 / v2.2.0.0

PREDICT–HD 2.0
BIOMARKER REDRAW
Lab Requisition Form

PARTICIPANT NO. ☐☐☐☐ SITE NO. ☐☐☐

VISIT NO. 2☐☐ TODAY'S DATE ☐☐ (DD) ☐☐☐ (MMM) ☐☐☐☐ (YYYY)

Instructions: Complete information as indicated. Ship biomarker samples to Coriell Institute. Please retain one copy for your records and send the original to Iowa.

*****PLEASE NOTE THAT THIS FORM IS ONLY USED FOR INSTANCES OF REDRAWS OR RE-COLLECTION OF ONE OR MORE BIOSAMPLES.**

Indicate which samples were re-collected:

Redrawn? 0=No, 1=Yes	SAMPLE	TUBE TYPE
	RNA	2.5ml Paxgene tube
	RNA	2.5ml Paxgene tube
	DNA	10ml Yellow Top ACD solution vacutainer tubes
	Whole Blood	Plastic 5ml red top whole blood
	Plasma	Plastic 6ml green top lithium heparin vacutainer
	Plasma	Plastic 6ml lavender top K2EDTA vacutainer
	Plasma	Plastic 6ml green top lithium heparin vacutainer
	Plasma	Plastic 6ml lavender top K2EDTA vacutainer
	Plasma	Plastic 6ml green top lithium heparin vacutainer
	Plasma	Plastic 6ml lavender top K2EDTA vacutainer
	Urine	5ml screw top
	Urine	50ml conical tube

Indicate reason redraw was obtained:

☐ Notified by Data Management Core that original biomarker samples for this visit was not viable and new samples needed to be obtained

☐ Biomarkers were not obtained during visit (see Signature Form)

Please complete items 1-16 for each biomarker sample obtained.

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NINDS Repository Sample Record Shipping Form

(Please seek electronic version on SharePoint or PREDICT Management)

Page 1 OF 2

The NINDS Repository PREDICT-HD Sample Record Summary and Shipment Notification	
Site Number	
Principal Investigator	
Institution Name	
Coordinator	
Coordinator's Telephone	
Coordinator's E-mail	
Date Sample(s) Shipped	
FedEx tracking #	
Number of unique individuals represented in this shipment	

Note: This form must be completed and emailed to ninds@coriell.org and predict-management@uiowa.edu **at least 24 hours prior to the arrival of the samples at Coriell.**

In addition, please include a hard copy of this form in the box with your samples.

NINDS Repository Sample Record Shipping Form

(Please seek electronic version on SharePoint or PREDICT Management)

Page 2 OF 2

DATE SAMPLE PREPARED IN THE LAB	4 DIGIT PARTICIPANT ID	3 DIGIT VISIT ID	SPECIMEN TYPE	Number of Tubes	VOLUME (ML)	TUBE TYPE	Comments
			RNA		2.5	PAXgene	
			DNA		10	Yellow ACD Tube	
			plasma		6	Green Heparin 6ml tube	
			plasma		6	Lavender EDTA tube 6ml	
			whole blood		5	Red top SST 5ml tube	
			urine		5	Orange top 5ml tube	
			urine		50	Conical -50 ml	
			CSF		1.5	Cryo tube 2ML	

Shipping Condition and Schedule for Biospecimens (ambient and frozen shipping)

Specimen Type	Shipping Condition	Arrival at Coriell	Shipping Schedule
Whole Blood in ACD Tube (Domestic and International)	• Ambient • Maximal **three (3)** tubes per shipping container	• Ambient same day overnight delivery. • Ambient samples may be shipped Monday – Friday (**preferably Monday – Thursday**), provided samples are received at Coriell within 5 Days of collection.	Same day of blood drawn
Domestic Frozen Specimens	• Dry ice • No more than **two** (2) Tyvek envelopes included per shipping container (two subjects if CSF is not collected; one subject if CSF is collected. See Appendix XI for shipping instruction)	• Frozen shipments must be scheduled for delivery to **arrive at Coriell Tuesday through Thursday**	Up to every two weeks
International Frozen Specimen	• Dry ice • No more than **Five** (5) Tyvek envelopes included per shipping container, in any arrangement.	• Frozen shipments must be scheduled for delivery to **arrive at Coriell Tuesday through Thursday**	Up to every four weeks

****Reminder: Saliva sample should be sent to the University of Iowa!!**

United States
Shipments of 2.2 biomarkers to NINDS Repository at Coriell

IMPORTANT!
Baseline visit AMBIENT SAMPLE MAY BE SHIPPED MONDAY-FRIDAY (PREFERABLY MONDAY-THURSDAY) PROVIDED THEY ARE RECEIVED AT CORIELL WITHIN 5 DAYS OF COLLECTION

Sample Packaging and Shipment Instructions

1. Contact FedEx to confirm service is available and schedule package to be picked up.

2. Notify Coriell of shipment by emailing ninds@coriell.org and predict-management@uiowa.edu the completed Sample Record Summary and Shipment Notification Form.

- **Yellow Top ACD Blood Tube (AMBIENT SHIPMENT)**

3. Insert yellow top ACD tube in the foam-lined plastic box and close securely.

4. Place the plastic container into the clear plastic bag and seal. Enclose this sealed bag in the cardboard shipping container.

5. Apply the UN3373 label to the outside of the cardboard container.

6. Place the cardboard shipping container and the completed Sample Record Summary and Shipment Notification Form in the FedEx Clinical Pak, making sure the UN3373 label is visible through the Clinical Pak, and seal according to the instructions on the envelope.

7. Complete the "From" portion of the provided FedEx air waybill by filling in your name, address and phone number. FedEx is likely to reject or return your shipment without this information.

8. Apply completed FedEx air waybill to outside of package and arrange for FedEx pick up.

9. Ship the sample to Coriell on the day of collection. If sample cannot be shipped the same day as collected, hold at room temperature until shipping can be arranged. Sample must be received at Coriell within 5 days of collection.

- **Frozen Samples (FROZEN SHIPMENT)**

IMPORTANT!
FROZEN SHIPMENTS MUST BE SHIPPED MONDAY THROUGH WEDNESDAY AND SCHEDULED FOR ARRIVAL AT CORIELL TUESDAY THROUGH THURSDAY **No more than two Tyvek envelopes included per shipping container**

10. Insert PAXgene, red-top whole blood, green-top and lavender-top plasma tubes and orange, screw-top urine vial into bubble-wrap slots. Wrap 50 ml polypropylene urine vial within the bubble-wrapped tubes.

11. Place all frozen samples in the provided clear plastic biohazard bag (do NOT remove the absorbent material found in the bag) and seal according to the instructions on the bag. Insert this into the white Tyvek biohazard envelope and seal according to the instructions on the envelope.

12. Place the envelope upright in the provided Styrofoam-lined shipping carton, as shown below:

OPTIONAL: <u>IF CSF is also collected</u>,

13. Place all frozen 1.5 ml aliquots of CSF in the provided cardboard cryobox. Label the outside of the cryobox with the subject ID (four digit number on specimen labels).

14. Place the cryobox in the clear plastic biohazard bag (do NOT remove the absorbent material found in the bag) and seal according to the instructions on the bag. Insert this into the white Tyvek biohazard envelope and seal according to the instructions on the envelope.

15. Place both envelopes upright and side-by-side in the provided Styrofoam-lined shipping carton, as shown below:

16. **<u>FILL</u> the remaining space in the shipping carton with approximately 10 lbs of dry ice, ensuring ice surrounds the envelope and reaches the <u>top</u> of the carton, as shown below:**

17. Place the completed Sample Record Summary and Shipment Notification Form in the package, replace the lid on the Styrofoam carton, and close and seal the outer cardboard shipping carton with packing tape.

IMPORTANT!
Complete the required fields on the FedEx air waybill and Class 9 Dry Ice label, or FedEx may reject or return your package.

18. Complete the FedEx air waybill with the following information
    a. Section 1, "From": fill in your name, address and phone number
    b. Section 6, "Special Handling and Delivery Signature Options": under "Does this shipment contain dangerous goods?" check the boxes for "Yes, Shipper's Declaration not required" and "Dry Ice". Enter the number of packages (1) x the net weight of dry ice in kg.

19. Complete the Class 9 UN 1845 Dry Ice label (black and white diamond) with the following information:
    a. Your name and return address
    b. Net weight of dry ice in kg
    c. Consignee name and address: Coriell Institute, 403 Haddon Ave, Camden, NJ 08103
    d. Do not cover any part of this label with other stickers, including pre-printed address labels.

20. Apply all provided warning labels and the completed FedEx air waybill to outside of package, taking care not to overlap labels.

21. Hold packaged samples in -80°C freezer until time of FedEx pick-up/drop-off.

22. Complete the sample-specific electronic NINDS Repository Sample Record Shipping Form(s) which contains up to 2 tabs. Be sure to complete the tab labeled "Site Info" as well as the tab labeled "Sample Info". Then e-mail to NINDS@coriell.org and predict-management@uiowa.edu prior to shipment.

23. **Shipment of all frozen samples must be Monday through Wednesday with scheduled arrival at NINDS/Coriell Tuesday through Thursday; do not schedule for arrival on holidays (holiday schedule is posted on the SharePoint HOME page and in Appendix VI)**

FROZEN Blood, Plasma, CSF, RNA and urine samples should be shipped to:

NINDS Repository
Coriell Institute for Medical Research
403 Haddon Avenue
Camden, NJ 08103-1559
856- 966-5068 voice
856- 966-5067 fax
NINDS@coriell.org

Australian, Canadian, and European
Shipments of 2.2 biomarkers to NINDS Repository at Coriell

IMPORTANT!
Baseline visit AMBIENT SAMPLE MAY BE SHIPPED MONDAY-FRIDAY (PREFERABLY MONDAY-THURSDAY) PROVIDED THEY ARE RECEIVED AT CORIELL WITHIN 5 DAYS OF COLLECTION

Sample Packaging and Shipment Instructions

1. Contact FedEx to confirm service is available and schedule package to be picked up.

2. Notify Coriell of shipment by emailing ninds@coriell.org and predict-management@uiowa.edu the completed Sample Record Summary and Shipment Notification Form.

- **Yellow Top ACD Blood Tube (INTERNATIONAL AMBIENT SHIPMENT)**

3. Insert yellow top ACD tube in the foam-lined plastic box and close securely.

4. Place the plastic container into the clear plastic bag and seal. Enclose this sealed bag in the cardboard shipping container.

5. Apply the UN3373 label to the outside of the cardboard container.

6. Place the cardboard shipping container and the completed Sample Record Summary and Shipment Notification Form in the FedEx Clinical Pak, making sure the UN3373 label is visible through the Clinical Pak, and seal according to the instructions on the envelope.

7. Complete the FedEx air waybill with the following information
   a. Section 1, "From": fill in your name, address and phone number
   b. Section 6, "Special Handling and Delivery Signature Options": under "Does this shipment contain dangerous goods?" check the boxes for "NO".

8. Apply all provided warning labels and the completed FedEx air waybill to outside of package, taking care not to overlap labels.

9. Complete "**USDA International Declaration Letter Template Human Blood"** (See **Addendum A**). This form is required for samples to pass through US Customs. If not completed and attached, your shipment may be delayed or returned.

   a. Copy the entire template onto your institution's letterhead paper.
   b. Please enter the total number of Vacutainers on the sheet and also sign the form.
   c. This **must** be placed on the outside of the package and should be in the same pouch as the air waybill.

10. Ship the sample to Coriell on the day of collection. If sample cannot be shipped the same day as collected, hold at room temperature until shipping can be arranged. Sample must be received at Coriell within 5 days of collection

IMPORTANT!
FROZEN SHIPMENTS MUST BE SCHEDULED FOR ARRIVAL AT CORIELL TUESDAY THROUGH THURSDAY **No more than five Tyvek envelopes included per shipping container**

- **Frozen Samples (INTERNATIONAL FROZEN SHIPMENT)**

11. Insert PAXgene, red-top whole blood, green-top and lavender-top plasma tubes and orange, screw-top urine vial into bubble-wrap slots. Wrap 50 ml polypropylene urine vial within the bubble-wrapped tubes.

12. Place all frozen samples in the provided clear plastic biohazard bag (do NOT remove the absorbent material found in the bag) and seal according to the instructions on the bag. Insert this into the white Tyvek biohazard envelope and seal according to the instructions on the envelope.

13. Place the envelope upright in the provided Styrofoam-lined shipping carton (Thermal 350), as shown below:

IMPORTANT!
Thermal 350 Styrofoam-lined Shipping Carton May Hold Up To 5 Tyvek Envelopes

14. **<u>FILL</u> the remaining space in the shipping carton with up to 40 lbs of dry ice, ensuring ice surrounds the envelope and reaches the <u>top</u> of the carton, as shown below:**

15. Place the completed Sam ad Shipment Notification Form in the package, replace t carton, and close and seal the outer cardboard shipping carton with packing tape.

IMPORTANT!
Complete the required fields on the FedEx air waybill and Class 9 Dry Ice label, or FedEx may reject or return your package.

16. Complete the FedEx air waybill with the following information
    a. Section 1, "From": fill in your name, address and phone number
    b. Section 6a, "Special Handling": under "Does this shipment contain dangerous goods?" check the boxes for "Yes, Shipper's Declaration not required" and "Dry Ice". Enter the number of packages (1) x the net weight of dry ice in kg.

17. Complete the Class 9 UN 1845 Dry Ice label (black and white diamond) with the following information:
    a. Your name and return address
    b. Net weight of dry ice in kg
    c. Consignee name and address: Coriell Institute, 403 Haddon Ave, Camden, NJ 08103
    d. Do not cover any part of this label with other stickers, including pre-printed address labels.

18. Apply all provided warning labels and the completed FedEx air waybill to outside of package, taking care not to overlap labels.

19. Complete "**USDA International Declaration Letter Template Human Biospecimens"** (See **Addendum B**). This form is required for samples to pass

through US Customs. If not completed and attached, your shipment may be delayed or returned.

a. Copy the entire template onto your institution's letterhead paper.
b. Please enter the total number of Vacutainers on the sheet and also sign the form.
c. This **must** be placed on the outside of the package and should be in the same pouch as the air waybill.

***Hold packaged samples in -80°C freezer until time of FedEx pick-up/drop-off.

20. Complete the sample-specific electronic NINDS Repository Sample Record Shipping Form(s) which contains up to 2 tabs. Be sure to complete the tab labeled "Site Info" as well as the tab labeled "Sample Info". Then e-mail to NINDS@coriell.org and predict-management@uiowa.edu prior to shipment.

21. **Shipment of all frozen samples must be scheduled for arrival at NINDS/Coriell Tuesday through Thursday; do not schedule for arrival on holidays (holiday schedule is posted on the SharePoint HOME page and in Appendix VI)**

FROZEN BLOOD , Plasma, CSF, RNA and urine samples should be shipped to:

NINDS Repository
Coriell Institute for Medical Research
403 Haddon Avenue
Camden, NJ 08103-1559
856- 966-5068 voice
856- 966-5067 fax
NINDS@coriell.org

Addendum A: International Ambient Shipment

USDA International Declaration Letter Template Human Biospecimens

Detailed description of material:

Human blood specimens

# of glass 10ml Vacutainers _____
# of glass 5ml Vacutainers _____

Human material containing no animal material.

Material not obtained from humans that have been exposed to any livestock or poultry disease agent exotic to the United States.

This material is not of tissue culture origin.

Biological Substance, Category B UN3373

NON-INFECTIOUS

For research only

For in vitro use only

Not for plant or animal use

No commercial value

DO NOT REFRIGERATE!

Signature:

Addendum B: International Frozen Shipping

USDA International Declaration Letter Template Human Blood

Detailed description of material:

Frozen human biospecimens:
# of plastic vials _____
# of glass 5/6 ml Vacutainers _____
# of glass 15 ml plastic tubes _____
# of glass 50 ml plastic tubes _____

Human material containing no animal material.

Material does not come from a facility where work with exotic viruses affecting livestock and avian species is conducted.

Material is not recombinant.

Biological Substance, Category B UN3373

NON-INFECTIOUS

For research only

For in vitro use only

Not for plant or animal use

No commercial value

Signature:

HOLIDAY SCHEDULE

Avoid shipping for delivery on or around these dates.

2012-2013 HOLIDAYS FOR NINDS REPOSITORY AT CORIELL INSTITUTE and University of Iowa

Thanksgiving Day	Thursday, November 23, 2012
Day after Thanksgiving Day	Friday, November 24, 2012
Christmas Day	Tuesday, December 25, 2012
New Year's Day	Tuesday, January 1, 2013
Martin Luther King, Jr Day	Monday, January 21, 2013
President's Day	Monday, February 18, 2013
Memorial Day	Monday, May 27, 2013
Independence Day	Thursday, July 4, 2013
Labor Day	Monday, September 2, 2013
Thanksgiving Day	Thursday, November 28, 2013
Day after Thanksgiving Day	Friday, November 29, 2013
Christmas Day	Wednesday, December 25, 2013

CEREBROSPINAL FLUID (CSF) FORMS

PREDICT-HD 2.0
CSF Collection Follow Up Phone Call

All items must be completed.

PARTICIPANT NO. ☐☐☐☐ SITE NO. ☐☐☐

VISIT NO. 2☐☐ PHONE CALL DATE ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

INSTRUCTIONS: To be completed by qualified medical professional within 72 hours (3 days) of CSF sample collection. Site should attempt to reach the participant at least once per day, for a minimum of 3 days, after the CSF draw.

1. Was contact made during this telephone call? (0 = No, 1 = Yes) 1. ☐

1a. If No (0) please indicate the reason: 1a. ☐
1 = phone disconnected
2 = multiple messages left on answering machine were not returned
3 = other (specify) _____

If YES (contact was made), ask the following questions:

2. Has he/she experienced any unusual symptoms or medical problems since the CSF collection? (0=No, 1=Yes) 2. ☐

2a. If yes, please describe here:
_____
_____
_____
_____
_____

3. Has there been a serious adverse event related to the CSF collection? (0=No, 1=Yes) 3. ☐
(e.g., Death; any life-threatening adverse event; hospitalization; any persistent or significant disability or incapacity; outpatient medical intervention required)

***If yes, the site coordinator must complete the Reportable Events Log and Incident Report Form, and forward to Central Study Management predict-management@uiowa.edu within 72 hours of the site learning of the event.**

Complete only if YES to questions 2 and/or 3:

Please describe the event and what follow up was advised to the participant:
_____
_____
_____
_____

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PREDICT–HD 2.0

CSF Collection Laboratory Requisition

PARTICIPANT NO. ☐☐☐☐ SITE NO. ☐☐☐

VISIT NO. 2 ☐☐ EVAL. DATE ☐☐ ☐☐☐ ☐☐☐☐ (DD MMM YYYY)

Instructions: Complete information as indicated. CSF samples should be sent to Coriell Institute. Please retain one copy for your records and send the original to Iowa.

1. Date of last food intake: 1. ☐☐ ☐☐☐ ☐☐☐☐ (DD MMM YYYY)

2. Time of last food intake: 2. ☐☐:☐☐ (24 hour clock)

3. Did the participant fast for twelve hours prior to CSF draw? (0=No, 1=Yes) 3. ☐

***NOTE** proper fasting means the participant ingested nothing but water during this 12-hour period. The use of tobacco products, regular medication, and dental hygiene products are acceptable. The use of gum, sugar-free gum, coffee, tea, and sodas (even diet sodas) is prohibited.

4. Is the participant on medication for HD? (0=No, 1=Yes) 4. ☐

4a. Date of most recent HD medication dose: 4a. ☐☐ ☐☐☐ ☐☐☐☐ (DD MMM YYYY)

4b. Time of most recent HD medication dose: 4b. ☐☐:☐☐ (24 hour clock)

5. PRE-COLLECTION VITALS

5a. Time (24 hour clock)	___:___ (24 hour clock)
5b. Temperature (in Celsius)	°C
5c. Arm used to measure blood pressure (1=Left Arm; 2=Right Arm)	
5d. Seated blood pressure (systolic/Diastolic mmHg)	/
5e. Seated heart rate (beats per minute)	bpm
Comments:	

6. Was Cerebrospinal fluid (CSF) collected? (0=No, 1=Yes) 6. ☐

6a. Date CSF collected: 6a. ☐☐ ☐☐☐ ☐☐☐☐ (DD MMM YYYY)

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PREDICT–HD 2.0

CSF Screening Blood Samples

PARTICIPANT NO. | | | | | SITE NO. | | |

VISIT NO. 2 | | EVAL. DATE | | | | | | | | | |

DD MMM YYYY

Instructions: Complete information as indicated.

Sample Collected? 0=No, 1=Yes	Sample Type	Time Collected (24 hour clock)	Time Sent to Lab (24 hour clock)
	Plastic 3ml Lavender top K2EDTA	:	:
	Plastic 5ml Green PST	:	:
	Plastic 3 ml Light Blue Na Citrate	:	:

Lab	Results	Comments
Sodium (Na)		
Potassium (K)		
Chloride (Cl)		
Carbon Dioxide (CO2)		
Blood Urea Nitrogen (BUN)		
Glucose		
Calcium (Ca)		
Creatinine (Crn)		
Billirubin Total		
Albumin		
Total Protein		
Aspartate aminotransferase (AST)		
Alanine aminotransferase (ALT)		
Alkaline Phosphatase (ALKP)		
Uric Acid		
Prothrombin time (PT)		
International Normalized Ratio (INR)		
Partial Thromboplastin Time (PTT)		
White Blood Cell Count (WBC)		
Red Blood Cell Count (RBC)		
Hemoglobin (Hb)		
Hematocrit (HCT)		
Platelet Count (PLT)		

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PREDICT–HD 2.0

General Neurological Exam

PARTICIPANT NO. ☐☐☐☐ SITE NO. ☐☐☐

VISIT NO. 2☐☐ EVAL. DATE ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Instructions: Complete information as indicated.

1. Cranial Nerves 0=Normal; 1=Abnormal (if abnormal, describe briefly); 2=Not tested; 3=Unable to test	
1a. I	1a. ☐
1b. II	1b. ☐
1c. III, IV, VI	1c. ☐
1d. V	1d. ☐
1e. VII	1e. ☐
1f. VIII	1f. ☐
1g. IX, X	1g. ☐
1h. XI	1h. ☐
1i. XII	1i. ☐
Motor System	
2. Muscle Strength 0=Normal; 1=Abnormal (if abnormal, describe briefly); 2=Not tested; 3=Unable to test	
2a. Right Arm	2a. ☐
2b. Left Arm	2b. ☐
2c. Right Leg	2c. ☐
2d. Left Leg	2d. ☐

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PREDICT–HD 2.0

General Physical Exam

PARTICIPANT NO. ☐☐☐☐ SITE NO. ☐☐☐

VISIT NO. 2☐☐ EVAL. DATE ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Instructions: Complete information as indicated.

Organ System Abnormalities By Examination
Use the following Key for items 1-11:
0=Normal
1=Abnormal (if abnormal, describe briefly)
2=Not tested
3=Unable to test

1. Skin	1. ☐
2. Head/Neck/Lymphatic	2. ☐
3. Eyes	3. ☐
4. Ears/Nose/Throat	4. ☐
5. Lungs	5. ☐
6. Cardiovascular (including peripheral vascular)	6. ☐

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PREDICT–HD 2.0
CSF SCREENING VITALS

All items must be completed

PARTICIPANT NO. ☐☐☐☐ SITE NO. ☐☐☐ VISIT NO. 2☐☐

TIME (24 hour clock) ☐☐:☐☐ EVAL. DATE ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

To be completed in conjunction with the General Physical Exam for CSF Screening purposes.

1. WEIGHT (in Kilograms) 1. ☐☐☐.☐ (kg)
2. HEIGHT (in Centimeters) 2. ☐☐☐.☐ (cm)
3. TEMPERATURE (in Celsius) 3. ☐☐.☐ °C
4. ARM USED TO MEASURE BLOOD PRESSURE (1 = Left Arm; 2 = Right Arm) 4. ☐
5. SEATED BLOOD PRESSURE (Systolic/Diastolic mmHg) 5. ☐☐☐ / ☐☐☐
6. SEATED HEART RATE (Beats Per Minute) 6. ☐☐☐
7. COMMENTS:

_____

_____

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