22. Specimens for NIDDK Repository

Archive Note: All FHN serum and plasma collected during FHN Trials and Extension Studies are stored at NIDDK's Central Biorepository at Information Management Services, Inc. (IMS) in Maryland. Permission to use biosamples must be requested through NIDDK at **https://www.niddkrepository.org**.

22.1 Background

Participants who are enrolled in the FHN Study will be invited to volunteer to provide biological samples to be stored for use in possible future studies. A separate repository informed consent will be required, although it may be part of the main consent form (Note: NIH approval is required for Repository Consents before specimens can be taken out of the Repository). A template repository consent form is provided in Appendix A. Among those participants who consent for storage of biological specimens, pre- and post-dialysis serum and plasma specimens will be collected at study months baseline, 4, and 12 for the Daily Trial and at study months baseline, 5, and 14 for the Nocturnal Trial. At each time point, the samples from U.S. centers will be shipped to the NIDDK Biosample Repository at Fisher BioServices, Germantown, Maryland.

See Section 22.6- 22.8 for when and how to ship samples from Canadian centers.

Contact information can be found in the FHN Address Directory. For general questions and biosample shipment notification, use 'bio-niddkrepository@fishersci.com."

22.2 Schedule, Type and Volume of Samples

Blood Samples Collected for NIDDK Repository

Specimen Type	Collection Time	Collection Periods*		
		Baseline	Month 4 (5)	Month 12 (14)
Serum	Pre-dialysis	3 x 7.5 ml	2 x 7.5 ml	3 x 7.5 ml
	Post-dialysis	1 x 7.5 ml	1 x 7.5 ml	1 x 7.5 ml
Plasma	Pre-dialysis	2 x 8 ml	2 x 8 ml	2 x 8 ml
	Post-dialysis	1 x 8 ml	2 x 8 ml	1 x 8 ml
Totals		54 ml	52.5 ml	54 ml

* Collection months in parentheses are specific to the Nocturnal Trial.

22.3 Training Requirements for Personnel Sending Samples

Each person shipping diagnostic specimens should be trained and certified according to DOT and IATA regulations. Someone at each institution will be responsible for training the appropriate personnel.

For U.S. Centers only: Before sending FHN patient specimens to Fisher BioServices, each U.S. center will participate in a trial labeling and mailing of sample vacutainer tubes. All study personnel who will potentially be shipping specimens to Fisher should participate in the preparation of this test package.
Dummy tubes will be supplied by Fisher BioServices and dummy labels will be supplied by the DCC for this exercise. The coordinators will label and ship water in a set of tubes with the aim of correctly recording the IDs on both the collection tubes and the mail-in form (# 255). Fisher personnel will evaluate the material upon receipt and notify the Center and DCC when problems are encountered. Coordinators may be required to repeat the exercise before sending actual patient samples. Approval of the test kit is required before a U.S. center can enroll patients.

For Canadian Centers only: Before sending FHN patient specimens to Fisher BioServices, each Canadian center will participate in a trial aliquoting, labeling and mailing of sample cryovials on dry ice. All study personnel who will potentially be shipping specimens to Fisher should participate in the preparation of this test package.

A dummy test kit containing vacutainers, cryovials, a specimen box, and mailing labels will be supplied by Fisher BioServices and dummy labels will be supplied by the DCC for this exercise. The coordinators will label and ship frozen water in a set of cryovials with the aim of correctly recording the IDs on both the cryovials and the mail-in form (# 256). Fisher personnel will evaluate the material upon receipt and notify the Center and DCC when problems are encountered. Coordinators may be required to repeat the exercise before sending actual patient samples. Approval of the test kit is not required before a Canadian center can enroll patients but needs to be completed prior to collecting and shipping actual patient samples.

22.4 Logistics for Biosample Repository for U.S. Centers

Overview: The BioRepository will provide sample collection kits including the necessary blood collection tubes, packing and shipping materials, and Federal Express labels for collection and shipping of the samples. The sample collection kits will be shipped to the clinical centers by Fisher. The tube labels to be used with all repository specimens will be supplied to the clinical centers by the DCC with detailed completion instructions provided. The tube labels include pre-printed 3-digit identification numbers, in which the first 3 digits designate the NIDDK BioRepository Site Identification code; the study team member will write in the FHN Participants' ID in the final 6 spaces on the label. The labels will also include two spaces in which the study staff should mark the participant's FHN alpha code, which will be used as an alternative ID by Fisher BioServices. Circle the appropriate type of specimen (plasma/serum) and the time of collection (pre-HD/post HD). Tubes should be labeled immediately prior to when blood is drawn from the patient.

The tubes should be centrifuged prior to shipment, at room temperature, within 2 hours after the draw, and then refrigerated. Follow the procedure identified in Section 22.5 for specific processing information.

For consenting participants, study staff will fill the number of pre- and post-dialysis serum shipping tubes (SST tubes) and pre- and post-dialysis plasma shipping tubes (PST tubes) and then store them in a refrigerator at +4 degrees Centigrade that is roughly equivalent to 39 degrees

Fahrenheit. When enough tubes are collected, they should be shipped refrigerated and in bulk to Fisher BioServices using the shipping kits and packing materials provided by Fisher.

A completed paper copy of the U.S. Biological Specimen Repository Mailing Form (Form # 255) should also be included in the kit shipped to Fisher. The information on the form must also be entered in the database.

On arrival at the BioRepository, a Fisher BioServices staff member will divide the serum and plasma into aliquots (twenty 0.2 mL aliquots for the first 4 mL of both serum and plasma, and 0.5 mL aliquots for the remainder) and then freeze the aliquots for storage.

22.5 Fisher BioServices Repository Procedure Instructions for U.S. Centers

1. Be sure that the vacutainer tubes have not expired. Check that the date shown above "Exp" in the lower right corner of the BD label is equal to or later than the current month.

2. Complete and attach the participant I.D. labels provided by the DCC to the blood samples immediately prior to collection. Use the labels provided and place them lengthwise on the tubes. Circle whether the sample is serum or plasma and the timing of the collection either pre-HD or post HD. DO NOT write the participant's name or any other personal identification information (e.g., SS#, DOB) on the tubes.

Sample label:

5 x x - __ __ __ __ __ __ - __ __
Serum Plasma
Pre-HD Post-HD

The tube labels include pre-printed 3-digit identification numbers, in which the first 3 digits designate the NIDDK BioRepository Site Identification code; the study team member will write in the FHN Participants' ID in the final 6 spaces on the label. The labels will also include two spaces in which the study staff should mark the participant's FHN alpha code, which will be used as an alternative ID by the BioServices Repository.

3. Collect the specimen in the appropriate container; either SST/PST vacutainer tube.

4. After filling:
   Invert each SST tube gently at least 5 times to mix the blood with the additives. Let the SST tubes stand in a rack at room temperature for at least 30 minutes or until the blood is separated, but not longer than 60 minutes prior to centrifuging SST tubes for at least 15 minutes at 1300 g. Blood tubes containing anti-coagulants such as heparin or warfarin may take longer to clot in SSTs so it requires a longer centrifugation time.

   Invert each PST tube 8-10 times to mix the blood with the additives. PST tubes can be centrifuged immediately. Centrifuge the PST for at least 10 minutes at 1300 g.

Then move the tubes to the refrigerator until the shipment is ready to be sent. Be sure that the refrigerator is securely closed.

5. Double check the subject ID, and verify that ID information on the vacutainer tubes matches that on the U.S. Biological Specimen Repository Mailing Form # 255.

6. Date and identify the person completing the NIDDK Biological Specimen Shipment Form (#255). Make a copy of each form; keep the copy and send the original with the shipment.

7. Prepare shipments for FedEx pickup on Monday through Thursday. ***No Friday shipments, please.*** The facility is not fully operational on Saturday and Sunday when the package would be delivered. If there must be an exception, please coordinate with the Biosample Repository (see item 10 under Assembling the Shipper) before close of business on Thursday (5 pm, EST). Keep in mind major U.S. holidays when shipping.

8. Assemble the package according to the instructions for the refrigerated shipment.

9. Call Federal Express, 1-800-GO-FEDEX (1-800-463-3339). Give them the account number (in Section 7 - Payment) of the pre-printed FedEx Air bill, and your pickup address. FedEx will dispatch a courier to pick up the package.

10. Notify Fisher BioServices at 'bio-niddkrepository@fishersci.com' or by fax when you have scheduled the pickup and provide them the Federal Express tracking number(s). Use the contact information in the FHN Address Directory.

Assembling the FHN Refrigerated Laboratory Shipper

1. Insert each type of vacutainer tube into a separate bubble wrap pouch.
2. Place the pouches with a white absorbent strip, each inside a leak proof, zip-lock bag. Squeeze out the air and seal the bags.
3. Place a frozen ice pack in the bottom of the foam cooler. Put a piece of bubble wrap on top of the ice pack to separate it from the zip-lock bags.
4. Place the zip-lock bags containing the vacutainer tubes on top of the bubble wrap. If necessary, add additional packing to prevent contents from shifting.
5. Place the lid on the foam cooler. Place the completed shipping document (Mailing Form #255) on top of the cooler.
6. Close and tape the outer cardboard box.
7. Stick the label "UN3373 DIAGNOSTIC SPECIMENS" on the top of the box in the upper left corner.
8. Place the repository address label on the top of the box on the upper right corner.
9. Use the pre-printed Fed Ex air bill to ship the specimens to the repository. Fill in the date, your return address, and phone number in Section 1. Leave "Sender's FedEx Account Number" blank.
10. Ship only on Mondays - Thursdays. **PLEASE DO NOT SEND** shipments on FRIDAYS for Saturday delivery. **The tubes can be refrigerated and stored through the weekend and then sent on Monday.**
11. In Section 6, check the "No" block indicating no dangerous goods are contained in the shipment. Attach the airbill to the side of the box, opposite "Rush!! Perishable Shipment".
13. **Call Federal Express, 1-800-GO-FEDEX (1-800-463-3339)**. Give them the account number in Section 7, Payment, of the pre-printed FedEx Air bill, and your pickup address. FedEx will dispatch a courier to pick up your package.
12. In Section 7, enter "1" under "Total Packages", and a total weight of 2 lbs. Follow the peel and stick instructions on the back of the air bill.

US Fedex airbill needs to be added here

22.6 Logistics for Biosample Repository for Canadian Centers

The BioRepository will provide sample collection kits including the necessary blood collection tubes, cryovials, labels, freezer boxes, packing and shipping materials, and International Federal Express labels for collection and shipping of the samples. Additional documentation will be required to ship biological samples from Canada to the U.S. (see Sections 22.6-22.8 of the MOP.

The sample collection kits will be shipped to the Canadian centers by Fisher BioServices. The aliquot labels to be used with all repository specimens will be supplied to the Canadian centers by Fisher. The cryovial labels will include pre-printed 9-digit identification numbers, in which the first 3 digits designate the NIDDK BioRepository Site Identification code and the final 6 digits designate the participant's FHN Participant ID. The labels will also include two spaces in which the FHN Center should mark the participant's FHN alpha code, which will be used as an alternative ID by the Biosample Repository. After adding the participant's alpha code, serum or plasma and timing of the collection (pre-HD/post HD), the aliquot labels provided by Fisher should be placed on each cryovial prior to placing in a -70^{o}C (or greater) freezer.

For consenting participants, the FHN Center will collect the number of pre- and post-dialysis serum shipping tubes (SST tubes) and pre- and post-dialysis plasma vacutainers (PST tubes), aliquot the serum and plasma, place in a freezer box, and then store in -70^{o}C (or greater) freezer.

When enough samples are collected, they should be shipped on dry ice to Fisher BioRepository using the shipping kits and packing materials provided by Fisher. Regardless of the number of specimens stored, specimens should be shipped on a *quarterly* basis.

A completed paper copy of the International Biological Specimen Repository Mailing Form (Form # 256) for each participant should also be included in the kit shipped to Fisher. The information on the form must also be entered in the database.

On arrival at the BioRepository, a Fisher staff member will count the number of aliquots received for both serum and plasma and report any discrepancies to the shipping center and the DCC. Fisher will then place the aliquots in frozen storage.

22.7 Fisher Biosample Repository Procedure Instructions for Canadian Centers

1. Be sure that the SST and PST vacutainer tubes have not expired. Check that the date shown above "Exp" in the lower right corner of the BD label is equal to or later than the current month.

2. Complete and attach the participant I.D. labels provided by the DCC to the blood samples immediately prior to collection. Use the labels provided and place them lengthwise on the cryovials. Circle whether the sample is serum or plasma and the timing of the collection either pre-HD or post HD. DO NOT write the participant's name or any other personal identification information (e.g., SS#, DOB) on the tubes.

Sample label:

5 x x - __ __ __ __ __ __ - __ __
Serum Plasma
Pre-HD Post-HD

The tube labels include pre-printed 3-digit identification numbers, in which the first 3 digits designate the NIDDK BioRepository Site Identification code; the study team member will write in the FHN Participants' ID in the final 6 spaces on the label. The labels will also include two spaces in which the study staff should mark the participant's FHN alpha code, which will be used as an alternative ID by the BioService Repository.

3. Collect the specimen in the appropriate container; either SST/PST vacutainer tube.

4. After filling:
   Invert each SST tube gently at least 5 times to mix the blood with the additives. Let the SST tubes stand in a rack at room temperature for at least 30 minutes or until the blood is separated, but not longer than 60 minutes prior to centrifuging SST tubes for at least 15 minutes at 1300 g. Blood tubes containing anti-coagulants such as heparin or warfarin may take longer to clot in SSTs so it requires a longer centrifugation time.

   Invert each PST tube 8-10 times to mix the blood with the additives. PST tubes can be centrifuged immediately. Centrifuge the PST for at least 10 minutes at 1300 g.

5. Divide the serum and plasma into aliquots: twenty 0.2 mL aliquots for the first 4 mL of both serum and plasma, and 0.5 mL aliquots for the remainder. Prepare the aliquots for storage by placing them in the freezer box and then placing the specimen box(es) in -70^{o}C (or greater) freezer.

   Note: If more than one patients' samples are drawn on the same day, more than one patients' aliquots can be placed in one freezer box as there are 81 slots available. Keep an empty row between each patients' samples to delineate the start of another patient's samples. However, do not separate one patient's samples into two boxes.

6. Double check the subject ID, and verify that ID information on the aliquots match that on the International NIDDK Specimen Shipment Form (# 256). Store the completed Form 256 until a sample shipment is ready to be sent to Fisher.

7. Date and identify the person completing the International NIDDK Specimen Shipment Form (# 256). Make a copy of each form; keep the copy and send the original with the shipment when it is time to do so.

8. Prepare shipments for FedEx pickup on a Monday or Tuesday in case there is a customs delay before the weekend.. Keep in mind the various major holidays for both Canada and U.S.

9. Assemble the package according to the instructions for dry ice shipping.

10. **Schedule a pickup with your local FedEx office**. Give them the repository account number, the time that pickup is required, the type of samples being sent, the number and type of boxes being shipped, and whether dry ice is required.

11. Notify Fisher BioServices at 'bio-niddkrepository@fishersci.com' or by fax when you have scheduled the pickup and provide them the Federal Express tracking number(s). Use the contact information in the FHN Address Directory.

22.8 Canadian Dry Ice Shipping Instructions - Instructions for Large Diagnostic Shipper, International (E-65)

1. Place the specimen box containing the frozen aliquots and the absorbent strip inside the inner leak-proof plastic bag. Seal the bag.
2. Place the plastic bag inside the Tyvek envelope by placing the box inside the far end of the long pocket of the envelope. Crease the envelope near the middle, fold the envelope over, and place the end of the envelope containing the box inside the short pocket on the opposite side of the envelope. Push the box firmly into the short end of the envelope.

3. Put a layer of dry ice in the bottom of the box. (You can use dry ice rice pellets or blocks). Place up to 5 Tyvek envelopes containing boxes on the dry ice.

4. Fill the remainder of the space in the shipper with dry ice up to about four inches from the top.

5. Put the foam insert on top of the dry ice in the opening. Place the original Form 256s inside a zip-lock bag, and set it on top of the foam insert under the lid flaps.

6. Close and tape the cardboard box.

7. Attach all labels to the same side of the box:
    a. Affix the dry ice label to the side of the box in the upper right corner. Enter the weight of dry ice in kilograms.
    b. Place the “UN3373 Diagnostic Specimens” label on the top, center, to the left of the dry ice label.
    c. Place the small repository address label below the “Up” arrows.
    d. Affix the document pouch below the dry ice label.

8. Use the pre-printed International air bill to ship the specimens to the NIDDK Biosample Repository at Fisher BioServices.
    a. Place the air bill along with the completed declaration statement and customs invoice inside the document pouch.
    b. If necessary, attach the documents to the lower right corner of the box below the dry ice label.

9. **Schedule a pickup with your local FedEx office**. Give them the repository account number, the time that pickup is required, the type of samples being sent, the number and type of boxes being shipped, and that dry ice is required.

10. Notify Fisher BioServices at 'bio-niddkrepository@fishersci.com' or by fax when you have scheduled the pickup and provide them the Federal Express tracking number(s). Use the contact information in the FHN Address Directory.

11. Notify the repository of the shipment and tracking number on the day the package is picked up by the courier.

International Fedex airbill here:

You will need the following documents needed for international shipments

DECLARATION STATEMENT
Importation of Diagnostic Specimens into the USA

The contents of this package are as follows:

- Frozen human serum and plasma in leak proof containers.
- These samples have not been exposed to any animal derived materials such as products derived from livestock or avian disease agents.
- This material is not of tissue culture origin.
- These samples are not known to be infectious or contagious.
- **Diagnostic specimens packed in compliance with Packing Instruction 650 (IATA).**

These samples are being shipped to the NIH/NIDDK Biosample Repository, Germantown, MD, USA, for investigational purposes funded under the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Central Repositories - Biosample (Contract #N01-DK-3-2608). Samples are packed in the appropriate containers and are perishable. Specimens are being collected for laboratory analysis and are not known to be infectious. **Please do not delay.**

These samples are for investigational purposes only and have not been screened for HIV or Hepatitis B or C.

These specimens have been packaged, labeled, and shipped in accordance with International Air Transport Association (IATA) regulations.

These materials are being used for medical studies and have no commercial value.

Principal Investigator (Signature)	Date
Printed Name	Organization

22.9 Access to Data and Privacy

The Fisher Repository will be under the supervision of an Institutional Review Board (IRB) in accordance with Department of Health and Human Services regulations at 45 CFR 46 (The Common Rule). This research material may only be utilized in accordance with the conditions stipulated by the Repository IRB.

During the course of the FHN Trials all studies employing biosamples from FHN participants stored at the Fisher repositories must receive approval from the FHN Clinical Trial Ancillary Studies Committee and from the FHN Steering Committee. The process for submission of ancillary studies is described in Section 27 of the MOP. Section 26 also provides guidelines for conduct and publication, which must be adhered to by all ancillary studies making use of the FHN specimens.

The FHN Steering Committee will relinquish its authority over the FHN specimens residing in the biorepositories following the completion of the FHN Trials. Subsequent to this time, an appropriate external panel appointed by NIH will review all requests to use Repository samples. That panel will include a bioethicist and other individuals with expertise in one or more areas including human genetics, clinical research, epidemiology, physiology, and genetics of complex traits, statistical analysis, and molecular genetics research. NIH Program and Review staff is excluded from membership on this panel, but can provide appropriate guidance, background information, and technical assistance.

Requests will be reviewed based on:

1. Consistency with the terms of the informed consent under which the sample was submitted

2. The experience and qualifications of the applicant principal investigator and co-investigators to store and handle the requested materials safely and carry out the study

3. The adequacy of research environment to ensure safe handling of the requested materials and to carry out the study

4. Ethical considerations

5. The significance of the proposed research project

6. The adequacy of proposed research design

7. The adequacy of the applicant principal investigator's funding resources to support the proposed study

8. The balance between potential exhaustion of a limited set of samples versus the relative importance of the research question

22.10 Usage Agreement

Every recipient investigator will be obligated to sign a Usage Agreement that stipulates the following conditions:

1. The project has the written approval, and continuing supervision, from an IRB that has executed an applicable Assurance with the Office for Human Research Protections for each research project that proposes to use human biological material acquired from the repository.

2. Recipient investigators shall conduct only research that is encompassed within the scope of the associated Informed Consent Document, as applicable.

3. Recipient investigators shall not attempt to ascertain personally identifiable information about the sample sources.

4. Recipients shall return all new data derived from the samples and/or data received within one year after receipt of samples and/or data, or upon publication of research in which the new data were presented, whichever comes first, and annually thereafter. This will continue until the Research Project is completed.

5. Recipient investigators shall not provide human biological material acquired from the repository to any other investigator, unless directed to do so by the NIDDK. Unused samples should be returned to the repository. All samples must be destroyed or returned to the repository after the approved period of use.

22.11 Withdrawal of Patient Consent for Usage of Repository Specimens

Patients who have consented and provided biospecimens (e.g., serum and plasma) to the NIDDK Repository can withdraw their consent for using their samples in research studies. During the study, the patient should make this request to the clinical center that enrolled them, who will then notify the DCC using the patient's ID and alpha code. The DCC will instruct the Repository to

destroy this patient's samples. After the study ends the patient should send a written request to: Mr. Shu-Cheng Chen, USRDS: 914 South 8th Street, Suite D-206, Minneapolis, Minnesota 55404, U.S.A. and provide their name and SSN. USRDS will use the matched patient ID and alpha code to notify the Repository to destroy this patient's samples.

Appendix A. Template Repository Consent for Provision of Biorepository Samples

This template consent can be downloaded from the FHN web page. Note: NIH approval is required for each IRB approved Repository consent before specimens from the FHN center's patients can be taken out of the Repository.

CONSENT TO PARTICIPATE IN FUTURE BIOCHEMICAL STUDIES (example pertaining to the Daily Trial)

Patient Name: _____
ID Number: _____
IRB Project Number: _____

Project Title: Frequent Hemodialysis Network: Daily Hemodialysis Trial
A multi- center randomized controlled study to demonstrate the efficacy, safety and feasibility of "Frequent Hemodialysis" in patients with End Stage Renal Disease**.**

You are being asked to take part in this process because you have chosen to participate in the "Daily Hemodialysis Trial". The purpose of this process is to keep samples of your blood and/or urine in a repository (like a bank for saving blood and other tissues) for future biochemical studies. Since new discoveries occur everyday, it is possible that there may be new tests in the future that can improve the search for more information about your illness and/or how to treat it more effectively.

If you choose not to take part in these future studies, it will not affect your participation in the main study in which you are participating.

Where the samples will be kept:

The National Institutes of Health (the NIH) is a government organization that is the sponsor for this study. They also pay for the storage of these blood samples. They have developed a special storage facility, called "Repository", to keep these blood samples. These samples are kept in special freezers so that they may be kept for long periods of time. We would like to send your blood samples to this Repository. The Repository collects, stores, and distributes biological samples and associated data from people with many kinds of disorders, from unaffected family members, and from other healthy people.

The NIH-authorized Repository is Fisher BioServices Corporation at 20301 Century Blvd., Bldg. 6, Suite 400, Germantown, MD 20874. The Director of the project is Mr. Richard Frome at (240) 686-4702.

Protecting Your Privacy

The Repository will take measures to protect your privacy, although no guarantee of confidentiality can be absolute. The Repository will not be able to give out your name, or other information that identifies you or your child, to the scientists who receive the samples.

Process for Collecting and Using Your Samples

Blood will be collected before and after three specified hemodialysis treatments (at the start of the study, after 4 month, and at the end of the study) throughout the 12-months of your participation in the main study. These samples would be stored in repository managed by National Institute of Health. Total amount of the blood for future biochemical studies approximately 150ml (about 10 tablespoons). Before the researchers in this study send samples to the Repository, each sample will be given a code number. Your name (or child's name) and all personal identifying information, such as address, social security number, and date of birth, will be removed. Therefore, the Repository will not be able to give out your name, or other information that identifies you or your child, to the scientists who receive the samples. However, the Repository and scientists will have some data about you, such as age, sex, diagnosis, race, and outcomes of the initial study.

The NIH and the investigators' Institutional Review Board will need to approve future studies done on your stored samples. Results from future studies on your stored samples can be merged with data from other sources, such as your Medicare data. This requires that we retain sufficient personal identifiers to permit merging data from the two sources (data from this trial and other future sources of data about you). Protections will be established to assure that your identifying information will not be available to anyone other than specific investigators approved to do these studies, and that your personal data will not be directly viewed other than as aggregated with that of many other individuals.

Potential Risks

There are very few risks in having your blood used for research. The greatest risk is the release of information from your health records. The NIH will protect your records so that your name will be kept private. Even if your blood and tissue is used for this kind of research, the results will not be put in your health records. The results from this future research will not be sent to you or your doctor, will not be used in planning your care, and will not become part of your medical record. These tests are only for research purposes and have no effect on your medical care.

Potential Benefits

If you agree to take part in donating your biosamples, there will not be any direct medical benefit to you. However, we hope that information learned from this possible future analyses of these samples will benefit other people who receive hemodialysis or may need hemodialysis in the future. Sending samples to the Repository may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases.

No Other Cost to You

Your blood will be used only for research and will not be sold. You will not be paid for allowing your leftover blood and tissue to be used in research even though the research done with your blood and tissue may help to develop new products in the future. Similarly there will be no cost to you for any blood and tissue collected and stored by the repository. You and/or your insurance company will not be charged for submission or testing of the samples. These tests are only for research purposes and have no effect on your medical care. No funds have been set aside to pay you for allowing your blood to be stored.

Your Rights as a Participant

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study, or choosing not to take part, will not result in any penalty or loss of benefits to which you are entitled. Your physician will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you agree to have your sample(s) stored in the Repository, you can change your mind up at any time, up until the end of the "Daily Hemodialysis Trial". You should contact your study doctor and let him or her know that you do not want us to use your blood and tissue. Then the blood will no longer be used for research. When study researchers receive written instructions from you, they will destroy your sample and all information that identifies you. After the main study ends, you will not be able to withdraw your sample. Therefore, once the study ends, your blood samples will stay in the Repository indefinitely and can be used for research.

Contacts

For questions about the study or a research-related injury, contact the principal investigator _____ at _____

Signature

I consent to the future use of my blood samples in future medical studies.
(Check Y or N) Y N

You will be given a copy of this form.

Participant: _____ Date: _____