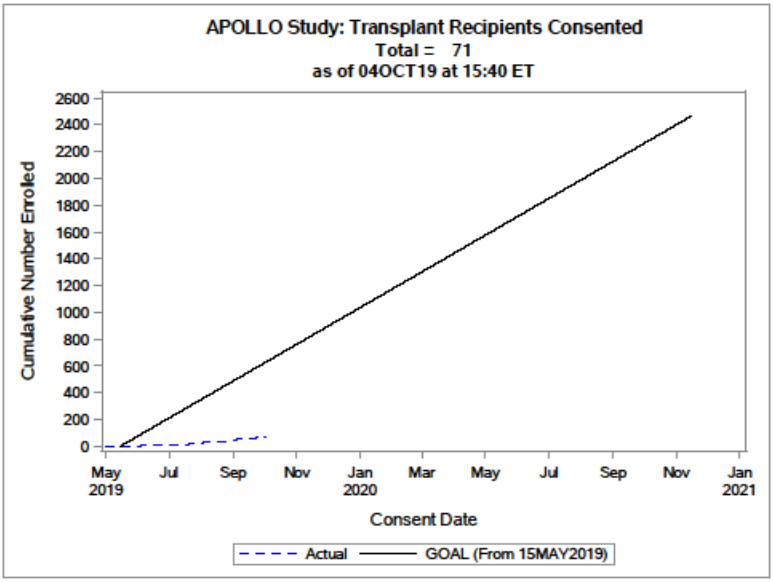

APOLLO Study: Transplant Recipients Consented
Total = 71
as of 04OCT19 at 15:40 ET
Cumulative Number Enroled
2600
2400
2200
2000
1800
1600
1400
1200
1000
800
600
400
200
0
May 2019
Jul
Sep
Nov
Jan 2020
Mar
May
Jul
Sep
Nov
Jan 2021
Consent Date
Actual
GOAL (From 15MAY2019)

AA	African American
ACD	acid citrate dextrose
AOPO	Association of Organ Procurement Organizations
APOL1	apolipoprotein L1 gene
APOLLO	*APOL1* Long-term Kidney Transplantation Outcomes Network
DNA	deoxyribonucleic acid
NIH	National Institutes of Health
HLA	human leukocyte antigen
IRB	institutional review board
MOP	manual of procedures
NOK	next of kin
OPO	organ procurement organization
SC	Steering Committee
SDRC	Scientific and Data Research Center (also called Coordinating Center)
UNOS	United Network for Organ Sharing
WFSM	Wake Forest School of Medicine

1. Overview

Collection of DNA from deceased African American (AA) kidney donors is the most critical aspect of the APOLLO study. OPOs and HLA Labs are collaborating with the APOLLO study to collect, process, and ship biosamples from deceased donors who are AA or have African ancestry. The procedure for enrollment and processing is intended to be as non-disruptive as possible for the OPOs and HLA Labs. Though deceased donors are not considered research participants by the National Institutes of Health Office for Human Research Protections for this study, all OPOs and HLA Labs will have the opportunity to review and approve the proposed APOLLO activity. The study and these procedures have been reviewed and approved by the IRB responsible for oversight of the Scientific Data Research Center (SDRC).

Established protocols for authorizing organ donation and research from donor families should not be affected by the APOLLO protocol. Deceased donors are eligible for APOLLO if they are AA or have African ancestry and, there is authorization for research; the donor or their family representative agrees that the donor's biosamples may be included in research studies. Each OPO is being asked to determine eligibility, collect 2 additional tubes of blood and 1 tube of urine and ship them to its HLA lab along with other routinely collected samples which are sent to that lab. Following their existing local procedures, HLA Labs will extract DNA, separate serum, and store the frozen DNA, serum and urine. The HLA Labs will ship APOLLO samples in batches to the APOLLO Central Lab. A video with detailed specimen handling and shipping instructions for HLA Labs is available on the APOLLO website (www.TheApolloNetwork.org). Near the end of the study, when all genotyping for enrolled deceased donors is complete, each OPO will send a letter to the deceased organ donors' Next of Kin (NOK) offering them access to the genotyping results through the APOLLO website.

2. Procedures for Organ Procurement Organizations

2.1 Who is Eligible for Inclusion in APOLLO, and Who Determines Eligibility?

To be eligible, a deceased donor must be reported as AA by the OPO, based on having "African ancestry" which for this study is defined as AA, Afro-Caribbean, Hispanic Black, or African from whom kidneys will be recovered for transplantation. The OPO can determine this by using the Deceased Donor Registration Worksheet or whatever other sources are used to complete the Ethnicity/Race question on the Deceased Donor Registration Worksheet. It can also be determined by reports from family members or by hospital records. In addition, there must be authorization for research by the donor or NOK to be included in the APOLLO project. Authorization for research will be facilitated by each OPO following their normal procedures. There are no exclusions for age, gender, causes of death or other reasons.

2.2 Instructions for Blood and Urine collection, Labelling and Shipping to the HLA Lab:

APOLLO will provide each OPO with labels with the words 'APOLLO sample' and 10 mL urine tubes (Fisher Scientific Cat. # NC9054766).

During routine sample collection, each OPO will collect an additional 2 tubes of whole blood and 1 tube of urine for each eligible deceased donor as follows:

For whole blood:

an 8.5 mL ACD tube (yellow top tube, provided by the OPO) and
a 10 mL serum tube (red top tube, provided by the OPO).

For urine:

a 10 mL urine tube (provided by APOLLO, and capable of cryopreservation).

Collection tubes can be labeled in advance if it is convenient to do so. All three APOLLO tubes will be labeled the same way that other specimen tubes are typically labeled for shipment to the HLA Lab; however, each APOLLO tube should also have an "APOLLO sample" label. The "APOLLO sample" labeling will alert the HLA lab that these are extra APOLLO study specimens. At a minimum, labels on the APOLLO tubes should include the UNOS ID number and if possible the date and time of collection.

The OPO will ship the APOLLO samples with other samples already going to the HLA Lab using their standard procedures (APOLLO samples follow the clinical samples). In addition, a one-page **APOLLO HLA Lab Instruction Sheet (Appendix 1) should be included**. The HLA lab instruction sheet is intended to help ensure the HLA Lab is aware that they should process, store and ship the APOLLO tubes as described in the instruction sheet.

The OPO will send an email to the APOLLO SDRC (**APOLLOLab@wakehealth.edu**) indicating that samples were collected and sent to their corresponding HLA Lab, and also notify the OPO's Donor Family Services team so the OPO will have that information for donor family follow-up letters. The email must include the UNOS number. The OPO may also choose to "cc" their HLA lab on this email.

If an additional ACD (yellow top tube) is not able to be collected, but there is authorization for research, the OPO should notify their HLA lab to secure any excess DNA material, after normal procedures and requirements for transplantation, and collect and store as otherwise described.

2.3 The APOLLO Study Notification Sheet to be Included with Recovered Kidneys:

Organ recovery procedures for APOLLO identified kidneys should follow standard practice for the OPO. If one or more kidneys are recovered and sent to a transplant program, OPOs will include the **APOLLO Study Notification Sheet (Appendix 2)** in the shipping container with each kidney. This sheet is intended to alert the transplant program to facilitate recruitment of the kidney transplant recipient into the APOLLO project.

3. HLA Labs

3.1 APOLLO will Provide to HLA Labs:

- 2 mL cryovials for DNA (sterile, freezer-safe; Fisher Scientific Cat # 03 337 7D). Alternatively, HLA labs can elect to use their own 2 mL freezer-safe cryovials
- 5 mL cryovials for serum (sterile, freezer-safe; Sarstedt Cat # 62.558.201)
- 5-inch 7x7 Cardboard Storage Boxes (Globe Scientific, Cat # 3098)

3.2 Receipt and Processing of APOLLO Samples:

a. The OPO will provide an additional 8.5 mL ACD-A (yellow top) tube, an additional 10 mL clot (red top) tube and a 10 mL tube with urine for every eligible deceased donor with African ancestry that has a kidney recovered for transplantation. These should be distinguished by additional labeling with the word "APOLLO" Study on each tube.

b. The most critical task is to collect DNA to ship to the APOLLO SDRC. The HLA Lab will obtain as much DNA as possible from each extra ACD-A tube (20 µg of DNA recovered would be excellent). This can be isolated using the HLA Lab's standard DNA isolation protocol. The recovered DNA should be transferred to the 2.0 mL cryovial provided by APOLLO (or the HLA Lab's own 2mL cryovial suitable for storage at -80°C).

c. In the unlikely event an additional ACD tube for the APOLLO project is not able to be recovered, the OPO may request that the HLA Lab, after securing the DNA needed for standard donor tissue typing purposes, will secure any residual DNA (provide at least 250 ng of DNA) for the APOLLO study in the 2.0 mL cryovial provided by APOLLO or their own 2.0 mL cryovial suitable for storage at -80°C.

d. The HLA lab should centrifuge the red top tube and isolate the 3-4.5 mL of serum into the 5ml cryovials provided by APOLLO.

e. The HLA Lab will label the tubes and cryovial as standard practice, including donor UNOS number and date of DNA isolation. If the laboratory is able to include the DNA concentration and 260/280 ratio with each DNA cryovial, that would be appreciated. The urine tube, serum tube, and DNA cryovial, grouped by UNOS ID, will be placed into a reusable 5-inch 7x7 cardboard box with the vials upright in the box for storage in an ultra-low temp freezer. The 5-inch 7x7 boxes will be re-used for sample storage by the HLA Labs (these boxes will not be shipped to APOLLO). A video with detailed specimen handling instructions is available on the APOLLO website (www.TheApolloNetwork.org). Processing and storage of samples should take place at the same time other samples for the donor are processed, or as soon as possible, to maintain the integrity of the samples.

3.3 Sample Storage and Shipping:

a. The HLA Lab will ensure that DNA and serum samples are each securely placed in a tube sufficient (volume, size and material) to allow for storage in an ultra-low temp freezer at -80°C. These tubes will be stored with the tube of urine from that donor in the ultra-low freezer. Samples will be **shipped** via FedEx on dry ice to the APOLLO SDRC Central Lab (see below). A video with detailed specimen shipping instructions is available on the APOLLO website (www.TheApolloNetwork.org).

b. Due to the large volume of samples to be received from across the country, the shipping process and costs are simplified by batch shipping of samples, preferably every 3 months from each HLA Lab. Thus, while stored in the HLA Lab, samples must be stored in an ultra-low temp freezer (-80°C) until shipped to the APOLLO Central Lab at Wake Forest School of Medicine via FedEx. A representative from the APOLLO SDRC Central Lab will contact each HLA Lab to arrange each shipment. The integrity of these samples is critical and freeze/thaw cycles kept to a minimum.

c. Each HLA Lab will be asked to complete and maintain an ongoing **APOLLO Sample Inventory Shipping Spreadsheet (Appendix 3)** on their local shared computer (to be accessed by different personnel who may be processing samples). The excel log will be completed for each participant after biosamples are collected, aliquoted and stored in freezers. Staff should enter the following information:

- Participant UNOS ID number

- Sample Type U/S/D (urine, serum, DNA)
- Date of preparation
- DNA concentration and 260/280 ratio
- Technician name
- Shipping date (when identified)
- Name of the person shipping the samples

A printed copy of the spreadsheet (with data relevant only to the current shipment) will serve as the "shipping log" to provide detailed sample information for each shipment to the APOLLO Central Lab. The printed lines of the shipping log will be included in the box to be shipped with samples and also e-mailed to the Apollo SDRC Central Lab (ApolloLab@wakehealth.edu). The excel file (APOLLO Inventory and Shipping Spreadsheet) will be maintained for every APOLLO sample collected; however, only the data relevant to the samples in each shipment will be printed and included with the samples. The **APOLLO Inventory and Shipping spreadsheet (Appendix 3)** is available on the APOLLO website for download by HLA Labs.

d. DNA, urine and serum samples must be shipped to the Wake Forest APOLLO Central Lab **on dry ice**. The costs of shipping, shipping containers and dry ice will be paid by APOLLO. If the HLA Lab is unable to store the samples, more frequent (perhaps immediate) shipping is possible. The APOLLO SDRC Central Lab will work with the HLA Lab to make the necessary arrangements.

e. Each HLA Lab should provide a primary contact individual for communication with the APOLLO Central Lab at the Wake Forest School of Medicine.

3.3 Detailed Shipping Instructions:

a. Shipments to the APOLLO Central Lab will include:
- The DNA cryovial, serum cryovial, and urine tube from each donor
- Reusable insulated box for shipping (supplied by APOLLO; returned to HLA Lab for subsequent shipments)
- FedEx clear pouch #158396, ordered from FedEx by APOLLO (free from FedEx)
- 9"x6" biohazard bag (Fisherbrand, Catalog No.23-700-211) supplied by APOLLO
- Paper towels (absorbent material) supplied by HLA Labs
- 13"x18" biohazard bag (Fisherbrand, Catalog No. 22-130-111) supplied by APOLLO
- Preprinted FedEx airbill – supplied by APOLLO
- Dry ice label taped to box, ordered from FedEx by APOLLO (free from FedEx) UN3373
- Biological Substance Category B label taped to box (supplied by APOLLO)
- 20 lbs / 9 kg dry ice (covering 2 days) invoice to APOLLO

b. To assemble the frozen sample shipments:
1. Locate the frozen 2 mL DNA cryovials, the 5mL serum cryovials and 10mL urine tubes (grouped in the freezer by UNOS ID) stored in reusable APOLLO 5-inch 7x7 specimen boxes. Remove the set of 3 samples from each donor case from the specimen box and check to be sure that each tube is properly labeled and the cap is securely tightened.
2. Wrap them with a paper towel (as absorbent material). Then place the samples into a 9"x6" biohazard bag and seal the bag. Samples from more than one participant can be placed in each 9"x6" biohazard bag. Multiple 9"x6" bags can be sealed in a larger 13"x18" biohazard

bag, and placed into the Styrofoam shipping box/cooler containing dry ice for shipping to the APOLLO SDRC Central Lab.

3. First place a layer of dry ice pellets on the bottom of Styrfoam shipping box. Place the larger 13"x18" biohazard bag with the 3 month collection of individual participant specimens on top of a layer of dry ice. Place additional dry ice pellets on top of the bag of specimens. Use at least twenty pounds (9 kg) of dry ice in each shipping box.
4. Place the lid on the Styrofoam box. Place the printed APOLLO Inventory and Shipping spreadsheet (Appendix 3, containing only data rows relevant to the current shipment) on top of the Styrofoam cover.
5. Close and tape the outer cardboard box.
6. Affix a dry ice label on **the side** of the shipping box. Enter the weight of dry ice on the label (20 lbs).
7. Affix the "UN3373 Biological Substance Category B" label to **the side** of the shipping box, near the dry ice label.
8. Use the pre-printed FedEx airbill provided by APOLLO to ship specimens to the APOLLO SDRC Central Lab.
    a. The "Ship date" on the APOLLO provided pre-printed airbill will need to be changed. The ship date should be the date on which the box is being shipped to the APOLLO SDRC Central Lab. The receipt date should be left empty.
    b. Fold the airbill in half and place inside the small clear FedEx pouch #158396 and adhere to **the top** of the package following the instructions on the pouch.
9. If there is not a routine FedEx pick-up procedure for the HLA Lab, call FedEx at 1-800-GO-FEDEX (1-800-463-3399). Give them the account number on the preprinted FedEx airbill (listed under the "To: Address" as REF#) and your pickup address. FedEx will dispatch a courier to pick up the package.
10. Send a notification of the shipment to the APOLLO SDRC Central Lab via email with the FedEx tracking number and the APOLLO Inventory and Shipping spreadsheet (Appendix 3) to: APOLLOLab@wakehealth.edu on the day the package is picked up by FedEx. The HLA lab will receive an email notification from the APOLLO SDRC Central Lab within 2 business days of receipt of the samples.
11. Contact the APOLLO SDRC Central Lab regarding questions about packaging and shipping at the phone number (336) 713-7208 or via email (preferred) APOLLOLab@wakehealth.edu.

c. Shipping containers to the APOLLO SDRC Central Laboratory should be addressed as follows:

Wake Forest School of Medicine
1 Medical Center Blvd
APOLLO Lab, NRC Rm 235
Winston-Salem, NC 27157-1053
Telephone: 336 713-7208
Fax: 336 716-4318

d. APOLLO SDRC Central Laboratory Hours:

Monday-Friday	8:00 am - 3:30 pm
Saturdays	Closed
Sundays	Closed

*A holiday schedule will be posted on the APOLLO website.

4. Return of Deceased Donor Genotyping Results to Next of Kin

As part of their routine donor family follow-up within the first three (3) months after donation, the OPO Donor Family Services department will provide information to the NOK of the deceased donor regarding their participation in the APOLLO project. Template language for the letter is provided **(Appendix 4: Template Letter Language)**, which confirms for the NOK that biosamples were collected for research.

Once research *APOL1* gene test results become available, approximately at the end of APOLLO year 3, the APOLLO SDRC will provide information to each of the OPOs. The OPOs will then contact the NOK for each deceased donor to inform them that test results are available, providing them with a unique, access code and directions to access that information securely (provided by the APOLLO SDRC).

Re: NIH *APOL1* Long-term Kidney Transplantation Outcomes Network (APOLLO) Study

Dear Colleague:

The donation and transplant community is embarking on an important National Institutes of Health-sponsored project to assess the effects of apolipoprotein L1 gene (*APOL1*) genotypes from organ donors with African ancestry, on transplant outcomes. For more information about this study, please visit: www.TheApolloNetwork.org. For the project to be successful, we request your assistance, as follows:

1. **Receipt and Processing of APOLLO Samples:**
   a. OPOs will provide an additional 8.5 mL ACD-A (yellow top) tube, an additional 10 mL clot (red top) tube and a 10 mL tube with urine for every eligible deceased donor with African ancestry that has a kidney recovered for transplantation. These will be distinguished from other samples by additional labeling with the word "APOLLO" Study on each tube.
   b. The most critical task is to collect DNA to ship to the APOLLO Central Lab. Please obtain as much DNA as possible from the extra ACD-A tube (20 µg of DNA recovered would be excellent). This can be isolated using your standard DNA isolation protocol. Transfer the DNA to a 2.0 mL cryovial (provided by APOLLO) or your own 2.0 mL -80°C freezer-safe cryovial.
   c. In the unlikely event an additional ACD tube for the APOLLO project was not received, we request that after you secure the DNA needed for standard donor tissue typing purposes, please secure any residual (preferably at least 250 ng) DNA for APOLLO in the 2.0 mL cryovial.
   d. We also ask you to recover 3-5 mL of serum from the red top tube. Centrifuge and isolate the serum into the 5ml serum cryovial tube provided by APOLLO.
   e. Please label tubes as you typically do, including the donor UNOS number and date of DNA isolation. If you are able to include the DNA concentration and 260/280 ratio on the shipping log, please do so.
   f. Please ensure that DNA and serum samples are each securely placed in a tube sufficient (volume, size and material) to allow for storage in an **ultra-low temp freezer** (-80°C). Please keep them with the tube of urine from that donor in the ultra-low freezer. Samples will be **shipped** via FedEx on dry ice to the APOLLO SDRC Central Lab (see below).

2. **Sample Storage and Shipping:**
   a. Please enter samples data on the "APOLLO Inventory and Shipping Spreadsheet" (**Appendix 3**) kept on your lab shared hard drive. Include a printed copy with each sample shipment.
   b. Please ensure that DNA and serum samples are each securely placed in a tube sufficient (volume, size and material) to allow for storage in an **ultra-low temp freezer** (-80°C). Please keep them with the tube of urine from that donor in the ultra-low freezer. Samples will be **shipped** via FedEx on dry ice to the APOLLO SDRC Central Lab (see below).
   c. Due to the large volume of samples to be received from across the country, we would like to simplify the process by batch shipping of samples, preferably every 3 months from each HLA Lab, if possible. Thus, while stored in your facility, samples must be stored in an ultra-low temp freezer (-80°C) until shipped to the APOLLO SDRC Central Lab at Wake Forest School of Medicine via FedEx. A representative from the APOLLO Central Lab will contact you to arrange shipment. The integrity of these samples is critical and freeze/thaw cycles kept to a minimum.
   d. DNA, urine and serum samples must be shipped to the APOLLO SDRC Central Lab **on dry ice**. The costs of shipping and dry ice will be paid by the APOLLO SDRC Central Lab. If your laboratory is unable to store the samples, more frequent (perhaps immediate) shipping is possible. The APOLLO SDRC Central Lab (Wake Forest) will work with you to make the necessary arrangements.

Thank you.

Appendix 2 APOLLO Study Notification Sheet

NIH APOLLO Research Study Kidney

Please contact your APOLLO Clinical Center after transplantation of this kidney.

Email: APOLLOstudy@wakehealth.edu

Website: www.TheApolloNetwork.org

Thank you from the NIH APOLLO Consortium!

Appendix 3 APOLLO Inventory and Shipping Spreadsheet

HLA Lab ID:		Ship Date:		
			Person Fedexing:	

UNOS ID	Sample type (U/S/D)	Status	Vial Type	Date of Processing	Person Processing
ABCD123	Urine	OK	10 ml	9/12/2018	Anna L
ABCD123	Serum	OK	5 ml	9/12/2018	Anna L
ABCD123	DNA volume (ul)	200.00	2 ml	9/12/2018	Anna L
	DNA concentration (ng/ul)	125.00			
	DNA OD (260/280)	1.81			
ABCD456	Urine	MISSING	10 ml	9/29/2018	Pam M
ABCD456	Serum	OK	5 ml	9/29/2018	Pam M
ABCD456	DNA volume (ul)	200.00	2 ml	9/29/2018	Pam M
	DNA concentration (ng/ul)	134.00			
	DNA OD (260/280)	1.80			
	Urine		10 ml		
	Serum		5 ml		
	DNA volume (ul)		2 ml		
	DNA concentration (ng/ul)				
	DNA OD (260/280)				
	Urine		10 ml		
	Serum		5 ml		
	DNA volume (ul)		2 ml		
	DNA concentration (ng/ul)				
	DNA OD (260/280)				
	Urine		10 ml		
	Serum		5 ml		
	DNA volume (ul)		2 ml		
	DNA concentration (ng/ul)				
	DNA OD (260/280)				
	Urine		10 ml		
	Serum		5 ml		
	DNA volume (ul)		2 ml		
	DNA concentration (ng/ul)				
	DNA OD (260/280)				
	Urine		10 ml		
	Serum		5 ml		
	DNA volume (ul)		2 ml		
	DNA concentration (ng/ul)				
	DNA OD (260/280)				
	Urine		10 ml		
	Serum		5 ml		
	DNA volume (ul)		2 ml		
	DNA concentration (ng/ul)				
	DNA OD (260/280)				

Appendix 4 Template Language to be Included with Donor Family Follow-up:

"In addition to the organs noted above that were recovered and transplanted, small samples of blood and urine were recovered and are a part of the APOLLO research project being performed by the National Institutes of Health (NIH). The goal of this research project is to determine whether alterations in a gene (called the apolipoprotein L1 gene or APOL1), sometimes found in kidney donors and/or recipients with African ancestry, will impact kidney transplantation outcomes.

Once blood samples have been collected from all kidney donors in the study, during an approximate 2 - 3 year study period, it may be possible for you to find out the results of the gene test for your loved one. For instructions on how to obtain your loved ones test results, please visit the APOLLO study website (www.TheApolloNetwork.org).

Table of Contents

Appendices

1 Recruitment of living donors and recipients

1.1 Recruitment of living donors and recipients

The APOLLO study is focused on kidneys from donors who are African American, Afro-Caribbean, Hispanic black or African, and on the recipients of those kidneys. Living donors are eligible for APOLLO if they self-identify as African American, Afro-Caribbean, Hispanic black or African. Kidney transplant recipients are eligible for APOLLO if the kidney being transplanted is from a living or deceased donor identified as African American, Afro-Caribbean, Hispanic black or African. Recipients of kidneys from these donors are eligible regardless of recipient race or ethnicity. Living donors and recipients who agree to participate will be asked to provide a one-time sample of blood (and possibly urine), and authorize access to their medical records. There are no study-related visits or other requirements.

Details of the recruitment and consent process differ depending on whether the transplant program is Engaged or Non-Engaged in the research process. At Engaged programs, the APOLLO study coordinators can approach, recruit and consent living donors and recipients. At Non-Engaged programs, local clinic staff must make arrangements for eligible potential participants to be consented over the phone by their aligned Clinical Center lead study coordinator with a witness present. Witnesses must be at least 18 years of age. They can include non-study staff employed by the Non-Engaged program or relatives of the participant.

1.2 Identification of eligible living donors

To identify a living donor for recruitment, study coordinators will work closely with living donor transplant teams to find potential living kidney donors who self-identify as African American, Afro-Caribbean, Hispanic black and African early in the process of donor evaluation. Clinical Center lead study coordinators will inquire about potential living donors at least monthly and remain vigilant to identify future eligible living kidney donors with their aligned Engaged program study coordinators and aligned Non-Engaged program contacts. Coordinators will regularly and systematically check for anticipated dates of upcoming kidney transplants from approved living donors and establish a plan to consent living donors. It is required that potential living donors be approached (or have had *APOL1* genetic testing) two or more weeks prior to the scheduled donor nephrectomy.

1.3 Identification of eligible donor kidneys and their recipients

APOLLO will attempt to identify and recruit every kidney transplant recipient from eligible deceased and living kidney donors over a fixed period of time. An eligible deceased donor will have consent for research approved by the deceased donor's Next of Kin (NOK). These recipients will have received a kidney transplant from a donor who self-reports or a deceased donor who is identified as: African American, Hispanic Black, Afro-Caribbean or African. Recipients of kidneys from eligible donors are eligible for APOLLO regardless of recipient race or ethnicity. Recruitment and bio-sample collection from eligible transplant recipients should ideally be performed within two weeks of receipt of the kidney, but can be collected up until 3 months after transplantation.

Study coordinators should formulate a plan to identify recipients of kidneys from living donors at their transplant program by working closely with their living donor program personnel. For the recruitment of recipients of deceased donors, there are two ways that transplant program personnel may learn an eligible kidney from a deceased donor has been sent to them for transplantation:

1. At the time of procurement, eligible deceased donor kidneys should be shipped with a one-page APOLLO Study notification sheet included in the shipping container from the OPO to transplant programs. The sheet includes the heading "NIH APOLLO Research Study Kidney" in large font and the study logo. Transplant teams should attempt to recruit recipients of these kidneys at the time of hospitalization for the transplant or during a follow-up clinic visit, ideally within two weeks of transplantation, but they can be consented up until 3 months after transplantation.
2. In addition, the SDRC will provide a report with information from UNOS on individuals who receive a kidney donated from an African American deceased donor. Via the password protected APOLLO website, the SDRC will make available a rolling number of potential APOLLO participants, which is updated daily. In addition to the number of APOLLO eligible kidney transplant recipients, the website report may also include columns indicating if next of kin agreed to research. Transplant program study coordinators are responsible for checking this report daily to identify transplant recipients to approach for participation in the APOLLO study. Because information from UNOS is delayed, this information may be available after the recipient has been discharged. In such instances, the recipient should be recruited at a follow-up routine post-transplant visit.

1.3.1 Deceased Donor Eligibility

There may be instances when an African American deceased donor kidney arrives at your transplant program without an APOLLO notification sheet in the box. In this case, APOLLO study coordinators should make every effort to determine if this is an APOLLO-eligible kidney. The first approach is to contact the OPO that procured the kidney to confirm eligibility for research and/or the APOLLO study. Information on deceased donor consent for research may also be found in Donornet. Eligibility would include authorization for research from the deceased donor's Next of Kin (NOK). If the signed consent for research or authorization form is present in Donornet and indicates research is acceptable, this kidney would be an APOLLO eligible kidney and the transplant recipient can be recruited into the study. However, the consenting transplant program must secure the deceased donor's DNA for the APOLLO study from the OPO or HLA lab before attempting to recruit the recipient (see 1.3.2 & 1.3.3).

The process for determining whether a deceased donor's NOK consented to research involves access to the Donornet website:

- https://portal.unos.org (access to the website must be requested, contact the transplant staff at your site for assistance)
- Once access is granted, users log-in with established username and password.
- Click on the Donornet tab >show all results> Match ID#> Donor ID # > Donor Summary> Attachments>
- Look for signed consent or authorization form.
    - Since these forms may vary by OPO, careful interpretation to determine eligibility is required. If the consent for research or authorization data indicates that research and APOLLO participation are acceptable, the study coordinator will need to secure biosamples from the deceased donor. At a minimum, DNA must be collected for the APOLLO study before attempting to recruit the recipient (see 1.3.2 & 1.3.3).

1.3.2 Obtaining Biosamples when no APOLLO Sheet came with the kidney

1. Call the procuring OPO to determine whether the donor is eligible for APOLLO and whether they collected additional research tubes for APOLLO. A list of contact personnel from all OPOs and HLA labs can be found on the APOLLO website. This list may also include OPO-specific requirements for APOLLO eligibility.

2. Educate the OPO staff about the APOLLO Study and the Notification Sheet that should be included in the shipping box with APOLLO-eligible kidneys. The APOLLO Notification Sheet can be found in the OPO/HLA MOP, appendix 2.
3. If the OPO collected biosamples, ask that the samples be sent to their aligned HLA lab. Notify the HLA lab of the incoming APOLLO biosamples and ask they complete the processing of the biosamples per the OPO/HLA lab MOP located on the public page of the APOLLO website.

1.3.3 Obtaining DNA when biosamples are not collected by the OPO

1. Find out which HLA lab the OPO is aligned with.
2. Call the HLA lab and request 250 ng (nanograms) to 20 ug (micrograms) of DNA in a separate APOLLO labelled cryovial be held for APOLLO.
3. Ask the HLA lab to freeze the DNA (at -80C°) and FedEx it to the APOLLO Central lab quarterly with their other APOLLO samples (the APOLLO Central lab will notify HLA labs and request quarterly shipments). DNA must be kept within CLIA-labs, do not send DNA to Clinical Centers or engaged transplant programs.
4. If the above fails, see whether the destination HLA lab (at the site where the organ is transplanted) has available DNA.

If DNA is obtained via the methods in #2 or #4 (above), please inform the SDRC of the deceased donor's inclusion in the APOLLO study (this can be done via email but can only contain the DD's UNOS ID; no other PHI can be included in the message). This is important because the deceased donor's NOK will need to be notified that their loved one has been included in the APOLLO study and that genotyping results can be provided in the future. The OPO will not have a record of this deceased donor's participation in the APOLLO study if they did not collect the biosamples.

If DNA is not obtained, do not recruit the recipient.

1.4 Recruitment

Potential participants (living donors and recipients) should be given adequate time to review all study materials and the opportunity to ask questions. Key points to stress include that participation in APOLLO will not alter their medical care except for collection of up to four teaspoons of blood and possibly one tablespoon of urine. Information on their future health will be collected using their medical records and there will be no additional study visits. There is also a Central IRB-approved introduction to APOLLO video available on the public-facing webpages for use as a recruitment aide.

After all questions have been answered, participants (living donors and recipients) can be consented for participation in the APOLLO study. Those who agree to provide consent should sign the appropriate Consent Form (either donor or recipient) and Authorization for Release of Medical Records form and complete the Participant Contact Information form. At Non-Engaged transplant programs ONLY, the Consent Form signed by the participant must also have the signature of a witness to the consent process. Witnesses must be at least 18 years of age. Witnesses can include non-study staff employed by the Non-Engaged transplant program or relatives of the participant. Once the consent process is complete, provide the participant with a copy of the Consent Form. Instructions for sample collection are located in MOP 2.1 and in a video on the APOLLO study website (www.TheApolloNetwork.org).

Potential participants (living donors and recipients), should be provided copies of recruitment materials, including:

1. APOL1 Long-term Kidney Transplantation Outcomes infographic,
2. Appropriate donor or recipient Consent Form (and corresponding assent form for children)

1.4.1 Living Donors

Initial contact with potential living donors should be made as early in the donor evaluation process as is possible, even before a determination is made that the donation will occur. Initial presentation of the APOLLO study to potential living donors should occur at least two weeks prior to donor nephrectomy. If not, performance of *APOL1* gene testing and discussion of results at least two weeks prior to the donor nephrectomy is acceptable for recruitment, as long as potential participants receive all relevant APOLLO educational materials and materials are reviewed prior to scheduled nephrectomy (see below). Living donors should have ample time to become familiar with *APOL1*, review study materials (including the APOLLO living donor consent form and appropriate infographic) and ask questions prior to scheduled nephrectomy surgery.

Living donor APOLLO consent form signatures can be obtained any time prior to nephrectomy or within 14 days post surgery provided either #1 or #2 below has occurred…

1. Initial APOLLO presentation in-person or by phone using the Living Donor Introduction to APOLLO Phone Script as a guide (Appendix 3) of the APOLLO study is documented as having occurred $\geq$2 weeks prior to surgery. This would be verified by the presence of the "living donor signature form" (Appendix 4) in the study chart. If APOLLO is discussed via phone, 1) there must be a witness present (with the coordinator) who will sign and date the living donor signature form the day of the call and 2) study coordinators will have potential living donors sign the Living Donor Signature form at their first in-person visit (dated the day of the in-person visit). IF the APOLLO study was presented $\geq$2 weeks prior to surgery and the Living Donor Signature form has been signed by the study coordinator and witness, the living donor may sign the actual consent form and the Living Donor Signature form before or after donation. The Living Donor Signature form confirms that the APOLLO study was discussed with the living donor at least two weeks prior to the scheduled nephrectomy; this form does not take the place of a signed consent form. Study participants must still sign the APOLLO consent form.

2. APOL1 testing was performed and results discussed $\geq$2 weeks before surgery. The date can be verified by documentation in the electronic medical record. In addition, the APOLLO study materials (consent form & infographics) must be provided and reviewed with the potential living donor in person or via telephone prior to nephrectomy surgery. If presented via telephone, the study materials can be sent to the potential living donor via email or US mail ahead of the discussion. For telephone presentations of the APOLLO study 1) there must be a witness present (with the coordinator) who will sign and date the living donor signature form the day of the call and 2) study coordinators will have potential living donors sign the Living Donor Signature form at their first in-person visit (dated the day of the in-person visit). IF the APOLLO study was presented prior to surgery and the Living Donor Signature form has been signed by the study coordinator and witness, the living donor may sign the actual consent form and the Living Donor Signature form before or after donation. The Living Donor Signature form confirms that the APOLLO study was discussed with the living donor prior to the scheduled nephrectomy; this

form does not take the place of a signed consent form. Study participants must still sign the APOLLO consent form.

Presence of the Living Donor Signature form in the study chart as described above does not substitute as the signature on the actual consent form. Study participants must still sign the appropriate APOLLO consent form. If a completed living donor signature form, in the participants research study chart, indicates that the APOLLO study was discussed prior to surgery, the consent form can be signed any time prior to surgery or up to 14 days post surgery.

After informed consent signature is received and a UNOS donor ID # assigned, biosamples can be collected prior to or after the donor nephrectomy. If collected after surgery, biosamples should be collected within approximately 14 days, but no longer than 3 months post-operatively. Once the permanent UNOS donor ID # is assigned, study coordinators will complete the Consent Log and Participant Contact form (on the APOLLO website) and the APOLLO Biosample Inventory Shipping Form. On the shipping manifest, record the date of collection of biosamples and whether samples were collected pre-nephrectomy or post-nephrectomy. However, if consent is obtained and the potential participant does not donate, the biosamples and all forms, EXCEPT the consent form, must be destroyed. The signed consent document should be kept at engaged transplant programs or CC's for non-engaged programs. Note: if a transplant programs' local IRB requires that all forms be kept, programs should follow their local procedures.

1.4.2 Recipients

Recipients of kidneys from living or deceased donors are approached for participation in APOLLO after transplantation (this applies even if the living donor and recipient know each other and you are consenting the living donor before surgery; the recipient cannot be consented until after surgery). Recipients are approached after transplantation and not more than three months after transplant. If not approached while in the hospital, recipients may be contacted by phone using the IRB-approved script for recipients as a guide (see Appendix 3).

The APOLLO identifier for Recipients is the UNOS assigned TRR# (transplant recipient record). The TRR# is assigned once the recipient is removed from the waitlist; biosamples should not be collected until the TRR# is available. If it is 24 hours after transplantation and the TRR# is not available, the APOLLO staff can inquire with their local transplant program personnel when the recipient will be removed from the wait list. Removal from the waitlist will immediately generate the TRR#.

Recipients who are children (i.e., under the age of legal consent) or unable to provide informed consent will sign an Assent Form, and the initial contact and consent process must be with parents or guardians who will sign the Adult Consent Form. Recipients under 7 years of age do not need to sign Assent Forms.

1.4.2.1 Process for locating the TRR number on the UNOS website - https://portal.unos.org

- Log-in with established username and password.
- Click on the TIEDI tab>Manage Data>Search>I want to find "a patient history".
- Enter last and first name.
- Click Search.
- Under Search Results
- Click on Subject's name corresponding with correct transplant date (current txp) and donor organ is kidney (KI, LKI, RKI, etc)

- Navigate down to section titled “Patient Records”
- Desired TRR # is listed beside KIR (Kidney TRR) in the Record ID column

1.5 Recruiting Living Donors and Recipients at Non-Engaged Transplant Programs:

If your aligned transplant program is non-engaged, you will need to facilitate contact between the potential participant and your Clinical Center study coordinator. Clinical Center study coordinators will approach and consent potential participants by phone. You should inform the identified potential participant that they may be eligible for a kidney transplantation research study sponsored by the National Institutes of Health and ask them to discuss the study with the Clinical Center study coordinator. If the potential participant agrees, arrange for a telephone or video call with the Clinical Center study coordinator. Provide recruitment materials relevant to either kidney donors or recipients, including APOL1 Long-term Kidney Transplantation Outcomes infographic and the appropriate donor or recipient Consent Form (and corresponding assent form for children), at the time of call with the Clinical Center. This will allow the Clinical Center study coordinator to review the appropriate materials with them and answer any questions they have. Once the participant has consented, the signed and witnessed Consent form and Authorization for Release of Medical Record form should be scanned to the Clinical Center study coordinator via secure methods (e.g. encrypted email, password protected WORD document, secure fax or US mail). A copy of the appropriate Consent Form should be provided to the participant. The APOLLO Study Coordinator at the CC will sign the same signed and witnessed consent form received from the non-engaged transplant program (with the current date of signature [not date of verbal consent]). The CC will maintain a study file containing all consent forms from their non-engaged transplant programs.

2 Bio-samples at Engaged Transplant Programs & APOLLO Clinical Centers

2.1 Sample Collection – General Instructions

Handle all specimens as potentially infectious for laboratory phlebotomists and staff. Blood borne pathogens such as hepatitis B, hepatitis C and human immunodeficiency virus (HIV) can be transmitted following contact of a tainted blood sample through "broken skin" or intact mucous membrane (mouth, eyes, or nose) or as a result of an inadvertent needle stick. Examples of "broken skin" include open cuts, nicks and abrasions, dermatitis, and acne. OSHA rules mandate that technicians always wear disposable protective gloves when collecting and processing specimens. When performing a venipuncture, the protective gloves worn by the phlebotomist must be intact (e.g., a fingertip cannot be torn off of the glove in order to locate a venipuncture site). If the phlebotomist accidentally sustains a stick with a contaminated needle, they are advised to immediately clean the wound thoroughly with disinfectant soap and water, notify a supervisor, and consult with a local physician at their Employee Health Center. In addition, they should notify the APOLLO physician if at an engaged transplant program or notify the principal investigator at their aligned APOLLO Clinical Center if this occurs at a non-engaged transplant program.

Use OSHA-approved cleaning solution to clean up any spills of blood, plasma, serum, or urine. Use this solution to clean all laboratory work surfaces at the completion of work activities. OSHA regulations require that all needles and sharp instruments be discarded into puncture resistant containers. Do not attempt to bend, break, or recap any needle before discarding it. Discard the butterfly set following each specimen collection. Do not perform any pipetting by mouth; especially of any blood, plasma, serum, or urine.

Avoid formation of potentially infectious aerosols when removing the rubber stoppers from Vacutainer tubes. In addition to wearing protective gloves, hold a piece of gauze over the stopper while slowly removing it from the tube. Careful pipetting and centrifugation techniques can also diminish the creation of aerosols. Further steps to minimize infection risk while processing samples are described in the OSHA regulations stated in the Federal Register of December 6, 1991 (Vol. 56, No. 235, page 64177). Wear a mask in combination with an eye protection device, such as goggles or glasses with solid side shields or a chin-length face shield when working with potentially infectious materials that have the potential for splashing, spraying, or spattering. An alternative to these devices would be a desk-mounted or under-shelf-mounted clear plastic shield, which would offer similar protection from possible infectious splashes or sprays.

Place all blood-contaminated products in biohazard bags for proper disposal. Universal Precautions websites: http://www.osha.gov or http://www.niehs.nih.gov

2.1.1 Venipuncture

It is preferable to obtain blood by venipuncture. In the event that a suitable vein for blood drawing is not accessible, blood can be collected from a peripheral or a central line. Each transplant program will need to use their locally-approved protocol to access peripheral or central lines in sterile fashion.

Instructions for venipuncture follow. The preferred arm to draw from is the arm that does not have a functioning hemodialysis vascular access site (e.g., AV fistula or graft).

PRECAUTIONS WHEN USING A TOURNIQUET: If a tourniquet is necessary, it should be placed on the arm for the shortest time possible. If the participant has a skin problem, place the tourniquet over the participant's shirt or use a piece of gauze or paper tissue so as not to pinch the skin.

A. Apply tourniquet.
   1. Wrap the tourniquet around the arm 3 to 4 inches (7.5 to 10.0 cm) above the venipuncture site.
   2. Tuck the end of the tourniquet under the last round.
   3. If a Velcro tourniquet is used, adhere the ends to each other.

B. Identify vein.
   Palpate and trace the path of veins several times with the index finger. Unlike veins, arteries pulsate, are more elastic, and have a thick wall. Thrombosed veins lack resilience, feel cord-like, and roll easily. If superficial veins are not readily apparent, lowering the extremity over the arm of the chair will allow the veins to fill to capacity. Identify the best available vein.

C. Assemble the butterfly-Vacutainer set.
   1. Attach the Luer adapter to the Vacutainer holder.
   2. Attach the Luer end of the butterfly needle set to the Luer adapter.

D. Cleanse the venipuncture site.
   1. Remove alcohol prep from its sterile package.
   2. Cleanse the vein site with the alcohol prep using a circular motion from the center to the periphery.
   3. Allow the area to dry to prevent possible hemolysis or contamination of the specimen and a burning sensation to the patient when the venipuncture is performed.
   4. If venipuncture becomes difficult, the vein may need to be touched again with a gloved hand. If this happens, cleanse the site again with alcohol and allow the skin to dry.

E. Perform venipuncture.
   1. Grasp the participant's arm firmly, using your thumb to draw the skin taut. This anchors the vein. The thumb should be 1 or 2 inches (2.5 or 5.0 cm) below the venipuncture site.
   2. With the needle bevel upward, enter the vein in a smooth continuous motion.
   3. Once blood appears in the catheter, place the collection tube (detailed in section 6.2) into the Vacutainer holder. Grasp the flange of the needle holder and push the tube forward until the butt end of the needle punctures the stopper, exposing the full lumen of the needle.
   4. Make sure the participant's arm is in a flat or downward position while maintaining the tube below the site when the needle is in the vein. It may be helpful to have the participant make a fist with the OPPOSITE hand and place it under the elbow for support.
   5. Remove the tourniquet after the first tube fills. Once the draw has started, do not change the position of a tube until it is withdrawn from the needle. The tourniquet may be reapplied if blood flow is slow without it. If the color of the arm turns red or blue, the tourniquet is applied too tightly. Loosen it and continue.
   6. Keep a constant, slight forward pressure (in the direction of the adapter) on the end of the tube. This prevents release of the shutoff valve and stopping of blood flow. Do not vary pressure nor reintroduce pressure after completion of the draw.
   7. Fill remaining Vacutainer tubes. Fill all Vacutainer tubes as completely as possible; i.e., until the vacuum is exhausted and blood flow ceases. If a Vacutainer tube fills only partially, remove the tube and attach another without removing needle from vein.
   8. When the blood flow into the collection tube ceases, remove the tube from the holder. The shutoff valve covers the point, stopping blood flow until the next tube is inserted (if necessary). Gently invert each tube no more than eight times immediately following removal of the tube from the adapter while the next tube is filling. (See section 6.1.1.b for mixing instructions.)

F. Troubleshooting.
If a blood sample is not forthcoming, the following manipulations may be helpful.
1. If there is a sucking sound, turn needle slightly or lift the holder in an effort to move the bevel away from the wall of the vein.
2. If no blood appears, move needle slightly in hope of entering vein. Do not probe. If not successful, release tourniquet and remove needle. A second attempt can be made. The same technician should not attempt a venipuncture more than twice. If a third attempt is necessary, a different phlebotomist should attempt the venipuncture.
3. Loosen the tourniquet. It may have been applied too tightly, thereby stopping the blood flow. Reapply the tourniquet loosely. If the tourniquet is a Velcro type, quickly release and press back together. Be sure, however, that the tourniquet remains on for no longer than two minutes at a time.

G. Bandaging the arm.
1. Under normal conditions:
   a. Slip the gauze pad down over the site, continuing mild pressure.
   b. Apply an adhesive or gauze bandage over the venipuncture site after making sure that blood flow has stopped.
2. If the participant continues to bleed:
   a. Apply pressure to the site with a gauze pad. Keep the arm elevated until the bleeding stops.
   b. Wrap a gauze bandage tightly around the arm over the pad.
   c. Tell the participant to leave the bandage on for at least 15 minutes.

H. Precautions.
When a participant feels/looks faint following the blood draw:
1. Have the person remain in the chair. If necessary, have him/her lie on the floor with legs elevated. Use of a transfer belt may be indicated in this situation.
2. Take an ammonia spirits ampule, crush it, and wave it under the person's nose for a few seconds.
3. Provide the person with a basin if he/she feels nauseous.
4. Have the person stay seated until the color returns and he/she feels better.
5. Have someone stay with the person to prevent them from falling and injuring themselves if he/she should faint.
6. Place a cold wet cloth on the back of the person's neck or on their forehead.
7. If the person continues to feel sick, take a blood pressure and pulse reading. Contact a medical staff member for further direction.

2.2 Collection Tubes & Processing at Engaged Transplant Programs & Clinical Centers

The following tubes will be collected from living donors and transplant recipients at Engaged Transplant Programs and APOLLO Clinical Centers. The collection of **DNA is priority** so the PAXgene tube should be collected first and then the serum tube

- 1 - 8.5 mL PAXgene DNA tube (blue/gray top)
- 1 - 10 mL serum tube (red top)
- Urine specimen collection of 10 mL of urine (collection cup provided by site)

When collecting blood from children, the blood draw is not to exceed 5% of total blood volume in a single blood draw, or within a 1 month period. Transplant program staff must be aware of daily blood draws for a youth recipient, because a blood draw for APOLLO might exceed the child's daily or monthly limit. Total blood volume is calculated at 70ml/kg. Most programs will not transplant a child who weighs

less than 10kg. So in a 10 kg child, the total blood volume (TBV) = 700 ml, and 5% of that = 35 ml. per single blood draw or per month. The chart below may be helpful for children under 100 pounds or 45 kg.

Pounds	Weight per kg	TBV x .05%	Max. allowed amount per single blood draw or per month
22	10	700	35 ml
33	15	1050	52.5 ml
44	20	1400	70 ml
55	25	1750	87.5 ml
66	30	2100	105 ml
77	35	2450	122.5 ml
88	40	2800	140 ml
99	45	3150	157.5

If the desired amount of blood in children for APOLLO exceeds the maximum limit, please fill (or partially fill) the DNA tube first, followed by partially filling the red top serum tube.

NOTE: Blood collection tubes have expiration dates and these will need to be monitored.

2.2.1 PAXgene DNA tube (blue/gray top)

a) Fill the tube completely
b) Invert ~6-8 times to ensure the anticoagulant has mixed with the blood. No centrifugation is needed.
c) Label the tube using DYMO LabelWriter Tags (labeling is described in 2.8 and available via the APOLLO website in the following location: MENU > Training Videos).
d) PAXgene tubes should be frozen upright in a re-usable 5" (7x7 grid) fiberbox at -80˚ C for temporary storage in the freezer prior to pre-specified quarterly shipping to the APOLLO Central Lab (On-site Storage Preparation is described in 2.9).
e) All PAXgene tubes will be stored together in the same re-usable 5" (7x7 grid) fiberbox prior to shipping.

NOTE: The PAXGene DNA tube can be stored at room temperature (15–25°C) for less than 14 days, at 2–8°C for up to 28 days, at –20°C up to 3 months, at –80°C for long term storage. Do not freeze tubes upright in a Styrofoam tray as this may cause the tubes to crack.

2.2.2 Serum tube 10 mL (red top)

a) Fill the tube completely
b) Invert ~6-8 times
c) The serum tube (red top) is to remain upright at room temperature to allow the blood to clot (blood at 4°C clots extremely slowly).
d) As close to approximately 30-60 minutes after venipuncture as possible, spin the serum red top tube at 1800-1900 relative centrifugal field (RCF) (g) for 10 minutes (if swinging bucket type) at room temperature. Increase time to 15 minutes if using a fixed angle type centrifuge. Consult the centrifuge manual for appropriate revolutions per minute (RPM) setting to achieve 1800-1900 RCF (g). Centrifuge operating instructions are located in 2.5.
e) When the centrifuge has come to a complete stop, remove the serum tube and place it in an upright rack. Remove the rubber stopper and the serum is ready for aliquoting.
f) Pipette available serum into 12 (2mL) labeled serum cryovials each containing 250µL (no less than 200µL) of serum. Note: You may not have enough serum to obtain 12 aliquoted cryovials. Any additional serum > 12 cryovials may be kept at the site or discarded.

g) For temporary on-site storage prior to designated shipping date, package labeled serum cryovials in 2" (9x9 grid) fiberbox and store in -80˚ freezer until shipped to APOLLO Central Lab on dry ice. (On-site storage is described in 4.8).

2.2.3 Urine Collection & Processing

A fresh urine sample is to be collected from each participant, either a mid-stream, clean catch or from the tubing of a Foley catheter (not from the Foley bag). The participant is instructed to void into a sterile urine cup labeled with participant name, filling it as much as possible, and replacing the lid securely on top of the container. In the event that a kidney transplant recipient does not make urine during the initial 14 days after receipt of the kidney, it is acceptable to not collect the urine sample (*e.g.*, delayed graft function).

The APOLLO staff member assesses the adequacy of the sample for processing. At least 10 mL of urine is required for processing. If insufficient amount is obtained, the participant is requested to void again in a clean container. The urine sample may be temporarily placed in an OSHA approved designated specimen refrigerator as soon as possible after the specimen has been collected if aliquoting will be delayed. However, procedures need to be set up at each engaged transplant programs to verify that urine samples are not inadvertently left out at room temperature. Refrigerated urine samples need to be processed the same day they are collected.

a) Urine collected in a sterile collection cup (provided by site) will be mixed gently by hand swirling and aliquoted into ~12 (2 mL) labeled cryovials each containing 800 uL of urine.
b) The 12 aliquoted urine cryovials will be put into the same 2" (9x9 grid) fiberbox following the participant's corresponding serum, leaving no spaces between serum and urine. (see diagram 2.8.1)
c) Labeled urine cryovials will be temporarily stored at -80°C until shipment on dry ice to the APOLLO Central Lab based on a pre-specified shipping schedule.

NOTE: Any additional leftover urine after aliquoting is completed may be kept at the site or discarded.

2.3 Procedures for Small Urine Samples

If the volume of urine sample is inadequate to process, check to see if a second sample can be obtained. If there is a second sample and it (in and of itself) is adequate for processing, use the second sample and discard the first sample.

2.4 Procedures for Urine Samples Contaminated with Blood

Although urine samples contaminated with blood will affect the measurement of albumin, these specimens should not be discarded. All urine samples collected from participants that have adequate volume for processing are kept, including those that are (grossly appear) contaminated with blood. If a urine sample is contaminated with blood, ask the participant to provide a second urine sample. Use the second sample if it has adequate volume and is less contaminated.

2.5 Operating the Centrifuge for the Serum (red top) tube

Refer to Centrifuge Operating Manual for specific operating and balancing instructions. In order to achieve 1800-1900 RCF (g) within the centrifuge, the corresponding RPM vary from centrifuge to centrifuge depending on the radius of the centrifuge's rotor. **Consult the centrifuge's operating manual for the appropriate RPM to achieve 1800-1900 RCF (g) for each centrifuge. Note: 1800-1900 is the optimal RCF (g) speed; if 1800-1900 RCF is unattainable in a certain centrifuge, then 1200-1300 RCF (g) is the minimal acceptable speed.** To balance the centrifuge, place tubes of the same size and with equal volume of blood as determined visually in opposite positions in the bucket adaptors. For tubes of blood that do not have another tube of equivalent blood volume, use a "balance tube" of the same size containing an equivalent volume of water. Wait for centrifuge to come to a complete stop before opening the lid.

The centrifuge should be routinely cleaned monthly, as directed in the Operator's Manual. We recommend removing the trunions (label or take note of the positions), soaking them for 20 minutes in Virex (Johnson Wax Company) diluted 1-128. Klero-ro may also be used. Rinse well, and allow to dry overnight. Wipe out the centrifuge with Virex diluted 1-128. Replace the trunions in the same positions as you removed them to ensure correct balancing. In case of a blood spill, wipe out the blood using 0.5% sodium hypochlorite (household bleach diluted 1:10), and then clean the centrifuge in the same manner as you do for monthly maintenance.

2.6 Kidney Biopsy Slides for Repository

All Clinical Centers, and select Engaged Transplant Programs with interest in the biopsy slide repository should work with their pathology departments to create 3 additional unstained slides from paraffin-embedded tissue blocks, when possible (each 3 mm slice thickness) from kidney biopsies performed within the first 24 months after transplantation in an APOLLO donor kidney. Biopsies may have been performed as part of usual clinical care, as pre-implantation, post-implantation (post-reperfusion), surveillance and for-cause. Each glass slide should be labelled with the transplant recipient record (TRR) number and date of biopsy. Slides should be stored in an Andwin Scientific 100-Slide Capacity Microscope Slide Storage Box; Fisher Scientific Catalog # 14-372-88; manufacture # Andwin Scientific 880120 https://www.fishersci.com/shop/products/andwin-scientific-100-slide-capacity-microscope-slide-storage-boxes-4/p-3238689 In one of the final years of APOLLO, slides will be shipped in the storage boxes from all Clinical Centers and select Engaged Transplant Programs to either the Cleveland Clinic APOLLO Clinical Center (Emilio Poggio, MD) or the APOLLO Central Lab at Wake Forest School of Medicine.

2.7 Labeling Samples (DNA PAXgene tubes and cryovials for aliquoted serum and urine)

Each of the Engaged Transplant Programs will be provided a DYMO LabelWriter 450 Turbo label printer by their affiliated APOLLO Clinical Center (Network Hub). Labels will be created on site for each sample collected/aliquoted. The labels will include the following four data fields separated by commas without spaces:

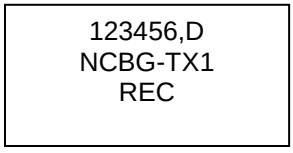
Each transplant RECIPIENT is issued a TRR number (Transplant Recipient Record) as a permanent UNOS identifier. The TRR# is a 6-digit number, e.g. 123456 (but may become a 7-digit number in the future).

- TRR numbers are immediately available when a recipient is removed from the wait list. The TRR# will be used as the identifying number on barcode labels (see 1.5.2.1 to obtain TRR#) – as follows:
    - Recipient TRR ID number
    - Recipient Sample type - D: DNA, S: Serum, U: Urine
    - Transplant Program Code (see Appendix 6) - expected format is …4 letters (a dash) TX1,
    - Sample source - REC: recipient

Example of a Recipient label when the TRR is available "123456":

123456,D,NCBG-TX1,REC

The above information will be coded into the QR code, and the actual label will read as



For biosamples from a LIVING DONOR, use the UNOS donor ID number in the first data field, followed by sample type (D: DNA, S: Serum, U: Urine), Transplant Program Code, and DON for Sample Source.

For example, AFED141,D,NCBG-TX1,DON will be coded into the QR code for a donor, and the actual label will read as

AFED141,D NCBG-TX1 DON

The label creation procedure is detailed on a demonstration video at: www.TheApolloNetwork.org (MENU > Training Videos).

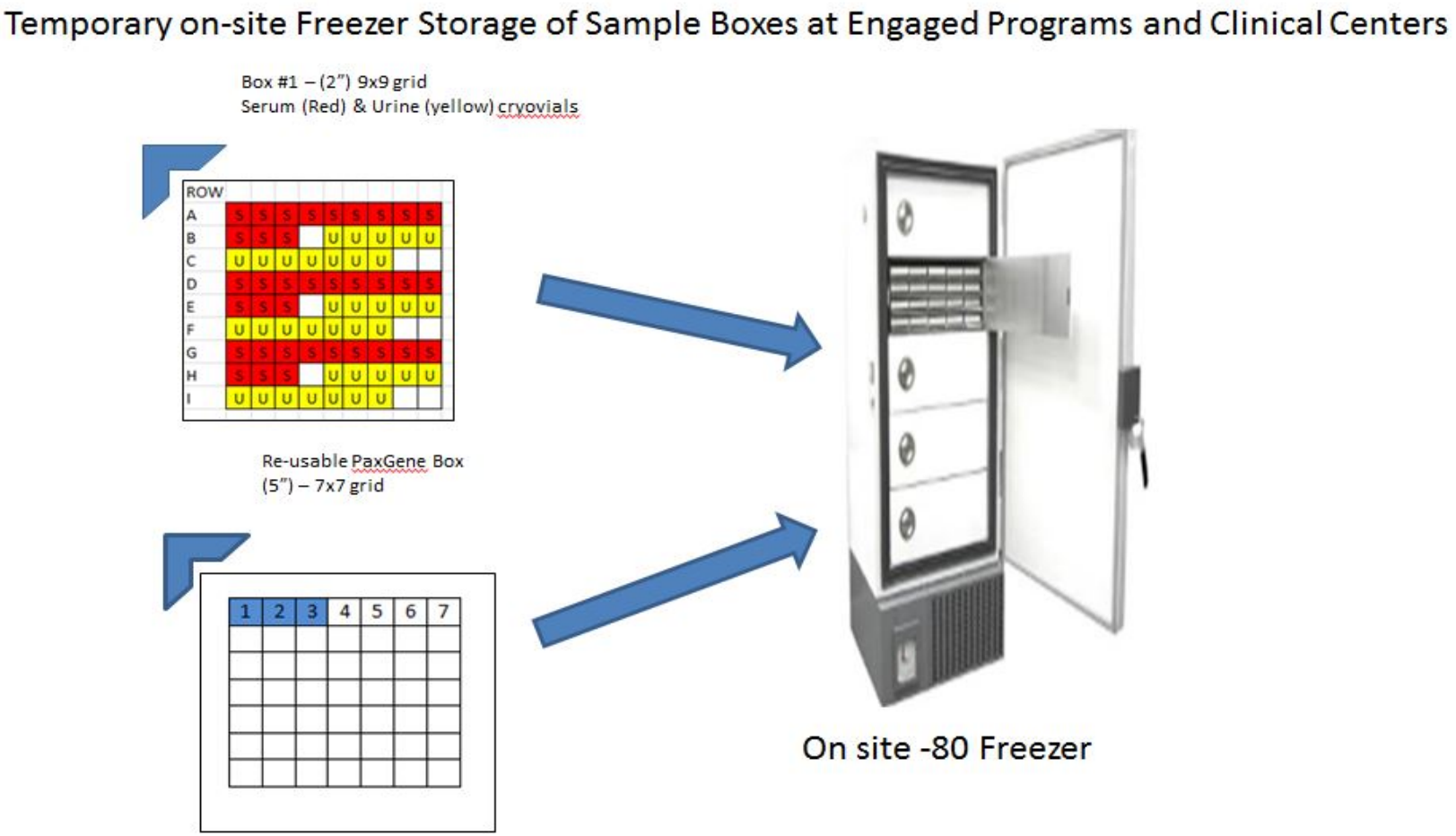
Engaged Transplant Programs will typically print 25 labels per participant: 12 will be sample type S (for the 12 serum cryovials), 12 will be sample type U (for the 12 urine cryovials), and 1 will be sample type D (for the DNA Paxgene tube). Although sample types differ on the labels from a single participant, the ID (either UNOS donor ID # for living donors or TRR # for transplant recipients), Transplant Program Code and Sample source will be the same on all 25 labels.

2.8 On-Site Sample Storage Preparation

Mark upper left corner of each, (sequentially numbered) fiberbox with permanent marker to indicate starting point. Write your transplant program identification code (appendix 6) on the fiberbox and fiberbox lid. Insert the aliquoted, labeled serum cryovials first (as indicated in red in diagram 2.8.1), then skip a space and add the aliquoted, labeled urine cryovials (as indicated below in yellow).

- Aliquoted serum and urine cryovials will be put into a 2” (9x9 grid) fiberbox and stored at -80°C for quarterly shipment to the APOLLO Central Lab on dry ice.
- Labeled PAXgene tubes will be put into a re-usable 5 “ (7x7 grid) fiberbox and stored at -80˚C for quarterly shipment to the APOLLO Central Lab on dry ice.

2.8.1 On-site Freezer Storage



Serum and Urine boxes will hold 3 participants each. PaxGene tubes will be stored in re-usable (5") 7x7 grid box. Samples will be shipped to SDRC on pre-assigned schedule.

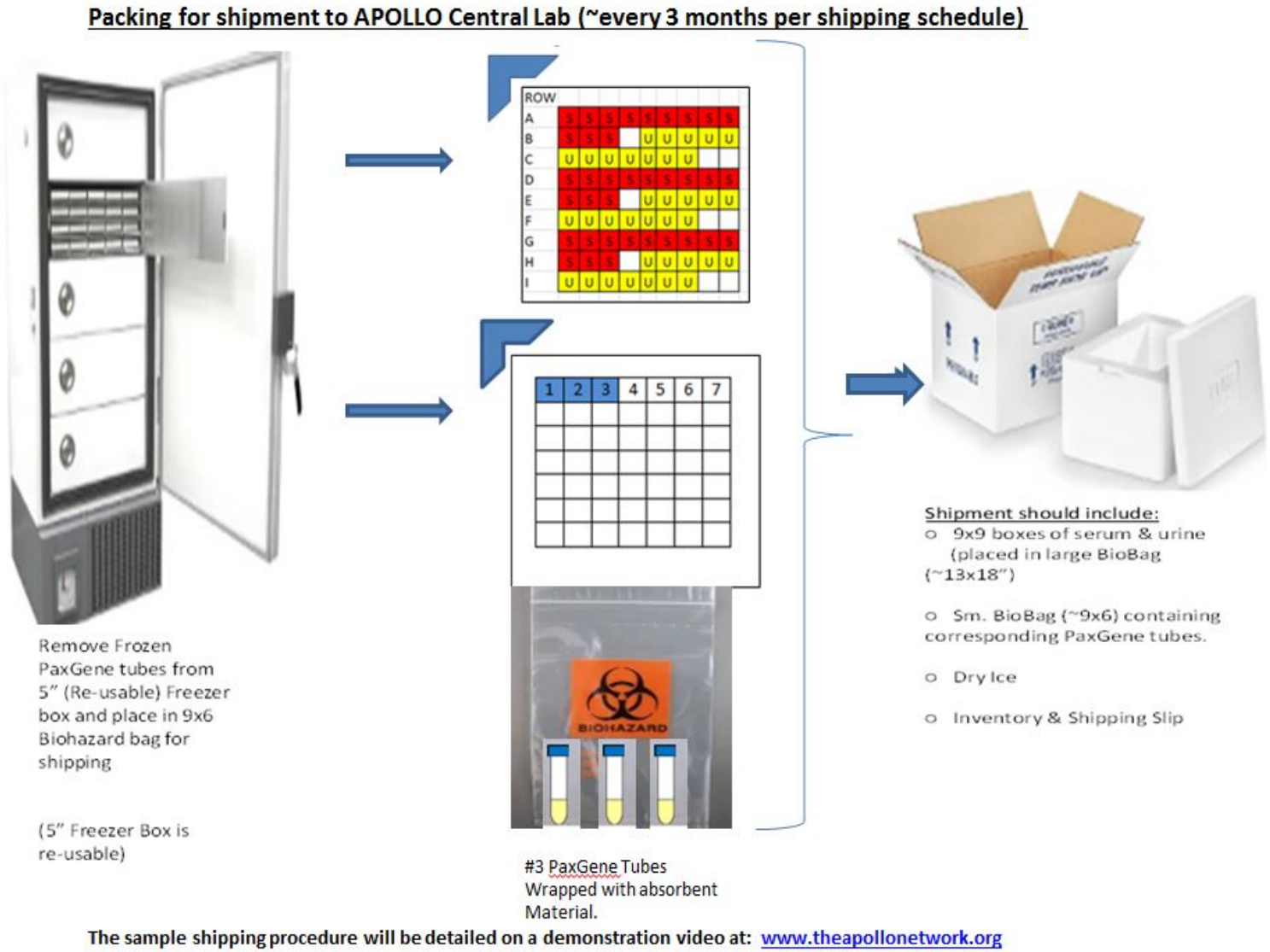
2.9 Assembling Frozen Samples for Shipment

a) Check to be sure that each tube is properly labeled and the cap is closed tightly.
b) Place each (serum & urine) cryovial specimen fiberbox and an absorbent sheet inside one or more large plastic biohazard bags ~ 13x18" and seal the bags.
c) Remove frozen PaxGene tubes from the re-usable cardboard freezer box and place multiple frozen tubes in a 9x6 ziplock Biohazard bag with absorbent material and then in a larger ~ 13x18" ziplock bag (double bagged) for shipping.
d) Place a layer of dry ice pellets on the bottom of Styrofoam shipping box. Place the plastic bag with boxes of aliquots on top of dry ice layer. Place bag of multiple PaxGene tubes on dry ice. Place additional dry ice pellets on top of specimens. Use at least twenty pounds (9 kg) of dry ice in each shipping box, i.e. 10 lbs per day.
e) Place lid on the Styrofoam box. Place the printed APOLLO Inventory & Shipping log on top of Styrofoam cover.
f) Close and tape the outer cardboard box.
g) Affix a dry ice label (see diagram 2.10.2) on the side of the shipping box. Enter the weight of dry ice on the label. (20 lbs. = 9 kg).
h) Affix the "UN3373 Biological Substance Category B" label (see diagram 2.10.2) to the side of the shipping box, near the dry ice label.
i) Use the pre-printed FedEx airbill to ship specimens to the APOLLO Central Lab.
    a. Ship date and receive date on the pre-printed airbill will need to be changed to reflect the correct dates.
    b. Fold the airbill in half and place inside the small clear FedEx pouch # 158396 and adhere to the top of the package following instructions on the pouch.
j) If you don't already have a routine scheduled FedEx pick-up, call FedEx at 1-800-GO-FEDEX (1-800-463-3399). Give them the account number on the preprinted FedEx airbill (listed under the "To: Address as REF #__") and your pickup address. FedEx will dispatch a courier to pick up the package (see example of an airbill in diagram 2.13.3).
k) Forward an electronic copy via "encrypted" email of the Inventory/Shipping spreadsheet to ApolloLab@wakehealth.edu. Include the FedEx tracking number located on the airbill. If you are unable to send "encrypted" email, password protect the excel spreadsheet. You will receive an email notification from the APOLLO Central Lab within 2 business days of receipt of the samples.

Contact the APOLLO Central Laboratory regarding questions about packaging and shipping (APOLLOLab@wakehealth.edu).

Printed Inventory & Shipping Log indicating relevant samples will be shipped by FedEx on dry ice to the APOLLO Central Lab based on a pre-specified quarterly shipping schedule.

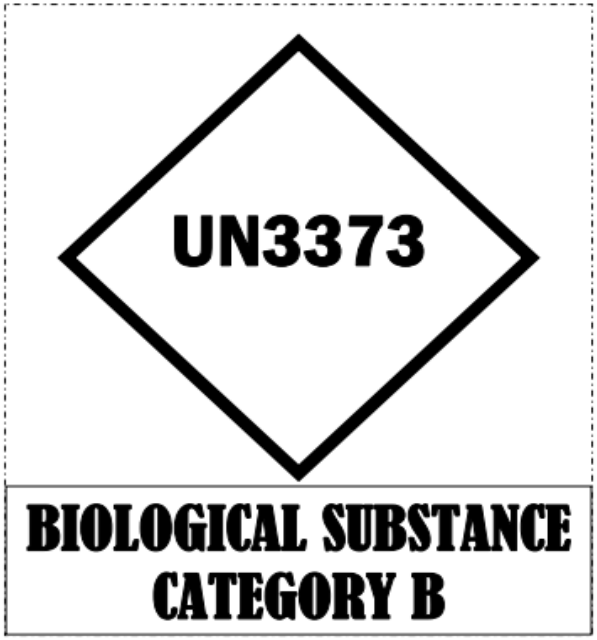
2.9.1 Packing for Shipments

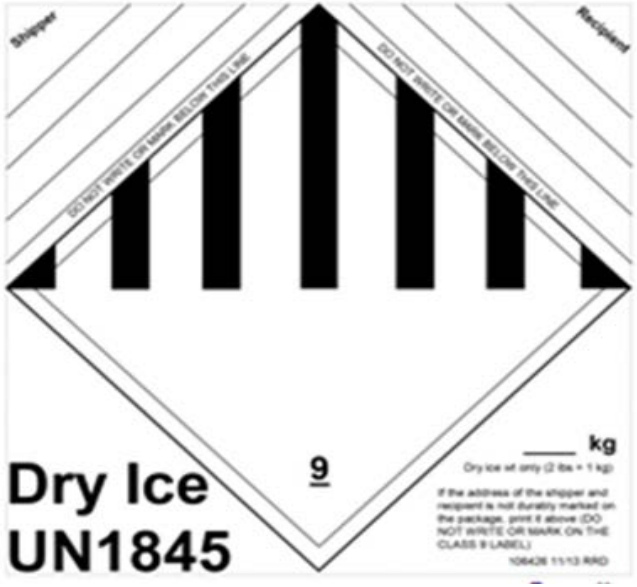


The sample shipping procedure will be detailed on a demonstration video at: www.TheApolloNetwork.org

2.9.2 Shipping Labels

Shipping Labels & Address





Shipping_Label_for_Biological_Substances_CategoryB.pdf

Shipping Address for APOLLO Central Lab:
Wake Forest School of Medicine
1 Medical Center Blvd.
APOLLO Lab, NRC Rm 235
Winston-Salem, NC 27157-1053

2.10 Shipping- From Engaged Transplant Programs & Clinical Centers

Samples will be shipped quarterly to the APOLLO Central Laboratory. Shipments will include:

- Insulated Shipper
- Specimen Boxes
- 13”x18” biohazard bag
- Paper towels (absorbent material)
- Preprinted FedEx airbill
- Dry ice label
- UN3373 Biological Substance Category B label
- 20 lbs / 9 kg dry ice (covering 48 hours)
- Inventory & Shipping Log

Sample shipments from Engaged Transplant Programs and Clinical Centers will be barcode labeled with participant ID (UNOS ID # of donor or TRR # of recipient, Transplant Program ID and sample type, as in 2.8. Sample shipment will include (per participant):

- 1 - 8.5 mL PaxGene DNA tube
- Up to #12 - 2 mL cryovials containing serum
- Up to #12 - 2 mL cryovials containing urine
- Printed Inventory Shipping Log detailing participant ID (UNOS donor ID # or TRR #) and relevant tubes shipped

2.11 Inventory & Shipping Log

Engaged transplant programs and Clinical Centers will maintain an excel file for Sample Inventory & Shipping Log (see diagram 2.12.1) on their local computer. The continuous log will be completed for each participant when biosamples are collected, aliquoted and stored in freezers. Staff will enter the following information in the file:

- Transplant Program Code (Appendix 6)
- Participant UNOS ID Number (or) TRR Number
- Sample Source (recipient or donor) REC or DON
- Shipping Date - will be entered when shipment is picked-up by FedEx
- Staff person’s name who put the FedEx shipment together

A printed copy of the Sample Inventory & Shipping Log will be included with each biosample shipment to the APOLLO Central Lab and should only include the Excel printed spreadsheet lines relevant to that shipment.

2.11.1 APOLLO Sample Inventory & Shipping Logs (Excel)

			DNA- PaxGene Inventory & Shipping Slip							
Engaged program code	*ID*	*Corrected ID*	*Sample source (DON/REC)*	*serum availabl e(Y/N)*	*urine availabl e(Y/N)*	*DNA Collection date*	*If recipient (REC), record donor's UNOS ID*	*Person Receiving DNA tube*	*Ship date*	*Person Fedexing*
NCBG-TX1	123456		REC	Yes	Yes	4/21/2019	ABCD123		9/17/2019	
NCBG-TX1	EFGH456		DON	Yes	Yes	5/11/2019	N/A		9/17/2019	
NCBG-TX1	234567		REC	Yes	Yes	7/11/2019	ABCD234		9/17/2019	

		Serum & Urine Inventory & Shipping Slip							
Engaged program code_ Box ID	*ID*	*Sample type (S/U)*	*Sample source (DON/REC)*	*How many vials?*	*Collection date*	*Living donor ONLY (pre/post operation) Recipient (N/A)*	*Person processing*	*Ship date*	*Person Fedexing*
NCBG-TX1_Box_1	123456	Serum	REC	12	4/21/2019	N/A		9/17/2019	
NCBG-TX1_Box_1	123456	Urine	REC	12	4/21/2019	N/A		9/17/2019	
NCBG-TX1_Box_1	EFGH456	Serum	DON	12	5/11/2019	post		9/17/2019	
NCBG-TX1_Box_1	EFGH456	Urine	DON	12	5/11/2019	pre		9/17/2019	
NCBG-TX1_Box_1	234567	Serum	REC	12	7/11/2019	N/A		9/17/2019	
NCBG-TX1_Box_1	234567	Urine	REC	12	7/11/2019	N/A		9/17/2019	
ProgramID_Box_2		Serum							
ProgramID_Box_2		Urine							
ProgramID_Box_2		Serum							
ProgramID_Box_2		Urine							
ProgramID_Box_2		Serum							
ProgramID_Box_2		Urine							

2.12 FedEx

Each of the 13 APOLLO Clinical Centers will set up a site-specific account with FedEx. Contact your local FedEx account representative and provide them with the NIH approved site-specific letter you received from the SDRC. The Representative will link your site account with the NIH account allowing for significant governmental discounted shipping rates. Once you receive an account number, Engaged Transplant Program staff will follow the instructions on the FedEx website to create your FedEx account explained in section 2.13.1.

Each of the 13 APOLLO Clinical Centers will cover the cost of shipping for each of their Engaged and Non-Engaged sites by using their established account to create a shipment (same as creating an airbill) as described in section 2.13.2.

Airbills for each site will be created prior to study start and two of each will be printed. Clinical Centers will keep one of the copies (for reference, if needed) and send the second copy to their Engaged Transplant Programs or Non-Engaged Programs to be used with each shipment. The same consecutive numbers will be written on both printouts for each site. Multiple airbills will be needed for each site. It is recommended that the Clinical Center Study Coordinator create and print 10-12 (duplicate) airbills for each of the aligned Engaged Transplant Programs and 3-5 for each Non-Engaged site, depending on recruitment history at each location.

Example: #1 Airbill -keep one printed copy
#1 Airbill -send to transplant program
#2 Airbill –keep one printed copy
#2 Airbill -send to transplant program

Write the same consecutive number you assigned on airbill onto the outside of the manila envelope kit and ask non-engaged programs to use the kits in numerical order.

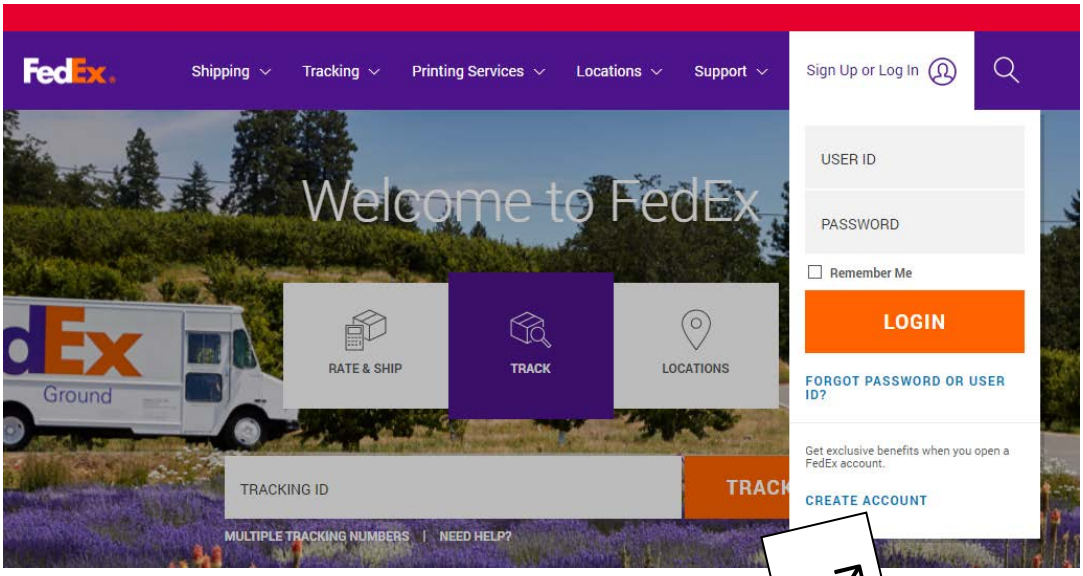
Information that will be needed to create an airbill includes:

- Center Addresses (each engaged & non-engaged program)
- Email address for coordinator at engaged site or email of designated staff member at non-engaged site.

2.12.1 Creating a FedEx Account with your NIH Shipping Account Number

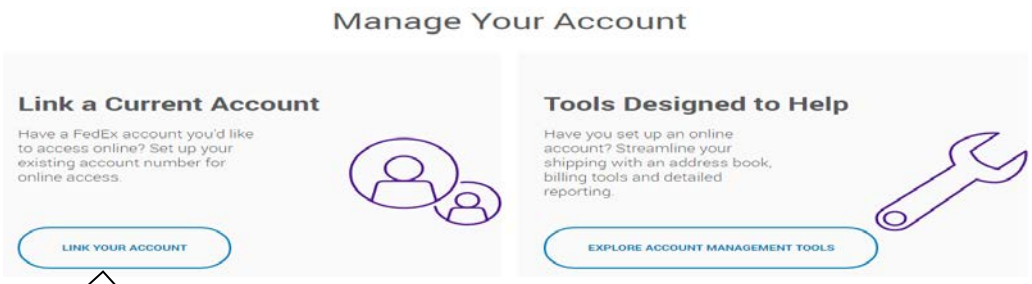
a) From the FedEx website (https://www.fedex.com/en-us/home.html), click "Create Account" from the "Sign Up or Log In" drop down menu (below).
b) Scroll to the bottom and click "LINK Your Account".
c) Complete the fedex.com Registration information and select "Use my account online" from the "Confirm Your Selected Account Option" at the bottom.
d) Click "Continue".
e) Enter your new NIH FedEx account number, nickname this account "APOLLO Study" and confirm.

(https://www.fedex.com/en-us/home.html),

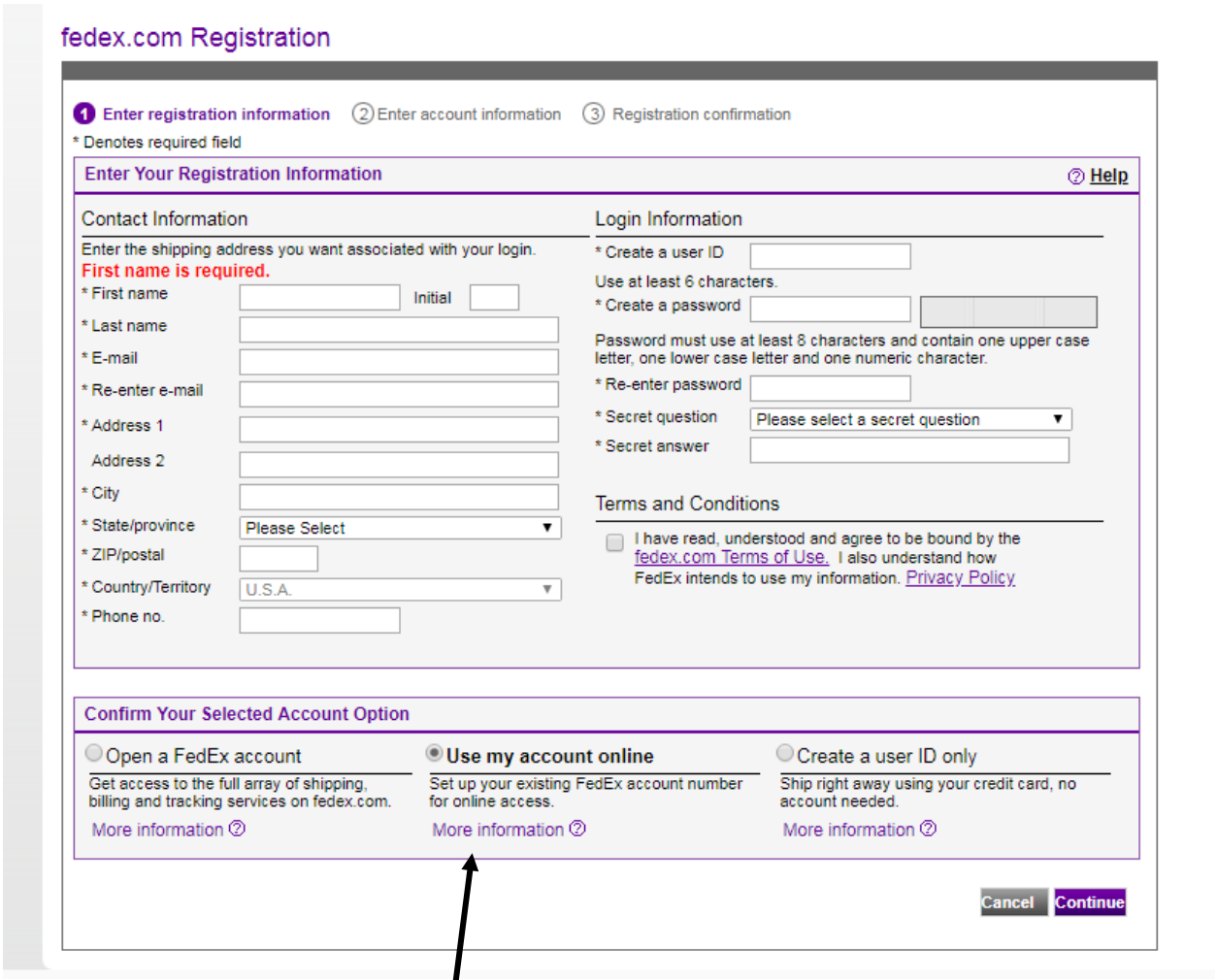


Click Create Account

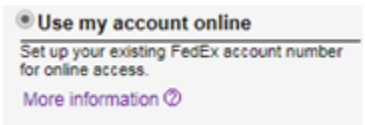
Scroll to the bottom and click on "LINK Your Account"



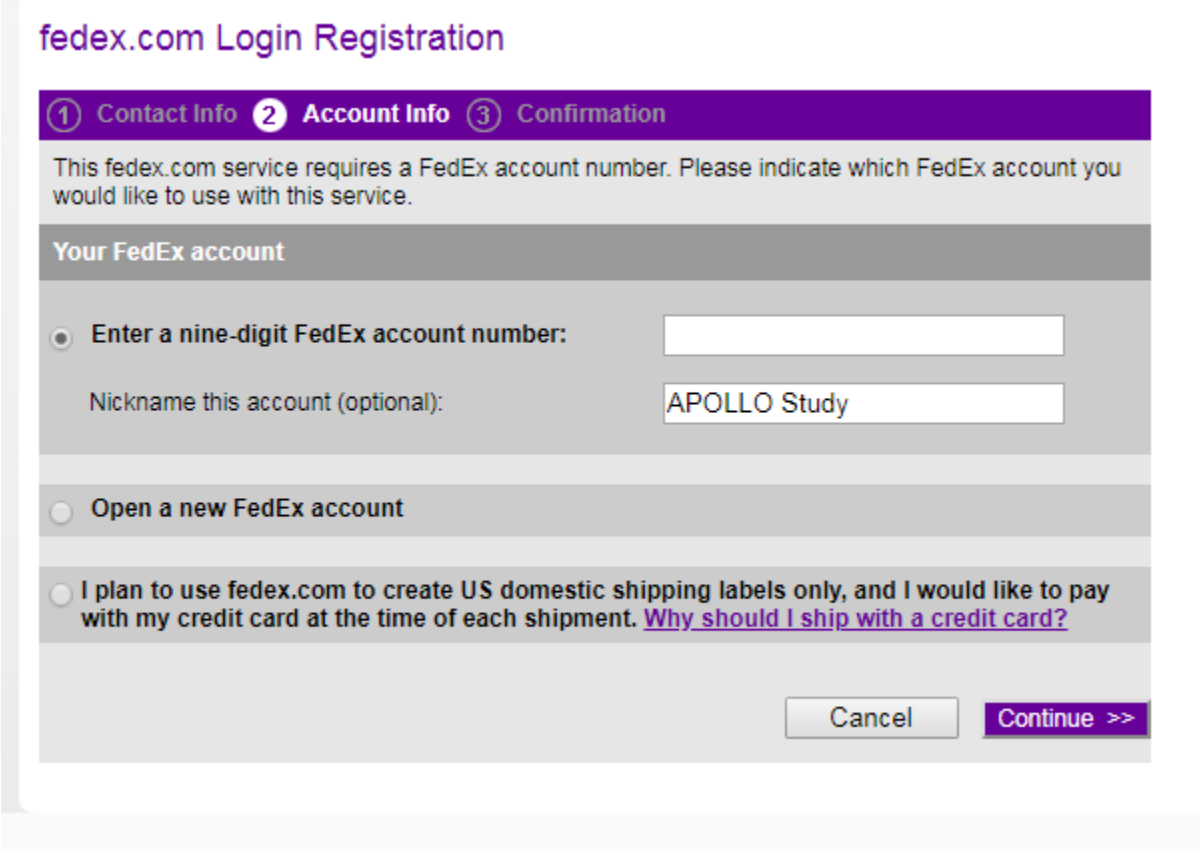
Click on Link your account



Complete the registration information above using this option.



Enter your new NIH FedEx account number below and continue



2.12.2 Create a Shipment or Airbill

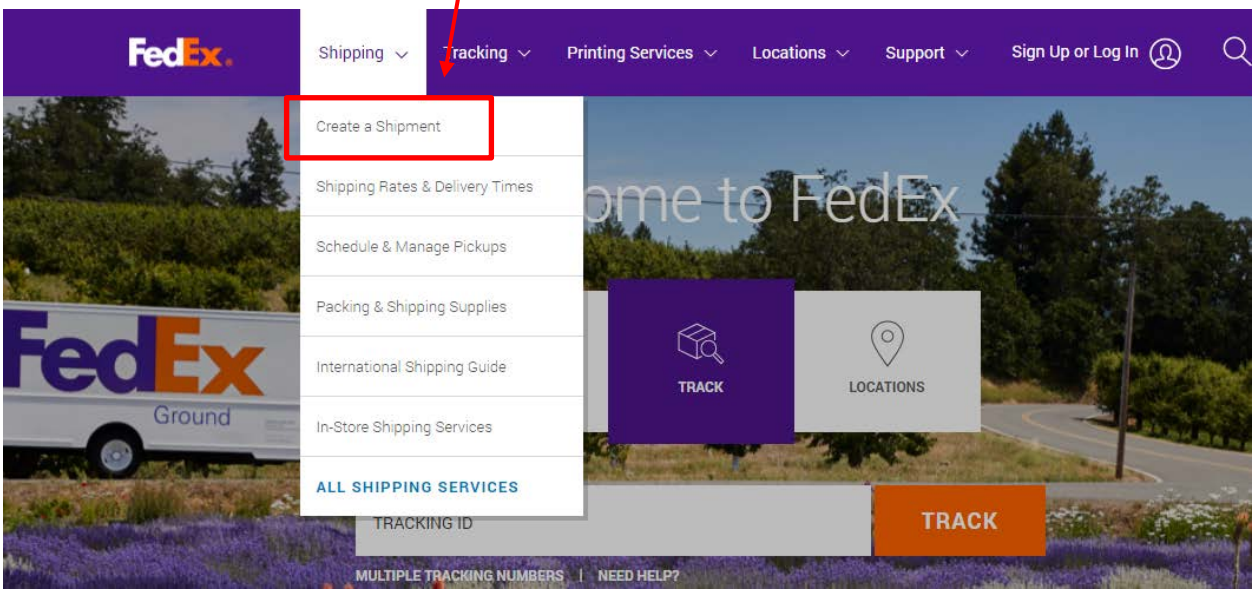
From the FedEx website (https://www.fedex.com/en-us/home.html), log in to the account created in 2.13 and click "Shipping" from the top menu and choose "Create a Shipment" (below)

Diagram Instructions to create a (Shipment or Airbill):

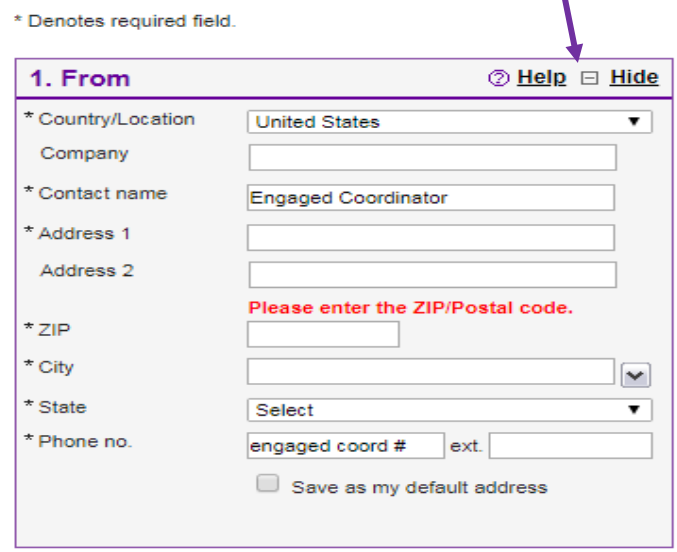
Go to FedEx website: https://www.fedex.com/en-us/home.html), (**Under the shipping tab (as indicated below in purple) choose "Create a Shipment"**

There are five sections to be completed on the "Create a Shipment" form:

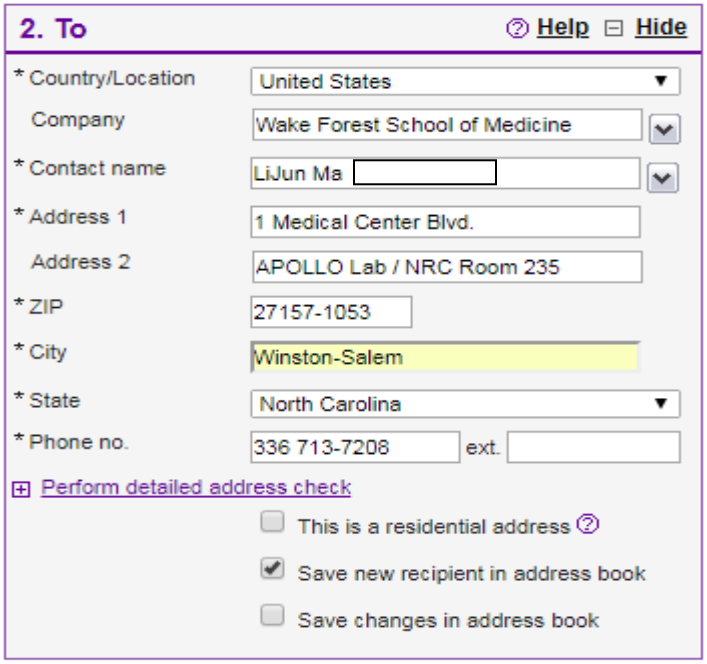
1. **From**
2. **To**
3. **Package & Shipment Details**
4. **Billing Details**
   - **Special Services (optional)**
   - **Pick-up/Drop-off (optional)**
   - **Shipment Notifications (optional)**
   - **Rates & Transit Time**
5. **Complete your Shipment**



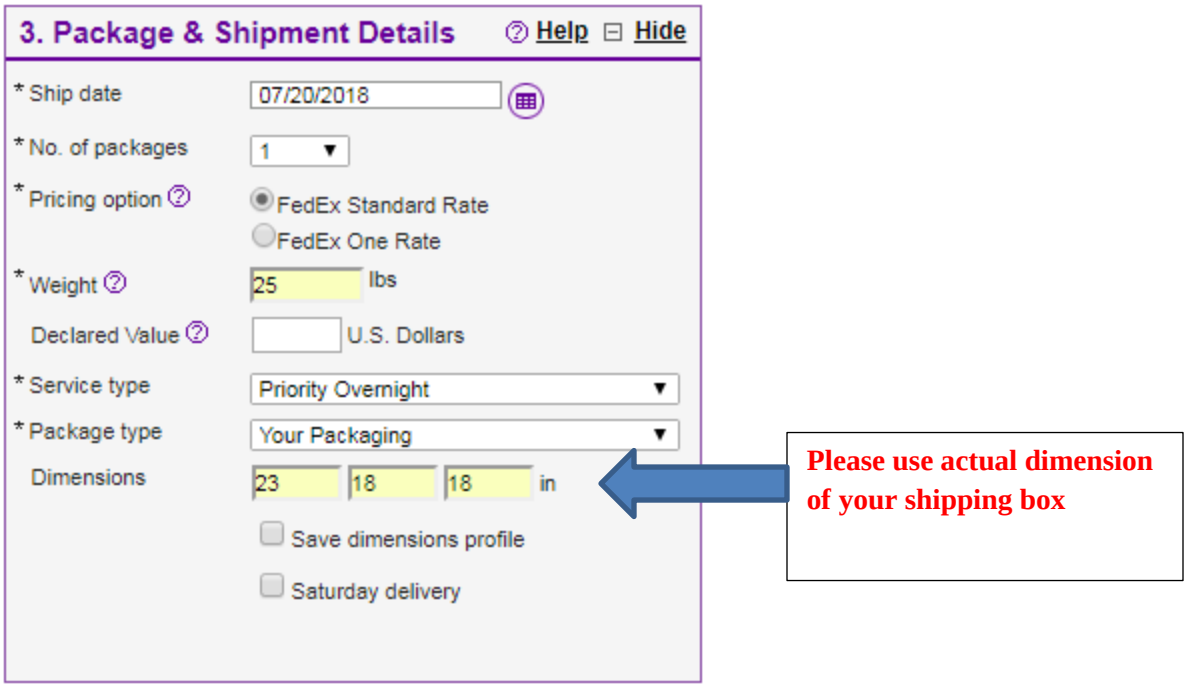
In the top right of each section there is a (–Hide) which will collapse each section and a (+Edit) button which will open each section.



NOTE: For Clinical Center Programs that will be completing this form for non-engaged samples, please list your name and Phone number with the non-engaged site address. This way, if there is a question FedEx will call you.



NOTE: You can save this address information so it will be auto-populated each time



The ship date above will not allow you to enter a date beyond 10 days. Most shipments will be beyond 10 days so, just enter today's date then mark it out on the printed airbill. You will need to instruct the engaged & non-engaged sites to write-in the correct ship date on the airbill (actual date of shipment).

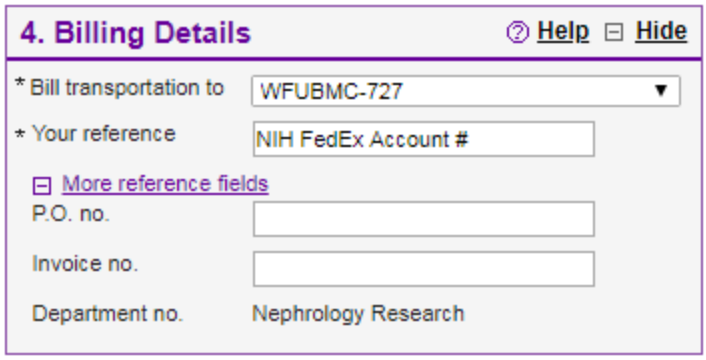
*Pricing option: Choose FedEx Standard Rate

*Declared value- Leave it blank.

*Service type: Specimens will always be shipped Priority Overnight (Engaged & Non-Engaged Transplant Programs)

*Package Type: Choose either…

1. FedExPAK –…i.e. Non-Engaged Transplant Programs only
   or
2. Your packaging-… i.e. shipping from HLA labs, Clinical Centers or Engaged Transplant Programs. You will need to enter dimensions for this option **L**ength, **W**eight, **H**eight



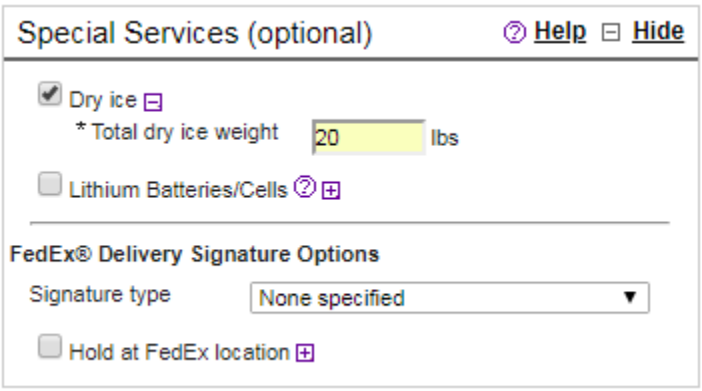
Bill transportation to: This section should be auto-populated upon logging in to your account with your created username and password.

Your reference: Enter your NIH FedEx account number so it will be printed on the airbill. When FedEx is telephoned to pick-up a package they will ask "What is the account number?" It will be printed on the airbill under the TO: address… as (REF- NIH FedEx Account #)

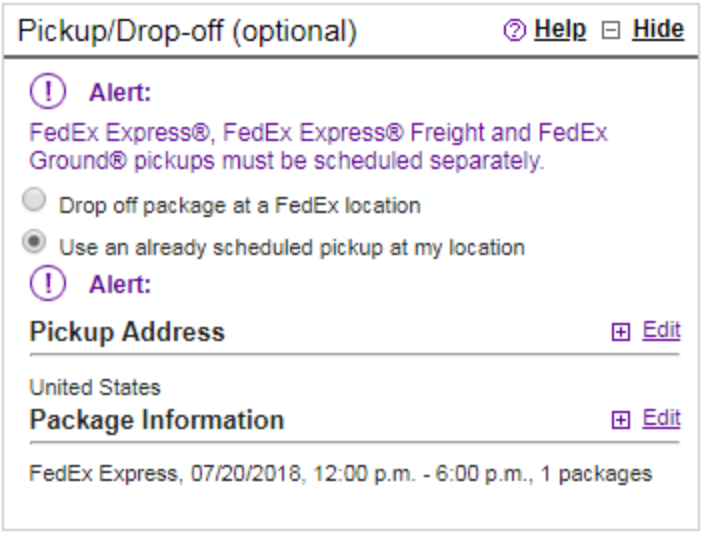
P.O.: Leave Blank

Invoice no.: Leave Blank

Department no.: Will be auto-populated.

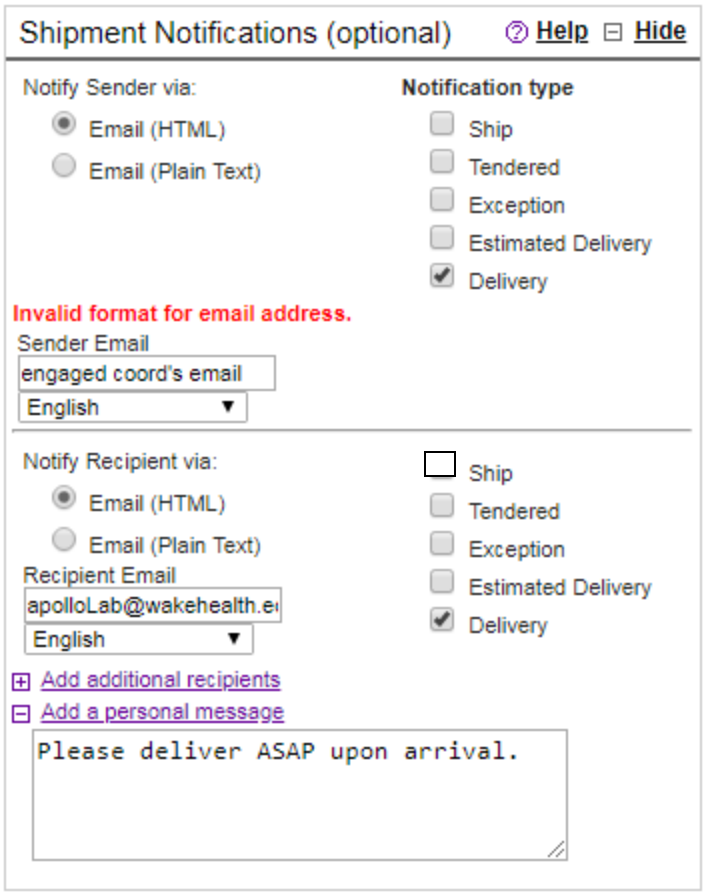


Enter this section as indicated above if using dry ice. If no, leave blank.



Complete this section as indicated above. The Pickup Address and Package Information sections are collaped because nothing needs to be entered in these fields.

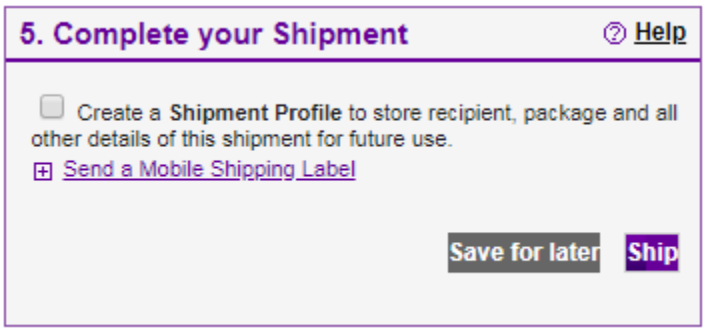
The site that telephones for a FedEx pick-up will verbally give the locatin address.



Notify Sender: Enter email for Engaged Transplant Program Study Coordinator.

Notify Recipient: Complete this section as indicated above.

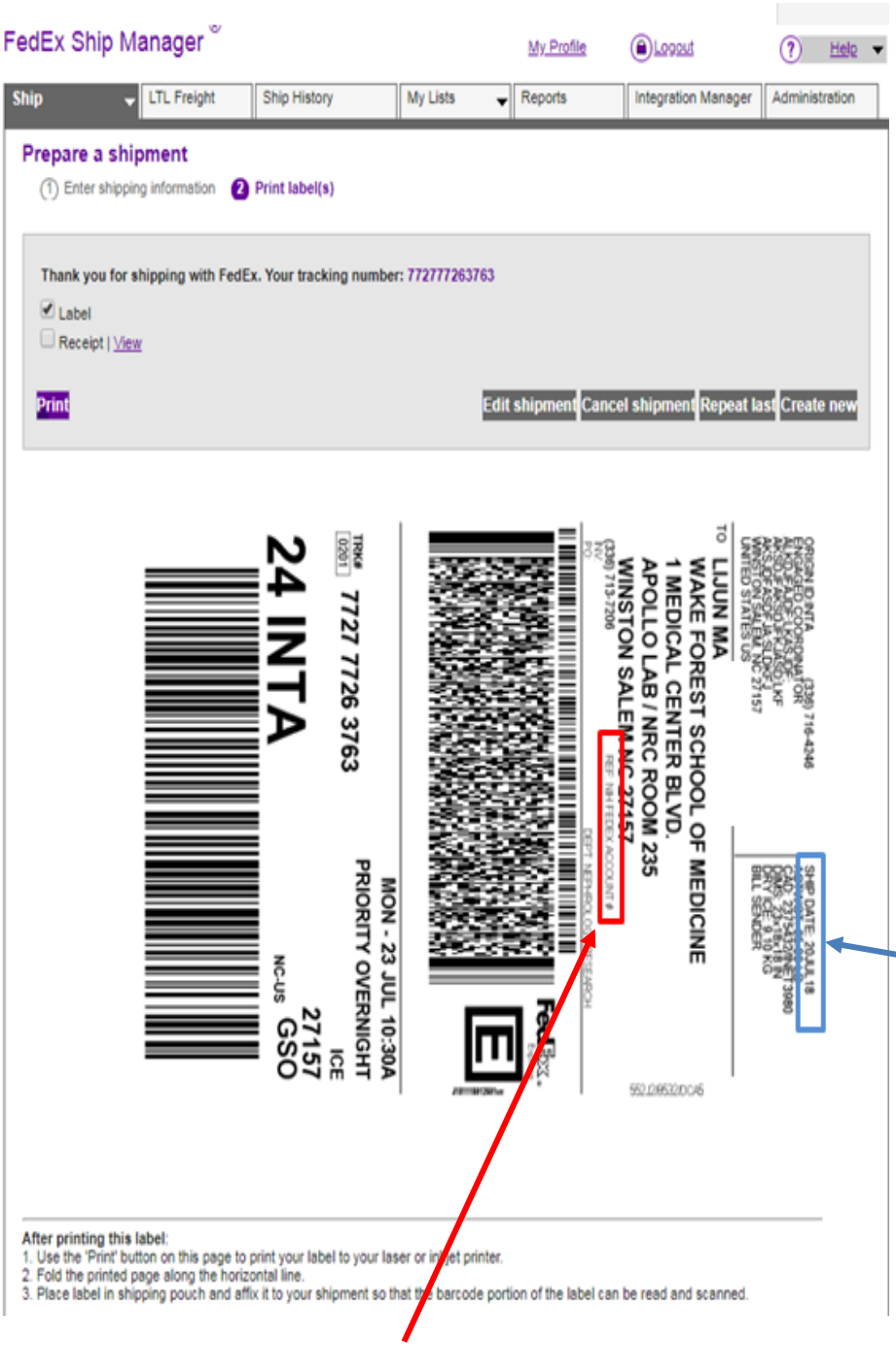
Add a Message: Complete as indicated above.



Click in square box to save Entered information for Auto-population next time. ←

Once you click "SHIP", an airbill (example below) will be generated with tracking numbers. **Print two copies…**

2.12.3 Example of AirBill



Print two copies:

1. Keep one copy for your records.
2. Place the second copy in the small clear FedEx pouch # 158396 and affix to package.
3. *Note: Mark thru the ship date if shipping will be at a later date.*
4. Notice the "REF" under the Wake Forest address is referring to your site's established NIH FedEx Account number. The non-engaged sites may be asked the account # when calling for a pick-up.

2.12.4 FedEx Shipping Supplies & Stickers

From the FedEx website (https://www.fedex.com/en-us/home.html), log in to the account created and click “Shipping” from the top menu and choose “Packing & Shipping Supplies” (below)

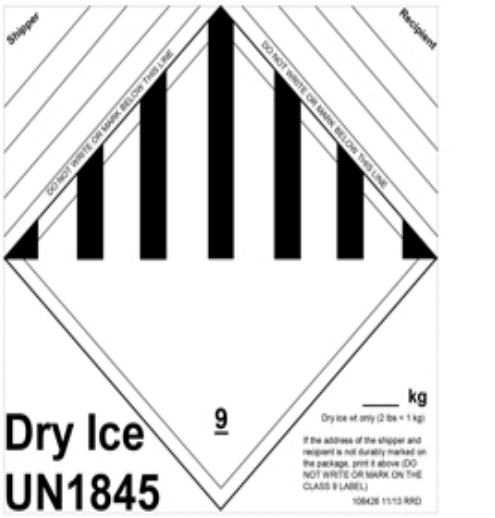
- FedEx UN3373 PAK # 163034 (for Non-engaged center shipping)
  Click PAKS, then Find Supplies (last one on the page).
- FedEx Small Pouch # 158396
  Click pouches, then Find Supplies (first one on the page).
- Dry Ice Labels #106426
  Click labels, then Find Supplies (first one on the page).

Your shipping package should contain two stickers:

1. UN3373 Biological Substance Category B (below, left)
2. Dry Ice sticker (below, right) indicating 20 lbs.

NOTE: The UN3373 sticker is already present on the FedEx PAK for Non-Engaged sites.

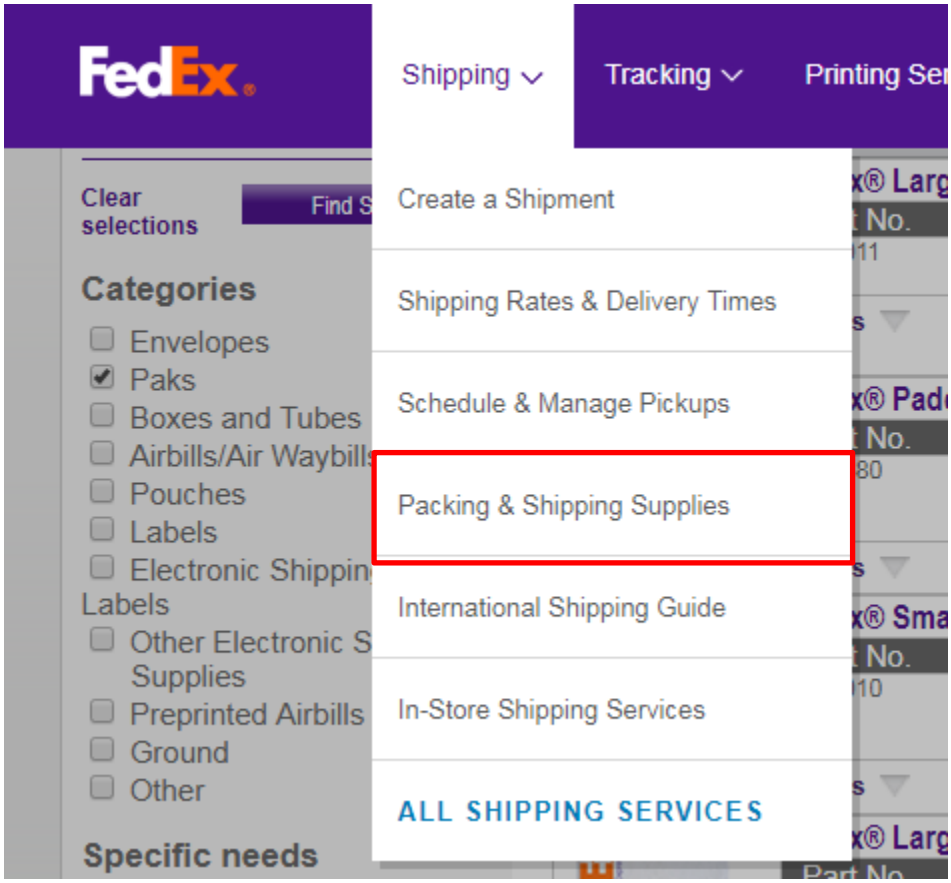
Place this label on large shipping boxes



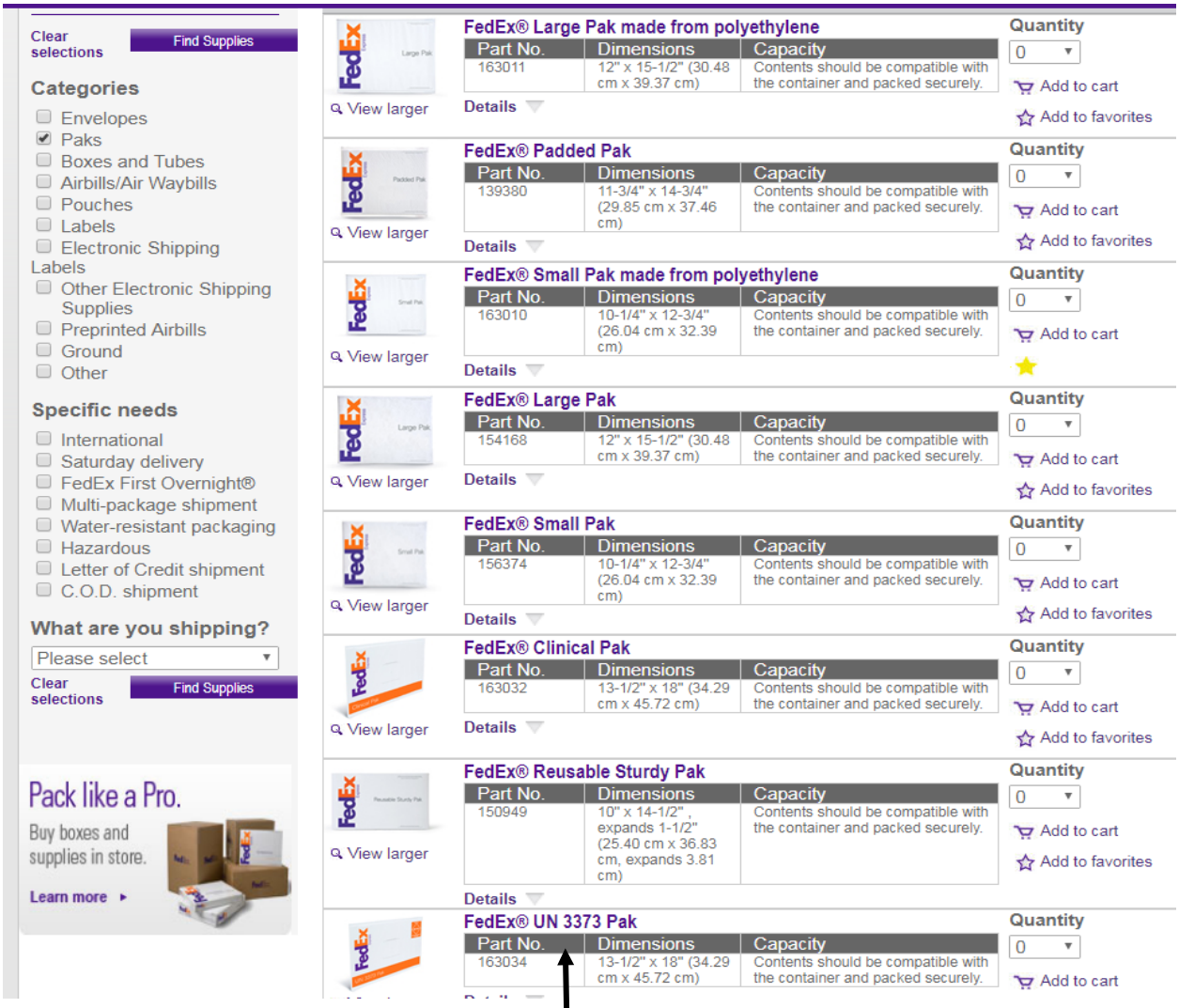
Place this label on large shipping boxes using dry ice

2.12.5 To Order FREE Fed Ex Supplies:

Go to Shipping Tab, then Packing & Shipping Supplies

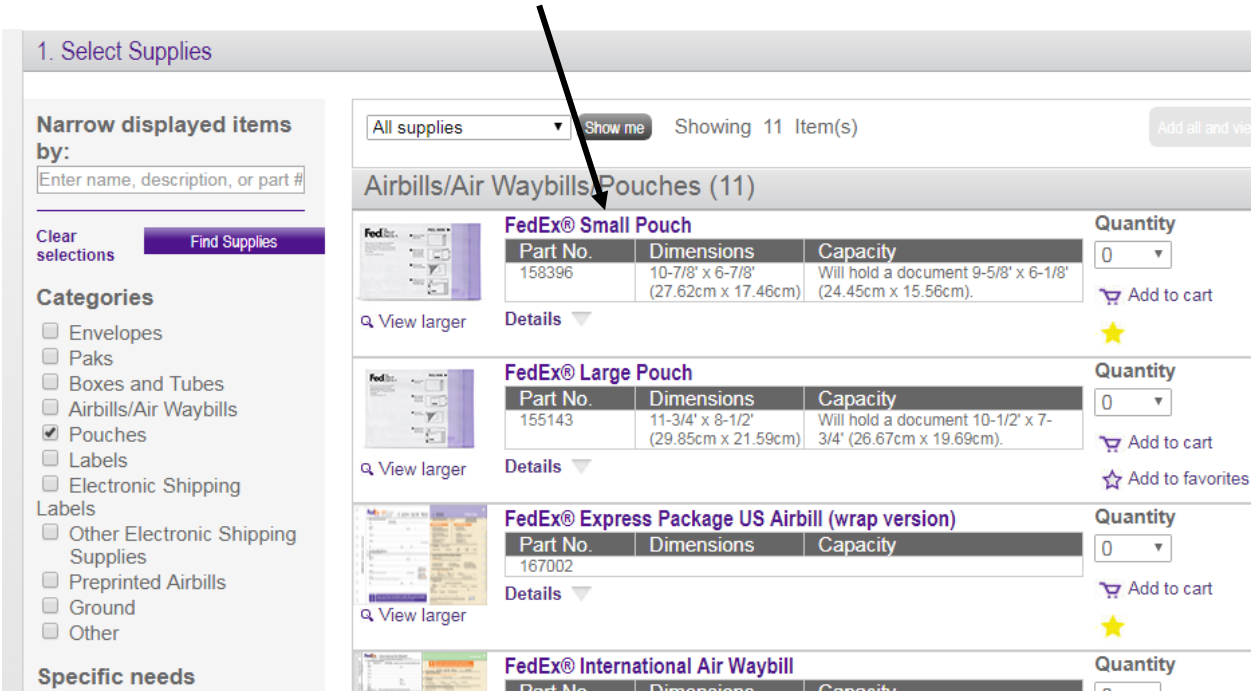


1. <u>To Order: FedEx UN3373 PAK # 163034 (for Non-engaged shipping)</u>
   Click PAKS, then Find Supplies…last one on the page.

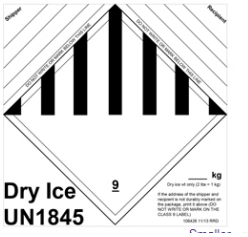


To Order: FedEx Small Clear Pouch # 158396

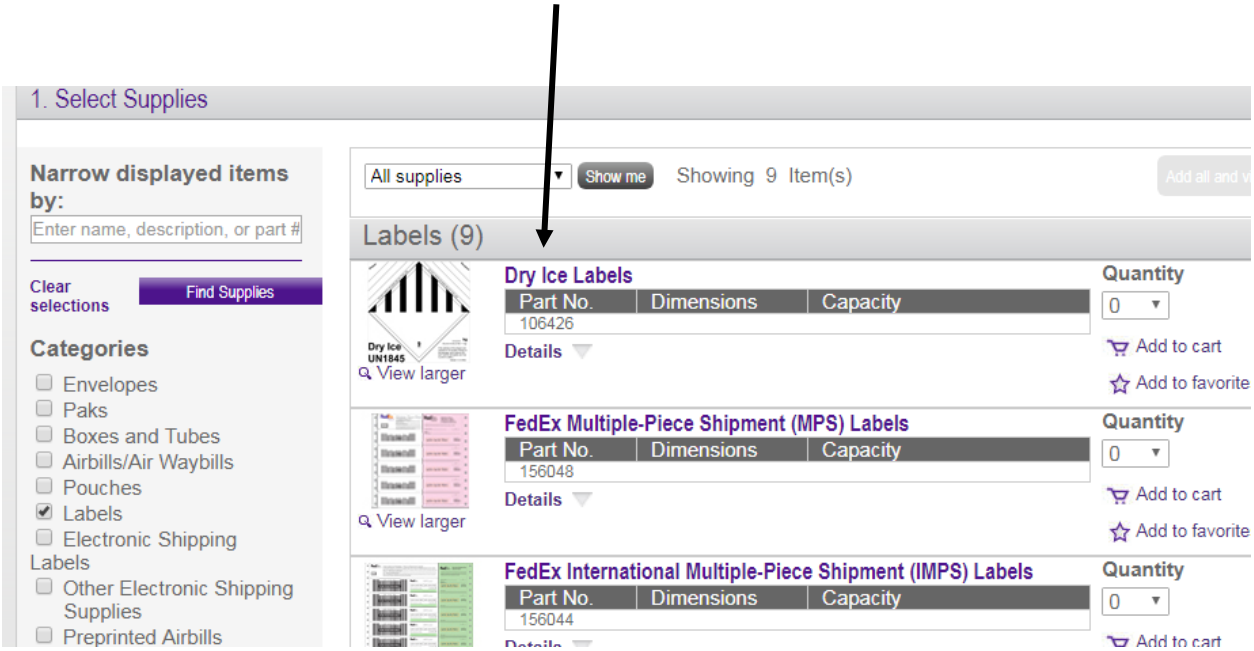
Click pouches, then Find Supplies…first one on the page.



2. <u>To Order: Dry Ice Labels #106426</u>



Click labels… then Find Supplies. First one on the page



3. Sample Processing & Shipping at Non-Engaged Transplant Programs

One 10 mL ACD-DNA tube will be collected from living donors and transplant recipients at Non-Engaged Transplant Programs. The timing of sample collection from living donors and transplant recipients is provided in Chapter 1. After Phone Consent is obtained, pre-designated local staff will:

a) Locate stored blood collection/shipping kits in sequentially numbered manila envelopes. Kits will be US mailed to your facility prior to study start by your aligned APOLLO Clinical Center Study Coordinator. Use the next sequentially numbered kit.

b) Open the kit and remove contents. Neatly write the participants' UNOS donor ID or TRR number directly on the ACD tube label. In addition, write the UNOS donor or TRR number and the date of collection on a separate piece of paper (Section 3, Diagram iii) that should be shipped via FedEx with the ACD tube.

c) Fill the tube completely with blood.

* To prevent clotting, gently invert the tube ~6-8 times immediately after collection to ensure the anticoagulant has mixed with the blood. No centrifugation or further processing is needed.

* When collecting blood from children, the blood draw is not to exceed 5% of body weight. Transplant program staff must be aware of daily blood draws for a youth recipient, because a blood draw for APOLLO might exceed the child's daily or monthly limit.

d) Place the collected blood tube in the provided Styrofoam mailer, then in the cardboard sleeve.

e) Place sample in provided 9x6 biohazard bag with absorbent material, seal, and place in provided FedEx UN3373 shipper.

f) Remove the pre-addressed affixed airbill from the FedEx Pak and handwrite the correct ship date in upper right corner and re-insert. Note: Your aligned APOLLO Clinical Center will cover the shipping cost with their NIH FedEx account number which is listed on the airbill.

g) Call 1-800-GOFEDEX (1-800-463-3339) for same day or next day pickup. If pickup is delayed through the weekend, or if it will be > 24 hours before shipment to the APOLLO Central Lab refrigerate the entire FedEx Pak and schedule pickup for early Monday morning. DO NOT SHIP ON A FRIDAY.

h) Immediately scan (same day) and send the (PDF) signed and witnessed Consent Form and completed Medical Records Release form via encrypted email, password protected WORD document, secure fax or US mail to your aligned APOLLO CC study coordinator. The original signed consent form will be given to the participant.

Copy of Shipping Instructions (Section 3, Diagram i) will be provided in each manila envelope kit. A demonstration video will also be available at www.TheApolloNetwork.org (login not required).

i. Non-Engaged Transplant Program Shipping Instruction Sheet

Instructions for Shipping Sample to SDRC

Hand write UNOS/TRR ID # on ACD

Place collected blood tube in Styrofoam mailer, then in cardboard

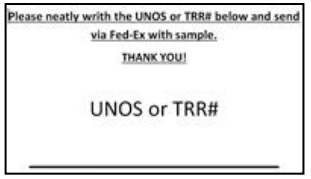
Place sample in biohazard bag w/absorbant material and seal. Place inside FedEx Pak for

Remove affixed air bill from FedEx Pak and hand write
The correct ship date in upper Rt corner.
Re-insert on outside of FedEx Pak.
*Account number is listed on air bill if

Call <u>1-800-GOFEDEX</u> for same day
Or next day pickup.

<u>DO NOT SHIP ON A FRIDAY</u>.

If pickup is delayed through the weekend,



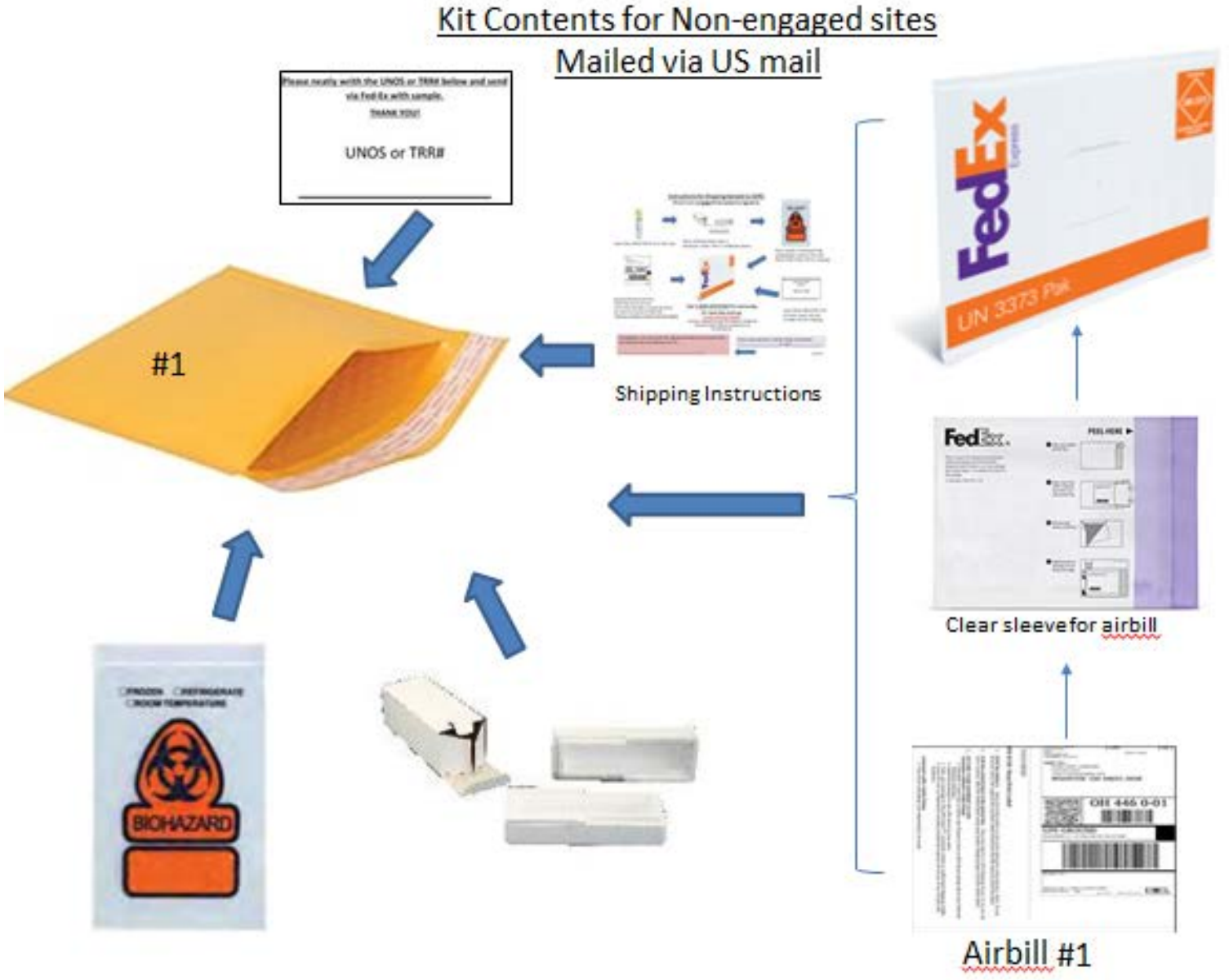
Hand Write UNOS/TRR ID #
On blank paper and put

Immediately scan and securely email (encrypted or password protected WORD document), secure fax or US mail the signed, witnessed consent form and Medical Records Release form to…

If you have questions call the Study Coordinator at ph #

10/03/19

ii. Kit Contents for Non-Engaged Transplant Programs



iii. UNOS Donor ID # or TRR #

Please provide UNOS Donor ID # or TRR # and date of collection below, then include this sheet with sample via FedEx.

Thank you!

UNOS Donor ID or TRR

_____

Date collected _____

Recipient samples:
Please use TRR (Transplant Recipient Registration) numbers as the sample ID.

Living Donor samples:
Please use UNOS Donor ID as the sample ID.

4 APOLLO Central Lab Sample Processing

4.1 Samples received from HLA Labs

4.1.1 Isolated DNA

Isolated DNA received from HLA Genotyping Centers will be immediately placed at -80°C upon receipt. DNA samples will be batched weekly for processing:

- Thawed at 20°C overnight
- DNA quality and concentration will be measured using the NanoDrop Spectrophotometer
    - Measurements will be made in triplicate and averaged
- An aliquot of DNA will be used to make a standardized dilution of 100ng/uL DNA in a 250 uL volume, i.e. "working stock".
- Using the "working stock", 25 uL of DNA, i.e. 2.5 ug of DNA, will be aliquoted into 4 pre-labeled 2 mL cryovials for shipment to the NIDDK Central Repository.
    - 4 – 2 mL cryovials will be barcode labelled with the UNOS ID
    - 25 uL of DNA will be transferred to each of the 4 barcode labelled cryovials
    - Aliquot cryovials will be stored at -80°C
    - Ship 4 DNA sample cryovials per participant to the NIDDK Central Repository on an every 6 month basis.
- Using the "working stock", 2 uL will be transferred to a 96-well plate for genotyping, i.e. *APOL1*, admixture, etc. Samples will be diluted with 38 uL of dH20 for a working concentration of 5 ng/uL.

4.1.2 Serum

Serum received from HLA Genotyping Centers will be immediately placed at -80^{0}C upon receipt. Serum samples will be batched weekly for processing:

- Thaw samples at 4ºC on ice overnight in a refrigerator.
- Before aliquoting, affix all barcoded labels lengthwise on 2 mL cryovials for ease of scanning at the sites and the NIDDK Central Repository. Ensure the label does not overlap with the top of the barcode to prevent interference with scanning the barcode.
- Verify that the specimens have been properly centrifuged.
- Pipet 0.25 mL of serum into each of 12 barcode-labelled 2 mL cryovials. Be careful not to disrupt any cellular debris at the bottom of the tube.
- Store all aliquots in a plastic rack or cardboard freezer box in an upright position at -80°C immediately.
- Ship 4 serum sample cryovials per participant to the NIDDK Central Repository on an every 6 month basis.

4.1.3 Urine

Urine received from HLA Genotyping Centers will be immediately placed at -80^{0}C upon receipt. Urine samples will be batched weekly for processing:

- Thaw samples at 4ºC on ice overnight in a refrigerator.
- Before aliquoting, affix all barcoded labels lengthwise on the 2 mL cryovial for ease of scanning at the sites and the NIDDK Central Repository. Ensure the label does not overlap with the top of the barcode to prevent interference with scanning the barcode.
- Pipet 0.8 mL of urine into each of the 12 barcode-labeled 2 mL cryovials. Be careful not to disrupt any cellular debris at the bottom of the tube.

- Store all aliquots in a plastic rack or cardboard freezer box in an upright position at -80°C immediately.
- Ship 4 urine sample cryovials per participant to the NIDDK Central Repository on an every 6 month basis.

4.2 Samples received from Engaged Transplant Programs & Clinical Centers

4.2.1 PAXgene DNA tube

PAXgene DNA tubes received from Engaged Transplant Programs will be immediately placed at -80°C upon receipt and intake scanning. Samples will be batched weekly for processing:

- For DNA isolation
    - PAXgene tube contents will be transferred to processing tubes filled with cell lysis buffer to lyse red and white blood cells.
    - Cell nuclei and mitochondria will be pelleted by centrifugation, washed, and resuspended in digestion buffer.
    - Protein contaminants are removed by incubation with a protease.
    - DNA is precipitated in isopropanol, washed in 70% ethanol, dried, and resuspended in resuspension buffer.
- DNA quality and concentration will be measured using the NanoDrop Spectrophotometer
    - Measurements will be made in triplicate and averaged
- An aliquot of DNA will be used to make a standardized dilution of 100 ng/uL DNA in a 250 uL volume, i.e. “working stock”.
- Using the “working stock”, 25 uL of DNA, i.e. 2.5 ug of DNA, will be aliquoted into each of 4 pre-barcode labeled 2 mL cryovials for shipment to the NIDDK Central Repository.
    - 4 – 2 mL cryovials will be barcode labelled as in 6.B.2.a.
    - 25 uL of DNA will be transferred to each of the 4 labeled cryovials
    - Aliquot cryovials will be stored at -80°C
    - Shipment of samples to the NIDDK Central Repository will take place on an every 6 month basis.
- Using the “working stock”, 2 uL will be transferred to a 96-well plate for genotyping, i.e. *APOL1*, admixture, etc. Samples will be diluted with 38 uL of dH20 for a working concentration of 5 ng/uL.

4.2.2 Serum

Serum sample aliquots (12 x 250 ul aliquots) received from Engaged Transplant Programs will be immediately placed at -80°C upon receipt and intake scanning. Shipment of 4 serum samples per participant to the NIDDK Central Repository will take place on an every 6 month basis.

4.2.3 Urine

- Urine sample aliquots (12 x 800 ul aliquots) received from Engaged Transplant Programs will be immediately placed at -80°C upon receipt and intake scanning. Shipment of 4 urine samples per participant to the NIDDK Central Repository will take place on an every 6 month basis.

4.3 Samples Received from Non-Engaged Transplant Programs

4.3.1 Acid citrate dextrose (ACD) Tube

ACD tubes from Non-Engaged Transplant Programs will be scanned and processed by the APOLLO Central Laboratory upon receipt:

- For DNA isolation
    - ACD tube contents will be transferred to processing tubes filled with cell lysis buffer to lyse red and white blood cells.
    - Cell nuclei and mitochondria will be pelleted by centrifugation, washed, and resuspended in digestion buffer.
    - Protein contaminants are removed by incubation with a protease.
    - DNA is precipitated in isopropanol, washed in 70% ethanol, dried, and resuspended in resuspension buffer.
- DNA quality and concentration will be measured using the NanoDrop Spectrophotometer
    - Measurements will be made in triplicate and averaged
- An aliquot of DNA will be used to make a standardized dilution of 100 ng/uL DNA in a 250 uL volume, i.e. "working stock".
- Using the "working stock", 25 uL of DNA, i.e. 2.5 ug of DNA, will be aliquoted in each of 4 pre-barcode labelled 2 mL cryovials for shipment to the NIDDK Central Repository.
    - 4 x 2 mL cryovials will be labeled as in 6.B.2.a
    - 25 uL of DNA will be transferred to each of 4 labelled cryovials
    - Aliquot cryovials will be stored at -80°C
    - Shipment of samples to the NIDDK Central Repository will take place on an every 6 month basis.
- Using the "working stock", 2 uL will be transferred to a 96-well plate for genotyping, i.e. *APOL1*, admixture, etc. Samples will be diluted with 38 uL of dH20 for a working concentration of 5 ng/uL.

4.4 APOLLO Central Lab Sample Genotyping

Genotyping of *APOL1* renal risk variants (RRVs) will be genotyped using the Sequenom technology. Genotyping of ancestry informative markers will follow this same protocol in lieu of implementing array-based genotyping.

4.5 APOLLO Central Lab Sample Shipments to the NIDDK Central Repository

At 6 month intervals, a subset of all samples will be shipped to the NIDDK Central Repository to increase the impact of the study by making biospecimens available to the broader scientific community.

4.5.1 DNA

The exact amount of DNA isolated varies by participant, sample collection method (ACD versus PAXgene tube), technique (manual versus automated) and lab. For each DNA sample stored at the APOLLO Central Laboratory, one-third will be aliquoted to 4 x 2 mL cryovials and sent to the NIDDK Central Repository.

4.5.2 Serum

Among the 12 cryovials stored at the APOLLO Central Laboratory, four will be sent to the NIDDK Central Repository.

4.5.3 Urine

Among the 12 cryovials stored at the APOLLO Central Laboratory, four will be sent to the NIDDK Central Repository.

4.6 APOLLO Central Lab Sample Information Database

An APOLLO Sample Entry Database will be created to scan in UNOS or TRR ID #, record information of sample type (DNA, serum, urine), sample source (donor or recipient), medical center/HLA genotyping center ID that performs the original sample collection, and the exact location of each sample in the freezers at the SDRC characterized by freezer ID, shelf, rack, Box ID, x by y location in the unique box. The Box ID covers the information of sample type and source (e.g. APOLLO SR Box 002, indicating the 2nd box containing serum of recipients at the SDRC repository). The samples shipped to the NIH repository will be properly indexed by the exact location in sample boxes with box ID covering the information of sample type and source (e.g. APOLLO NIH UD Box 001, indicating the first box containing urine from donors for the NIH repository).

Appendix 1 Supplies

Supplies for NON-Engaged transplant programs

The following supplies will be purchased by the CCs and distributed to transplant programs.
(note, if engaged transplant program subcontract budget allows for supplies, the CC will invoice).

The following supplies will be purchased by the CCs and distributed (as individual kits) to Non-engaged transplant programs :

• Sonoco ThermoSafe Lab Mailer (holds one ACD blood tube)	Fisher Scientific, Catalog No. 03-527
• Sleeve for Styrofoam blood tube mailer- thin cardboard	Fisher Scientific, Catalog No. 03-527A
• ZipLock Biohazard bag (~9x6) /with absorbent material	Fisherbrand, Catalog No. 23-700-211
• FedEx shipping PAK (UN3373 PAK-Biological Substance, Category B)	FREE from FedEx #163034
• Clear pouch for Airbill (attached to shipping PAK UN3373)	FREE from FedEx #158396
• FedEx Airbill- complete online (mark through date)	Create and print from the FedEx website
• Printed instruction sheet for FedEx shipping to SDRC	3.1.1 & APOLLO website under Manual of Procedures folder
• Blank sheet of paper with UNOS # _____	3.1.3 & APOLLO website under Manual of Procedures folder
• Padded Envelope (~ 11x15) all of the above items inside for mailing	Clinical Center's choice

The following supplies will be provided by the Non-engaged transplant program:

• 8.5 mL ACD tubes	Transplant Program's choice
• Paper Towel (as absorbent material)	Transplant Program's choice

*It is suggested that CCs Divide supplies proportionally based on transplant numbers & mail as individual kits to non-engaged programs

Appendix 1 cont.

Supplies for Engaged transplant programs

The following supplies will be purchased by the CCs and distributed to transplant programs.
(note, if engaged transplant program subcontract budget allows for supplies, the CC will invoice)

• Clear pouch for Airbill (attached to shipping PAK UN3373)	FREE from FedEx #158396
• Dry Ice Label	https://www.fedex.com/content/dam/fedex/us-united-states/services/Dry_Ice_Label.pdf
• UN 3373 label (for large shipping containers)	Label for Biological Substances Category B & posted on APOLLO website (*Documents > MOP > Biological Substance Category B label for shipping*)
• FedEx Airbill- complete online (mark through date)	Create and print from the FedEx website
• Sterile urine collection cups	Provided by transplant program
• 8.5 mL PaxGene DNA tubes (blue/gray top)	Qiagen, Catalog No. 761115
• 10 mL Red top serum tubes	Fisher Scientific , Catalog No.. 02-685-112
• 5-inch 7x7 Cardboard storage box (~2-3 Re-usable)	Globe Scientific, Catalog No. 3098
• 2-inch 9x9 Fiberbox box	Fisher Scientific, Catalog No. 03 395 464
• Insulated shipping container ~22x15x15	Fisher Scientific, Catalog No03-525-100
• BioHazard bags 13x18	Fisherbrand, Catalog No. 22-130-111
• BioHazard Bags 9x6	Fisherbrand, Catalog No. 23-700-211
• Paper towels (absorbent materials for biosamples shipment)	Provided by transplant program
• Dry ice for shipment to the SDRC q/3 months: 10 lbs/day	Site will order
• DYMO LabelWriter 450 Turbo label printer 	DYMO LabelWriter 450 is available at Amazon link: https://www.amazon.com/DYMO-LabelWriter-Thermal-Printer-1752265/dp/B0027JIIKQ/ref=sr_1_3?ie=UTF8&qid=1548256410&sr=8-3&keywords=dymo+labelwriter+450+turbo
• DT Cryo-Tags 2.00”x0.75” 500/roll (white)	USA Scientific, Catalog #9138-7000
• Cryovial Lab Rack	ThermoScientific Nunc Mfr# 376589 item# UX-03755-71
➢ 2 mL Cryovials*	*Provided by SDRC (shipped to CC, cost invoiced to CC)
➢ Dry Ice	Transplant Program Choice; transplant program will pay for dry ice

Supplies can be purchased in bulk and then divided between programs to reduce costs.

Appendix 2 Sample Processing Diagram

Tube	Description	Visual Reference	Collection/Processing
ACD (yellow top) Provided by non-engaged program	8.5 mL yellow-top (Becton Dickinson Cat# 364606)	Handwritten Label with UNOS donor or TRR ID# 	• Fill labeled tube completely with blood • Invert tube ~6-8 times • DO NOT Centrifuge • Ship immediately at room temperature (or refrigerate if >24h) until Shipment to APOLLO Central Lab • This is only for non-engaged sites
PaxGene DNA (blue/gray top) Engaged Programs	8.5 mL blue-top (Qiagen Cat# 761115)	Label Tube w/label machine 	• Fill labeled tube completely with blood • Invert tube ~ 6-8 times • DO NOT Centrifuge • Store at -80°C for long term storage • Ship to APOLLO Central Lab on a pre-specified quarterly shipping schedule on dry ice
Serum (red top)	10 mL red-top (Becton Dickinson Cat# 367820)	Label cryovials w/label machine 	• Fill labeled tube completely with blood • Invert tube ~ 6-8 times • Tube must sit 30-60 min at Room Temp • Blood will clot • Centrifuge • Aliquot serum into labelled cryovials x12 • Store cryovials at -80°C until Shipment • Ship to APOLLO Central Lab on a pre-specified quarterly shipping schedule on dry ice
Urine	Sterile Urine Collection Cup (as each Med Center's clinical routine, e.g. Sarstedt 75.562.105)	Label Urine cryovials w/label machine 	• Aliquot into labelled cryovials x12 • Store cryovials at -80°C until Shipment • Ship to APOLLO Central Lab on a pre-specified quarterly shipping schedule on dry ice

Appendix 3 APOLLO Phone Script

APOLLO
Introduction Phone Script

Hello,

My name is _____from _____. I work with/in _____.

I'm calling because your kidney transplant doctor, Dr. _____ suggested that you would be a great candidate for an ongoing nationwide NIH study about how genes may affect kidney function in transplantation. The study is observational, meaning there are no changes to your usual medical care if you participate and no additional study visits are required. In addition, your health care or transplant status will not be affected by whether or not you agree to learn more about the study or participate in APOLLO.

The purpose of this study is to improve outcomes for kidney transplant recipients and living kidney donors. APOL1 is the name of a gene that can cause kidney disease in some people who have changes (called variants) in this gene. The study is called APOLLO and it will test blood samples from study participants for APOL1 gene variants. Results will make it possible to see how the APOL1 gene might affect people who received a kidney transplant and how it may impact people who donated a kidney.

Does this study sound like something you might be interested in?

If yes, please allow me to give more details about the study and answer questions.

If no, thank you very much for allowing me to explain this study. I hope everything goes well with your surgery.

Appendix 4 Living Donor Signature form –

(Actual Consent signature can be obtained before or after surgery if #1 or #2 below has been completed).

APOLLO

Living Donor Signature Form

1. Initial APOLLO Presentation:

The APOLLO investigator/staff at _____

Transplant Program

discussed participation in the APOLLO study with me and reviewed the provided consent form and educational materials with me on (date): _____ (> 2 weeks prior to surgery)

All of my questions were satisfactorily answered.

_____ _____

Living Donor's printed name signature/ date

_____ _____

Witness (if telephone presentation) signature /date

_____ _____

Study staff administering discussion signature / date

---

2. Documented APOL1 Testing and Results: (> 2weeks prior to surgery)

The APOLLO investigator/staff at _____

Transplant Program

discussed participation in the APOLLO study with me and reviewed the provided consent form and educational materials with me on (date): _____ (prior to scheduled surgery)

All of my questions were satisfactorily answered.

_____ _____

Living Donor's printed name signature/ date

_____ _____

Witness (if telephone presentation) signature /date

_____ _____

Study staff administering discussion signature / date

When presenting APOLLO via telephone call, please have a witness present to verify phone call.

The living donor will sign this form during the in-person consent meeting.
This document will be stored in the participants APOLLO study file. A copy can be provided to the potential donor, if requested.

Appendix 5 HLA Lab Identification Codes

This table contains a complete listing of the HLA Labs are sorted by the Center Code. For each HLA Lab, the location and phone number are provided.

Code	HLA Genotyping Center	Location	Phone
ALUA	Alabama Regional Histocompatibility Laboratory	Birmingham, AL	205-934-4987
ARUA	Tissue Typing Laboratory at UAMS Medical Center	Little Rock, AR	501-364-1803
AZGC	Donor Network of Arizona Immunogenetics Laboratory	Phoenix, AZ	602-251-2800
AZTL	Blood Systems Laboratories	Phoenix, AZ	602-343-7062
AZMC	Mayo Clinic in Arizona Histocompatibility Laboratory	Scottsdale, AZ	480-342-2700
AZUA	Banner University Medical Center- Clinical HLA Laboratory	Tucson, AZ	520-694-6292
CALL	Histocompatibility and Flow Cytometry Laboratories at Loma Linda University	Loma Linda, CA	909-558-4000
CANI	VRL Eurofins	Los Angeles, CA	213-387-4199
CACL	HLA Laboratory at Childrens Hospital Los Angeles	Los Angeles, CA	323-361-2358
CACS	Cedars-Sinai Transplantation and Immunogenetics Laboratory	Los Angeles, CA	310-423-4979
CATL	University of California at Los Angeles, Immunogenetics Center	Los Angeles, CA	310-825-7651
CAST	Blood Systems Inc (BloodSource)	Mather, CA	916-453-3680
CAIL	University of California, Irvine HLA Tissue Typing Laboratory	Orange, CA	714-456-5889
CASU	Stanford Blood Center, Histocompatibility Lab-Hillview	Palo Alto, CA	650-723-5548
CASL	Stanford Blood CenterHistocompatibility & Immunogenetics Lab- Porter	Palo Alto, CA	650-724-0100
CAML	METIC Transplantation Laboratory	Pasadena, CA	323-419-0685
CAMT	METIC Immunogenetics Consultants, Inc	Pasadena, CA	323-489-2880
CASD	Histocompatibility and Immunogenetics Laboratory at UCSD	San Diego, CA	858-657-5740
CASH	Histocompatibility Laboratory at Sharp Memorial Hospital	San Diego, CA	858-650-5092
CAPM	Tissue Typing Laboratory at California Pacific Med Ctr	San Francisco, CA	415-600-3430
CAUS	UCSF Immunogenetics and Transplantation Laboratory	San Francisco, CA	415-476-3886
COHL	ClinImmune Labs	Aurora, CO	303-724-1300
COIA	LABS, Inc.	Centennial, CO	303-365-9000
CTHH	Hartford Hospital Transplant Immunology Laboratory	Hartford, CT	860-972-3938
CTYN	Histocompatibility and Immune Evaluation Laboratory at Yale	New Haven, CT	203-785-4812
DCGU	Histocompatibility Laboratory at Georgetown University	Washington, DC	202-444-3550
FLUF	Immunology Transplantation Laboratory/ Shands Hospital	Gainesville, FL	352-265-0072
FLSL	HLA Laboratory at Mayo Clinic Florida	Jacksonville, FL	904-956-3318
FLML	University of Miami Jackson Memorial Hospital Histocompatibility Testing	Miami, FL	305-243-3131
FLFH	Tissue Typing Laboratory at Florida Hospital	Orlando, FL	407-303-1681
FLSF	LifeLink Transplantation Immunology Laboratory	Tampa, FL	813-253-3866
GAEM	HLA Laboratory at Emory University	Atlanta, GA	404-712-7365
GAPH	Piedmont Hospital Histocompatibility & Immunogenetics Laboratory	Atlanta, GA	404-605-1833
GAMC	Histocompatibility Immunology Laboratory at the Medical College of Georgia	Augusta, GA	706-721-3311
HITL	Hawaii Cellular Therapy & Transplant Laboratory	Honolulu, HI	808-547-6127
IAMH	Histocompatibility Laboratory at Mercy Hospital Medical Center	Des Moines, IA	515-247-4152
IAIV	Iowa Regional Histo & Immunogenetics Laboratory at the V.A. Medical Center	Iowa City, IA	319-338-0581

ILNM	Transplant Immunology Laboratory at Northwestern Memorial Hospital	Chicago, IL	312-503-8069
ILPL	Rush Medical Laboratories Histocompatibility Laboratory	Chicago, IL	312-942-8393
ILUC	Transplant Immunology & Immunogenetics Laboratory	Chicago, IL	N/A
ILUI	Tissue Typing Laboratory at University of Illinois	Chicago, IL	312-996-1670
ILRL	Gift of Hope Organ & Tissue Donor Network Laboratory	Itasca, IL	630-758-2600
ILLU	Clinical Histocompatibility Laboratory at Loyola University Medical Center	Maywood, IL	708-216-3626
ILMM	Histocompatibility Laboratory at Memorial Medical Center	Springfield, IL	217-788-3905
INCI	Central Indiana Reg. Blood Center Transplant and Immunology Laboratory	Indianapolis, IN	317-916-5237
INIM	Histocompatibility Laboratory at Methodist Hospital of Indiana	Indianapolis, IN	317-962-6196
MWKC	Midwest Transplant Network Histocompatibility Laboratory Westwood	Westwood, KS	913-262-1668
KYUK	Immuno Molecular Pathology Laboratory at the University of Kentucky	Lexington, KY	859-323-8281
KYUL	University of Louisville Renal Transplant Laboratory	Louisville, KY	502-852-5865
KYJH	Histocompatibility Laboratory at Jewish Hospital	Louisville, KY	502-587-4373
LATL	Ochsner Histocompatibility and Immunogenetics Laboratory	New Orleans, LA	504-842-3027
LATM	Histocompatibility and Immunogenetics Lab / Tulane Univ School of Medicine	New Orleans, LA	504-988-5259
LAWK	Willis Knighton Medical Center Laboratory	Shreveport, LA	318-212-4400
MABI	Tissue Typing Laboratory at Beth Israel Deaconess Medical Center	Boston, MA	617-667-3500
MAMG	Histocompatibility Laboratory at Massachusets General Hospital	Boston, MA	617-726-3722
MANM	Tufts Medical Center Laboratory	Boston, MA	617-636-5791
MAPB	Brigham & Women's Hospital Tissue Typing Lab	Boston, MA	617-732-5872
MARC	American Red Cross HLA Laboratory	Dedham, MA	781-461-2148
MAUM	Histocompatibility Laboratory at UMASS Medical Center	Worcester, MA	508-334-6892
MDTL	Immunogenetics Laboratories at the Johns Hopkins University	Baltimore, MD	410-955-3600
MDUM	Immunogenetics Laboratory	Baltimore, MD	410-328-3955
DCWR	Transplant Immunology Lab at Walter Reed National Medical CenterBethesda	Bethesda, MD	301-319-7989
METL	Nordx Immunogenetics Laboratory	Scarborough, ME	207-396-7706
MITS	Gift of Life MichiganHistocompatibility Laboratory	Ann Arbor, MI	734-922-6014
MIUM	HLA Laboratory at the University of Michigan	Ann Arbor, MI	734-647-2783
MIHF	Cellular Immunology & Histocompatibility at Henry Ford Hospital	Detroit, MI	313-916-3165
MIHH	DMC University LaboratoriesHisto & Immunogenetics Laboratory	Detroit, MI	313-745-8090
MIRI	Immunohematology and Serology Laboratory at Michigan State University	East Lansing, MI	517-355-4616
MIBH	Histocompatibility Laboratory at William Beaumont Hospital	Royal Oak, MI	248-898-9011
MNUM	Clinical Histocompatibility Laboratory at University of Minnesota Med Ctr	Minneapolis, MN	612-273-3100
MNMC	Tissue Typing Laboratory at Mayo Clinic	Rochester, MN	507-284-2640
MOHL	HLA Laboratory at Barnes Jewish Hospital	St Louis, MO	314-362-5322
MOLB	Mid-America Transplant Services Laboratory	St. Louis, MO	314-735-8234
MOSL	St. Louis University HLA Laboratory	St. Louis, MO	314-577-8671
MSUM	Tissue Typing Laboratory of the University of Mississippi	Jackson, MS	601-984-1564
NCMH	Histocompatibility Laboratory at UNC Hospitals	Chapel Hill, NC	984-974-4057
NCCM	Immunology Laboratory at Carolinas Medical Center	Charlotte, NC	704-512-4915

NCDU	Clinical Transplantation Immunology Laboratory at Duke University Med. Ctr.	Durham, NC	919-684-3089
NCEC	Histocompatibility Laboratory at Vidant Medical Center	Greenville, NC	252-847-4941
NCBG	HLA/Immunogenetics Lab	Winston-Salem, NC	336-716-4456
NDTL	Sanford Histocompatibility Laboratory	Bismarck, ND	701-323-5457
NDTS	Sanford ClinicFargo Histocompatibility Laboratory	Fargo, ND	701-234-2411
NEUN	Molecular Diagnostics Laboratory at The Nebraska Medical Center	Omaha, NE	402-559-7630
NJTL	New Jersey Organ and Tissue Sharing Network Transplant Laboratory	New Providence, NJ	908-516-5400
NMTL	Regional Lab Corp/TriCore Reference Laboratories	Albuquerque, NM	505-938-8400
NVGL	Nevada Donor Network, Immunogenetics Laboratory in Nevada	Las Vegas, NV	855-683-6667
NYAL	Transplantation Immunology Laboratory of the Albany Medical College	Albany, NY	518-262-3070
NYMA	Transplant Immunology Laboratory at Montefiore Medical Center	Bronx, NY	718-920-5581
NYDS	Transplantation Immunology Laboratory at Brooklyn	Brooklyn, NY	718-270-1914
NYTL	IMMCO Immunogenetics	Buffalo, NY	716-566-5923
NYIL	Immunogenetics Lab / The Rogosin Institute	New York, NY	212-772-6700
NYCP	Immunogenetics Laboratory at Columbia Presbyterian Medical Center	New York, NY	212-305-6941
NYFL	Tissue Typing Laboratory at Strong Memorial Hospital	Rochester, NY	585-275-0985
NYSB	Histocompatibility and Immunogenetics Laboratory at Stony Brook	Stony Brook, NY	631-444-1789
NYSP	SUNY Health Science Center at Syracuse Histocompatibility Laboratory	Syracuse, NY	315-464-4775
NYWC	Clinical Laboratory Grasslands Reservation at Westchester Medical Ctr.	Valhalla, NY	914-493-8481
OHUC	Hoxworth Blood Center Tissue Typing Laboratory	Cincinnati, OH	513-558-1500
OHUH	Histocompatibility Laboratory at University Hospitals of Cleveland	Cleveland, OH	216-844-1225
OHAL	Allogen Laboratories, The Cleveland Clinic Foundation	Cleveland, OH	216-444-0384
OHOU	Clinical Histocompatibility Lab at Ohio State University Medical Center	Columbus, OH	614-293-8554
OHCO	Tissue Typing Laboratory at University of Toledo Medical Center	Toledo, OH	419-383-4292
OKDL	Diagnostic Laboratory of Oklahoma	Oklahoma City, OK	405-713-7002
OKMD	HLA Laboratory at OU Medical Center	Oklahoma City, OK	405-271-7726
OKSF	Saint Francis Hospital Histocompatibility Laboratory	Tulsa, OK	918-494-1300
ORUO	Laboratory of Immunogenetics and Transplantation at OHSU	Portland, OR	503-494-8394
PAHH	UPMC Pinnacle HLA Laboratory	Harrisburg, PA	717-231-8855
PALV	HLA Lab at Lehigh Valley Hospital	Allentown, PA	610-402-8014
PAHE	Histocompatibility and Clinical Immunology Lab at Hershey Medical Center	Hershey, PA	717-531-6264
PAHM	Histocompatibility Laboratory at Hahneman University Hospital Tenet	Philadelphia, PA	215-762-8602
PALN	LABS, IncLABSNortheast	Philadelphia, PA	720-528-4774
PATJ	Immunogenetics and Tissue Typing Lab at Thomas Jefferson Univ. Hospital	Philadelphia, PA	215-955-6564
PATU	Temple University Hospital Immunogenetics Laboratory	Philadelphia, PA	215-707-6959
PAUP	Immunology Laboratory at the University of Pennsylvania	Philadelphia, PA	215-662-6010
PACP	Children's Hosp. of Philadelphia Immunogenetics Lab	Philadelphia, PA	215-590-1000
PAAE	Immunology and Organ Preservation Lab at Albert Einstein Medical Center	Philadelphia, PA	215-456-7073

PAAG	Histocompatibility Laboratory at Allegheny General Hospital	Pittsburgh, PA	412-359-6175
PACH	Clinical Laboratory Services at the Childrens Hospital of Pittsburgh	Pittsburgh, PA	412-647-6151
PRSJ	Immunogenetics Laboratory at Auxilo Mutuo Hospital	Hato Rey, PR	787-758-2000
RIBC	HLA Laboratory/Rhode Island Blood Ctr	Providence, RI	401-453-8397
SCMU	Tissue Typing Laboratory at the Medical University of South Carolina	Charleston, SC	843-792-4311
SDMK	Avera McKennan Laboratory	Sioux Falls , SD	605-322-7099
TNDK	DCI LaboratoryKnoxville Transplant Laboratory	Knoxville, TN	865-305-9466
TNML	Mid-South Transplant Foundation Histocompatibility Laboratory	Memphis, TN	901-328-4438
TNVU	VA Medical Center Tissue Typing Laboratory	Nashville, TN	615-873-6987
TNDL	DCI LaboratoryNashville	Nashville, TN	615-321-0212
TXMC	Transplant Immunology Laboratory at Methodist Dallas Medical Center	Dallas, TX	214-947-3540
TXMS	Texas Medical Specialty	Dallas, TX	972-566-5761
TXSP	UT Southwestern Histocompatibility Laboratory	Dallas, TX	214-648-0900
TXTX	Transplant Immunology Laboratory at Baylor University Medical Center	Dallas, TX	214-820-2119
TXLP	Histo & Immunogenetics Lab at Las Palmas Medical Center	El Paso, TX	915-521-1841
TXJS	Tissue Antigen Laboratory at UT Galveston	Galveston, TX	409-747-9550
TXMH	Histocompatibility and Immunology Lab at Methodist Hospital	Houston, TX	713-790-2156
TXBL	Immune Evaluation Lab-Baylor College of Medicine	Houston, TX	713-798-3088
TXTH	Memorial Hermann-Texas Medical Center	Houston, TX	713-704-2721
TXSR	Histocompatibility and Immunogenetics Lab/University Health System	San Antonio, TX	210-358-0760
TXSI	Southwest Immunodiagnostics	San Antonio, TX	210-614-3703
TXSW	Histocompatibility Laboratory at Scott and White Memorial Hospital	Temple, TX	254-724-3905
UTMC	Histocompatibility and Immunogenetics Laboratory at the University of Utah	Salt Lake City, UT	801-581-3116
VAUV	Tissue Typing Laboratory at The University of Virginia HSC	Charlottesville, VA	434-924-5086
VANG	HLA Immunology Laboratory at Sentara Norfolk General Hospital	Norfolk, VA	757-388-3114
VAHD	Histocompatibility Laboratory at Henrico Doctors' Hospital	Richmond, VA	804-285-5132
VAMC	Tissue Typing Laboratory at the Medical College of Virginia	Richmond, VA	804-828-9543
VTMC	Histocompatibility Laboratory at Fletcher Allen Health Care	Burlington, VT	802-847-7640
WABC	Bloodworks Northwest Immunogenetics Laboratory	Seattle, WA	206-689-6580
WAST	Inland Northwest Blood Center	Spokane, WA	509-624-0151
WIUW	Histocompatibility Laboratory at the University of Wisconsin	Madison, WI	608-263-8815
WIBC	Blood Center of Wisconsin	Milwaukee, WI	414-933-5000
WISL	HLA Laboratory at Aurora St. Luke's Medical Center	Milwaukee, WI	414-649-7825

Appendix 6 Transplant Program Identification Codes

This table contains a complete listing of the 240 Kidney Transplant Programs; programs are sorted by the Center Code. For each Transplant Program, the associated APOLLO Clinical Center is denoted.

Code	Institution	Clinical Center
ALCH-TX1	Children's of Alabama	4 - University of Alabama - Birmingham
ALUA-TX1	Univ of Alabama Hospital	4 - University of Alabama - Birmingham
ALVA-TX1	Birmingham VA Medical Center	4 - University of Alabama - Birmingham
ARCH-TX1	Arkansas Children's Hospital	4 - University of Alabama - Birmingham
ARUA-TX1	UAMS Medical Center	4 - University of Alabama - Birmingham
AZCH-TX1	Phoenix Children's Hospital	5 - Columbia
AZGS-TX1	Banner- University Medical Center	9 - Boston
AZMC-TX1	Mayo Clinic Hospital	9 - Boston
AZSJ-TX1	St Joseph's Hospital & Medical Center	11 - University of Miami
AZUA-TX1		9 - Boston
CACH-TX1	Rady Children's Hosp & Health Center	10 - University of Maryland
CACL-TX1	Children’s Hospital Los Angeles	8 - Emory
CACS-TX1	Cedars-Sinai Med Center	9 - Boston
CAGH-TX1	Scripps Green Hospital	2 - Vanderbilt University Medical Center
CAIM-TX1	UCI Medical Center	11 - University of Miami
CALA-TX1	Harbor UCLA Med Center	12 - University of California - San Francisco
CALL-TX1	Loma Linda Univ Med Ctr	12 - University of California - San Francisco
CAMB-TX1	UCSF Medical Center at Mission Bay	12 - University of California - San Francisco
CAPC-TX1	Lucile Salter Packard Children's Hosp	11 - University of Miami
CAPM-TX1	California Pacific Med Ctr	12 - University of California - San Francisco
CARC-TX1	Riverside Community Hosp	2 - Vanderbilt University Medical Center
CASD-TX1	UCSD Medical Center	12 - University of California - San Francisco
CASF-TX1	Univ of CA San Francisco Med Ctr	12 - University of California - San Francisco
CASH-TX1	Sharp Memorial Hospital	11 - University of Miami
CASJ-TX1	St Joseph Hospital	8 - Emory
CASM-TX1	UC Davis Medical Center	12 - University of California - San Francisco
CASU-TX1	Stanford Health Care	12 - University of California - San Francisco
CASV-TX1	St. Vincent Medical Center	1 - University of Wisconsin
CAUC-TX1	UCLA Medical Center	12 - University of California - San Francisco
CAUH-TX1	Keck Hospital of USC	12 - University of California - San Francisco
COCH-TX1	Children's Hospital Colorado	11 - University of Miami
COPM-TX1	Centura Porter Adventist Hosp	2 - Vanderbilt University Medical Center
COSL-TX1	Presbyterian/ St Luke's Medical Ctr.	2 - Vanderbilt University Medical Center
COUC-TX1	University of Colorado Hospital/HSC	8 - Emory
CTHH-TX1	Hartford Hospital	5 - Columbia
CTYN-TX1	Yale New Haven Hosp	5 - Columbia
DCCH-TX1	Children's National Medical Ctr	10 - University of Maryland
DCGU-TX1	Georgetown Univ Med Ctr	10 - University of Maryland
DCGW-TX1	George Washington University Hospital	10 - University of Maryland
DCWR-TX1	Walter Reed National Military	2 - Vanderbilt University Medical Center
DEAI-TX1	Alfred I duPont Hospital for Children	9 - Boston
DECC-TX1	Christiana Care Health Services	10 - University of Maryland
FLCC-TX1	Cleveland Clinic Florida Weston	7 - Cleveland Clinic
FLFH-TX1	Florida Hospital Medical Center	11 - University of Miami
FLFR-TX1	Gulf Coast Medical Center	11 - University of Miami

FLHM-TX1	Halifax Medical Center	11 - University of Miami
FLJM-TX1	Jackson Memorial Hospital	11 - University of Miami
FLLM-TX1	Largo Medical Center	11 - University of Miami
FLMR-TX1	Memorial Regional Hospital	11 - University of Miami
FLSH-TX1	Sacred Heart Hospital Pensacola	11 - University of Miami
FLSL-TX1	Mayo Clinic Florida	11 - University of Miami
FLTG-TX1	Tampa General Hospital	11 - University of Miami
FLUF-TX1	UF Health Shands Hospital	11 - University of Miami
GAEH-TX1	Children's Healthcare of Atlanta	8 - Emory
GAEM-TX1	Emory University Hospital	8 - Emory
GAMC-TX1	AU Medical Center, Inc.	8 - Emory
GAPH-TX1	Piedmont Hospital	8 - Emory
HIQM-TX1	The Queen's Medical Center	12 - University of California - San Francisco
IAIM-TX1	Iowa Methodist Medical Center	1 - University of Wisconsin
IAIV-TX1	Univ of Iowa Hosp and Clinics	1 - University of Wisconsin
IAIV-VA1	Iowa City VA Medical Center	4 - University of Alabama - Birmingham
IAMH-TX1	Mercy Medical Center	1 - University of Wisconsin
IAVA-TX1	The Iowa City VA Health Care System	4 - University of Alabama - Birmingham
ILCH-TX1	Advocate Christ Medical Center	13 - WFU School of Medicine
ILCM-TX1	Ann & Robert H. Lurie Children's Hosp	2 - Vanderbilt University Medical Center
ILLU-TX1	Loyola Univ Med Center	9 - Boston
ILMM-TX1	Memorial Medical Center	3 - Johns Hopkins
ILNM-TX1	Northwestern Memorial Hospital	13 - WFU School of Medicine
ILPL-TX1	Rush University Med Ctr	1 - University of Wisconsin
ILSF-TX1	OSF St Francis Med Ctr	2 - Vanderbilt University Medical Center
ILUC-TX1	Univ of Chicago Med Ctr	7 - Cleveland Clinic
ILUI-TX1	University of Illinois Medical Center	13 - WFU School of Medicine
INIM-TX1	Indiana University Health	2 - Vanderbilt University Medical Center
INLH-TX1	Lutheran Hosp of Ft Wayne	8 - Emory
INSV-TX1	St Vincent Hosp and Health Care Ctr	7 - Cleveland Clinic
KSUK-TX1	University of Kansas Hospital	2 - Vanderbilt University Medical Center
KYJH-TX1	Jewish Hospital	13 - WFU School of Medicine
KYKC-TX1	Norton Children's Hospital	13 - WFU School of Medicine
KYUK-TX1	Univ of Kentucky Med Ctr	4 - University of Alabama - Birmingham
LACH-TX1	Children's Hospital	4 - University of Alabama - Birmingham
LAOF-TX1	Ochsner Foundation Hospital	4 - University of Alabama - Birmingham
LATU-TX1	Tulane Medical Center	4 - University of Alabama - Birmingham
LAWK-TX1	Willis-Knighton Medical Center	4 - University of Alabama - Birmingham
MABI-TX1	Beth Israel Deaconess Med Ctr	9 - Boston
MABS-TX1	Baystate Medical Center	9 - Boston
MABU-TX1	Boston Medical Center	9 - Boston
MACH-TX1	Boston Children's Hospital	9 - Boston
MALC-TX1	Lahey Clinic Med Ctr	9 - Boston
MAMG-TX1	Massachusetts General Hospital	9 - Boston
MANM-TX1	Tufts Medical Center	9 - Boston
MAPB-TX1	Brigham and Women's Hosp	9 - Boston
MAUM-TX1	UMass Memorial Medical Center	9 - Boston
MDJH-TX1	Johns Hopkins Hospital	3 - Johns Hopkins
MDUM-TX1	Univ of Maryland Med System	10 - University of Maryland
MEMC-TX1	Maine Medical Center	3 - Johns Hopkins
MIBH-TX1	William Beaumont Hospital	7 – Cleveland Clinic

MICH-TX1	Children's Hosp of Michigan	7 - Cleveland Clinic
MIDV-TX1	Helen DeVos Children's Hospital	7 - Cleveland Clinic
MIHF-TX1	Henry Ford Hospital	7 - Cleveland Clinic
MIHH-TX1	Harper Univ Hospital Detroit Med Ctr	7 - Cleveland Clinic
MISJ-TX1	St John Hosp and Med Ctr	7 - Cleveland Clinic
MISM-TX1	Mercy Health Saint Mary's	7 - Cleveland Clinic
MIUM-TX1	Univ of Michigan Med Ctr	7 - Cleveland Clinic
MNAN-TX1	Abbott Northwestern Hospital	1 - University of Wisconsin
MNHC-TX1	Hennepin County Med Ctr	1 - University of Wisconsin
MNMC-TX1	Rochester Methodist Hosp- Mayo Clinic	1 - University of Wisconsin
MNSM-TX1	St Marys Hospital (Mayo Clinic)	1 - University of Wisconsin
MNUM-TX1	Univ. of Minnesota Medical Center	1 - University of Wisconsin
MOBH-TX1	Barnes-Jewish Hospital	3 - Johns Hopkins
MOCG-TX1	Cardinal Glennon Childrens Hosp	3 - Johns Hopkins
MOCH-TX1	St. Louis Children's Hospital	3 - Johns Hopkins
MOCM-TX1	Children's Mercy Hospital	9 - Boston
MOLH-TX1	Saint Luke's Hospital of Kansas City	3 - Johns Hopkins
MORH-TX1	Research Medical Center	3 - Johns Hopkins
MOSL-TX1	SSM Health Saint Louis University Hos	3 - Johns Hopkins
MOUM-TX1	Univ of Missouri Hosp and Clinic	3 - Johns Hopkins
MSUM-TX1	Univ of MS Med Ctr	4 - University of Alabama - Birmingham
NCBG-TX1	Wake Forest Baptist Medical Center	13 - WFU School of Medicine
NCCM-TX1	Carolinas Medical Center	13 - WFU School of Medicine
NCDU-TX1	Duke University Hospital	13 - WFU School of Medicine
NCEC-TX1	Vidant Medical Center	13 - WFU School of Medicine
NCMH-TX1	UNC Hospitals	13 - WFU School of Medicine
NDMC-TX1	Sanford Bismarck Medical Center	1 - University of Wisconsin
NDSL-TX1	Sanford Medical Center Fargo	1 - University of Wisconsin
NEUN-TX1	The Nebraska Medical Center	1 - University of Wisconsin
NHDH-TX1	Mary Hitchcock Memorial Hosp	8 - Emory
NJBI-TX1	Newark Beth Israel Med Ctr	2 - Vanderbilt University Medical Center
NJHK-TX1	Hackensack University Medical Center	5 - Columbia
NJLL-TX1	Our Lady of Lourdes Med Ctr	6 - Mount Sinai
NJRW-TX1	Robert Wood Johnson University Hosp	6 - Mount Sinai
NJSB-TX1	St Barnabas Medical Center	5 - Columbia
NMAQ-TX1	University Hospital	12 - University of California - San Francisco
NMPH-TX1	Presbyterian Hospital	8 - Emory
NVUM-TX1	University Med Ctr of Southern NV	12 - University of California - San Francisco
NYAM-TX1	Albany Med Center Hospital	5 - Columbia
NYCC-TX1	Cohen Children's Medical Center	8 - Emory
NYCP-TX1	New York-Presbyterian/Columbia	5 - Columbia
NYDS-TX1	SUNY Downstate Medical Center	6 - Mount Sinai
NYEC-TX1	Erie County Medical Center	7 - Cleveland Clinic
NYFL-TX1	Strong Memorial Hospital	6 - Mount Sinai
NYMA-TX1	Montefiore Medical Center	13 - WFU School of Medicine
NYMS-TX1	Mount Sinai Med Center	6 - Mount Sinai
NYNS-TX1	North Shore University Hospital	6 - Mount Sinai
NYNY-TX1	New York-Presbyterian/Weill Cornell	6 - Mount Sinai
NYSB-TX1	University Hosp of SUNY	6 - Mount Sinai
NYUC-TX1	New York Univ Medical Center	6 - Mount Sinai
NYUM-TX1	SUNY Upstate Medical University	6 - Mount Sinai

NYVA-TX1	James J. Peters VA Medical Center	4 - University of Alabama - Birmingham
NYWC-TX1	Westchester Medical Center	6 - Mount Sinai
OHCC-TX1	Cleveland Clinic Foundation	7 - Cleveland Clinic
OHCH-TX1	Nationwide Children's Hospital	6 - Mount Sinai
OHCM-TX1	Children's Hosp Med Ctr	7 - Cleveland Clinic
OHCO-TX1	University of Toledo Medical Center	7 - Cleveland Clinic
OHOU-TX1	Ohio State Univ Med Ctr	7 - Cleveland Clinic
OHTC-TX1	The Christ Hospital	7 - Cleveland Clinic
OHUC-TX1	University of Cincinnati Medical Cen	7 - Cleveland Clinic
OHUH-TX1	University Hosp of Cleveland	7 - Cleveland Clinic
OKBC-TX1	Integris Baptist Med Ctr	3 - Johns Hopkins
OKCM-TX1	Children's Hosp of Oklahoma	13 - WFU School of Medicine
OKMD-TX1	OU Medical Center	3 - Johns Hopkins
OKSJ-TX1	St. John Medical Center	13 - WFU School of Medicine
ORGS-TX1	Legacy Good Samaritan Hosp Med Ctr	9 - Boston
ORUO-TX1	Oregon Health and Science University	12 - University of California - San Francisco
ORVA-TX1	VA Portland Health Care System	4 - University of Alabama - Birmingham
PAAE-TX1	Albert Einstein Med Ctr	5 - Columbia
PAAG-TX1	Allegheny General Hosp	9 - Boston
PACC-TX1	Crozer-Chester Medical Center	9 - Boston
PACH-TX1	Children's Hosp of Pittsburgh of UPMC	2 - Vanderbilt University Medical Center
PACP-TX1	Childrens Hosp of Philadelphia	5 - Columbia
PAGM-TX1	Geisinger Medical Center	5 - Columbia
PAHE-TX1	Penn State Milton S Hershey Med Ctr	9 - Boston
PAHH-TX1	Harrisburg Hospital	9 - Boston
PAHM-TX1	Hahnemann University Hospital	5 - Columbia
PALH-TX1	The Lankenau Hospital	9 - Boston
PALV-TX1	Lehigh Valley Hospital	1 - University of Wisconsin
PAPH-TX1	UPMC Hamot	10 - University of Maryland
PAPT-TX1	Univ of Pittsburgh Med Ctr	7 - Cleveland Clinic
PATJ-TX1	Thomas Jefferson Univ Hosp	5 - Columbia
PATU-TX1	Temple Univ Hospital	5 - Columbia
PAUP-TX1	The Hosp of the Univ of PA	5 - Columbia
PAVA-TX1	VA Pittsburgh Healthcare System	4 - University of Alabama - Birmingham
PRSJ-TX1	Auxilio Mutuo Hosp	11 - University of Miami
RIRH-TX1	Rhode Island Hospital	2 - Vanderbilt University Medical Center
SCMU-TX1	Medical Univ of SC	4 - University of Alabama - Birmingham
SDMK-TX1	Avera McKennan Hosp	1 - University of Wisconsin
SDSV-TX1	Sanford Health/USD Medical Center	1 - University of Wisconsin
TNEM-TX1	Erlanger Med Ctr	2 - Vanderbilt University Medical Center
TNLB-TX1	Le Bonheur Children's Med Ctr	2 - Vanderbilt University Medical Center
TNMH-TX1	Methodist University Hospital	2 - Vanderbilt University Medical Center
TNPV-TX1	Centennial Medical Center	2 - Vanderbilt University Medical Center
TNST-TX1	St. Thomas Hospital	2 - Vanderbilt University Medical Center
TNUK-TX1	University of TN Med. Ctr. at Knoxvil	2 - Vanderbilt University Medical Center
TNVU-TX1	Vanderbilt Univ Med Ctr	2 - Vanderbilt University Medical Center
TNVU-VA1	Nashville VA Medical Center	4 - University of Alabama - Birmingham
TXAS-TX1	Baylor All Saints Medical Center	6 - Mount Sinai
TXBC-TX1	University Hospital	9 - Boston
TXCF-TX1	Cook Children's Med Ctr	6 - Mount Sinai
TXCM-TX1	Children's Med Ctr of Dallas	10 - University of Maryland

TXDC-TX1	Driscoll Children's Hospital	10 - University of Maryland
TXDM-TX1	North Austin Medical Center	5 - Columbia
TXDR-TX1	Doctor's Hospital at Renaissance	10 - University of Maryland
TXFW-TX1	TX Health Harris Meth. Ft Worth Hosp	2 - Vanderbilt University Medical Center
TXHD-TX1	Medical City Dallas Hospital	9 - Boston
TXHH-TX1	Memorial Hermann Hospital	9 - Boston
TXHI-TX1	CHI St. Luke's Health Baylor College	1 - University of Wisconsin
TXHS-TX1	Methodist Specialty & Transplant Hosp	8 - Emory
TXJS-TX1	Univ of Texas Med Branch	3 - Johns Hopkins
TXLP-TX1	Las Palmas Medical Center	9 - Boston
TXMC-TX1	Methodist Dallas Medical Center	3 - Johns Hopkins
TXMH-TX1	Houston Methodist Hospital	1 - University of Wisconsin
TXPL-TX1	Medical City Fort Worth	3 - Johns Hopkins
TXPM-TX1	Parkland Health and Hospital System	8 - Emory
TXRM-TX1	Christus Santa Rosa Hospital Med. Ctr	13 - WFU School of Medicine
TXSP-TX1	UT Southwestern Medical Center/	8 - Emory
TXSW-TX1	Scott and White Mem Hosp	3 - Johns Hopkins
TXTC-TX1	Texas Children's Hospital	2 - Vanderbilt University Medical Center
TXTX-TX1	Baylor University Medical Center	3 - Johns Hopkins
TXVA-TX1	Michael E. DeBakey VA Medical Center	4 - University of Alabama - Birmingham
UTLD-TX1	Intermountain Medical Center	2 - Vanderbilt University Medical Center
UTMC-TX1	Univ of Utah Medical Center	12 - University of California - San Francisco
UTPC-TX1	Primary Children's Hospital	13 - WFU School of Medicine
VACH-TX1	Children's Hosp of King's Daughters	10 - University of Maryland
VAFH-TX1	Inova Fairfax Hosp	10 - University of Maryland
VAHD-TX1	Henrico Doctors' Hospital	10 - University of Maryland
VAMC-TX1	MCV Hospitals	13 - WFU School of Medicine
VANG-TX1	Sentara Norfolk General Hospital	10 - University of Maryland
VAUV-TX1	Univ of Virginia HSC	9 - Boston
VTMC-TX1	The University of Vermont Medical Cen	9 - Boston
WACH-TX1	Seattle Children's Hospital	10 - University of Maryland
WASH-TX1	Sacred Heart Med Ctr	9 - Boston
WASM-TX1	Swedish Medical Center	9 - Boston
WAUW-TX1	Univ of Washington Med Ctr	12 - University of California - San Francisco
WAVM-TX1	Virginia Mason Med Ctr	12 - University of California - San Francisco
WICH-TX1	Childrens Hosp of Wisconsin	3 - Johns Hopkins
WISE-TX1	Froedtert Mem Lutheran Hosp	3 - Johns Hopkins
WISL-TX1	Aurora St. Luke's Medical Center	3 - Johns Hopkins
WIUW-TX1	Univ of Wisconsin Hosp and Clinics	1 - University of Wisconsin
WVCA-TX1	Charleston Area Medical Center	7 - Cleveland Clinic

Supplementary materials: APOLLO Data Collection

In addition to data from UNOS, transplant and CC staff will perform primary data collection by abstracting information from participants' medical records onto APOLLO study forms at regular intervals as described in Table 1.

1. Timing for data elements and collection schedule

Recipients: Initial data collection will be made by a retrospective review several weeks after receipt of a kidney transplant to determine values at the time of, and shortly after, transplantation. Further data collection will be done to determine values at 3 months, 6 months, 12 months and 24 months post-transplant. Information will be abstracted from medical records onto APOLLO study forms which will be data entered by the CC staff or engaged transplant program study coordinators.

Living Donors: Initial data collection will be performed at least two weeks prior to donation of a kidney to determine pre-donation values. Subsequent values will be determined at 12 months and 24 months post-donation. Information will be abstracted from medical records onto APOLLO study forms which will be data entered by the CC staff or engaged transplant program study coordinators.

2. Types of data elements

Contact information. Names, addresses, phone numbers and other contact information for participants will be abstracted from participants' medical records during initial data collection and updated during follow-up data collection.

Socioeconomic status. Socioeconomic status elements such as education, income, zip code for geocoded income, social support, insurance status and employment will be obtained from social worker notes in the participants' medical record at time of data collection from living kidney donors and kidney transplant recipients.

Medical history. Elements of participants' medical history will be abstracted from transplant center medical records, including evaluation records, for history of cardiovascular disease (defined in MOP), smoking, and family history of ESRD or CKD in first-degree relatives. Medical records of living donors will additionally be abstracted for history of gestational diabetes or hypertension, and kidney stones.

Medications related to induction or maintenance therapy. Induction therapy from transplant center medical records will include: Thymoglobulin, Alemtuzumab/Campath, IL-2 receptor antagonists, Basiliximab/Simulect, corticosteroids and others defined in the MOP. Maintenance therapy will include: Prograf/Envarsus/Astagraf/Tacrolimus, MMF/mycophenolate mofetil/mycophenolic acid, corticosteroids, CsA/cyclosporine A, Imuran/Azathioprine, Belatacept, Everolimus/Afinitor, and Rapamune/Sirolimus. Additional medication classes: ACE/ARB, statins.

Physical exam. Values of weight, systolic and diastolic blood pressure closest to the target ascertainment date will be recorded.

Labs and viral studies. Results of testing for donor specific antibodies (DSA), therapy for donor specific antibodies, eGFR or 24-hour creatinine clearance, quantitative urine protein concentration and method used, serum creatinine, hemoglobin A1c, fasting plasma glucose, random plasma glucose, and polymerase chain reaction (PCR) testing for viral infections including Epstein-Barr virus (EBV), cytomegalovirus (CMV), BK virus, Parvovirus, and Adenovirus will be collected.

Biopsy. When a kidney biopsy is documented in the medical record, a scanned version of the final pathology report will be obtained. For follow-up in recipients, the following specific items will be abstracted: Banff score, presence of FSGS or recurrence of other kidney disease, viral infections, type of rejection, and whether DSA testing was performed.

Renal imaging. When renal imaging reports from living donors, prior to the time of kidney donation, are documented in the medical record, a scanned version of the report will be obtained.

3. Data for primary analyses

The primary APOLLO analysis is the effect of donor *APOL1* genotypes on time to death-censored renal allograft failure in the recipients of a kidney from African American deceased kidney donors. This will be a proportional hazards model extended to allow for correlation between pairs of recipients of kidneys from the same donor, stratified by transplant program, and covariate adjusted using recipient age, sex, recipient's self-reported ancestry (reported as race in the UNOS database), HLA match, cold ischemia time, panel reactive antibodies, donor age and the KDRI. Supporting analyses will include recipient APOL1 genotype and exploration of other covariate effects including transplant center characteristics that may be used to pool similar smaller centers into larger strata.

Table 1. APOLLO Data collection for transplant recipients and living kidney donors		**Recipients**		**Living Donors**	
Demographics & History	**Variable**	**Transplant**	**Follow-up**	**Donation**	**Follow-up**
	Socioeconomic status	X		X	
	Prevalent cardiovascular disease	X		X	
	Smoking history	X			
	Family history of ESRD/CKD	X		X	
	Gestational diabetes			X	
	Gestational hypertension			X	
	Kidney stones			X	
Medications & Physical Exam	Weight		X		
	Medical (non-)compliance		X		
	Induction therapy	X			
	Maintenance therapy	X	X		
	Blood Pressure	X	X		
	Donor-Specific Antibodies (DSA)	X			
	Therapy for DSA	X			

Biopsy	Kidney biopsy report	X	X	X	
	Banff score		X		
	FSGS recurrence/Recurrent disease		X		
	Viral (list)		X		
	AbMR/ACR/Mixed rejection/Other		X		
	DSA testing		X		
Labs & Viral	HbA1c/Fasting or random plasma glucose		X		X
	Serum creatinine		X		
	eGFR or creatinine clearance			X	
	Quant urine protein & method, units		X	X	X
	Donor Specific Antibodies (DSA)		X		
	EBV, CMV		X		
	BK virus, Parvovirus, Adenovirus		X		
Outcome	Transplant rejection and date		X		
Imaging	Renal imaging results			X	

Kidney Health


Healthy Diet


Exercise


No Smoking


Limit Alcohol


Get check-ups


Genes

Genes

Genes control traits we inherit from our parents, such as eye color.

Differences in some genes can put us at risk for getting some diseases.

Differences in the APOL1 gene can put us at increased risk for kidney disease.

APOL1 Gene

- 3 forms: G0, G1, G2
- Everyone inherits 2 copies of the gene

G0 - most common; no increased risk of kidney disease

G1 and G2 - can increase risk of kidney disease


G0/G0

- No increased risk of kidney disease


G0/G1 or G0/G2

- No increased risk of kidney disease
- Carrier: Could pass higher risk form of gene to children


G1/G1 or G2/G2 or G1/G2

- Increased risk of kidney disease
- Will pass higher risk form of gene to children

4 out of 5 people who have 2 copies of the higher risk forms of APOL1 DO NOT get kidney disease

People with recent African ancestry, such as African Americans, Afro-Caribbeans, Hispanic Blacks, and Africans are more likely to have the APOL1 gene variants that increase risk of kidney disease.

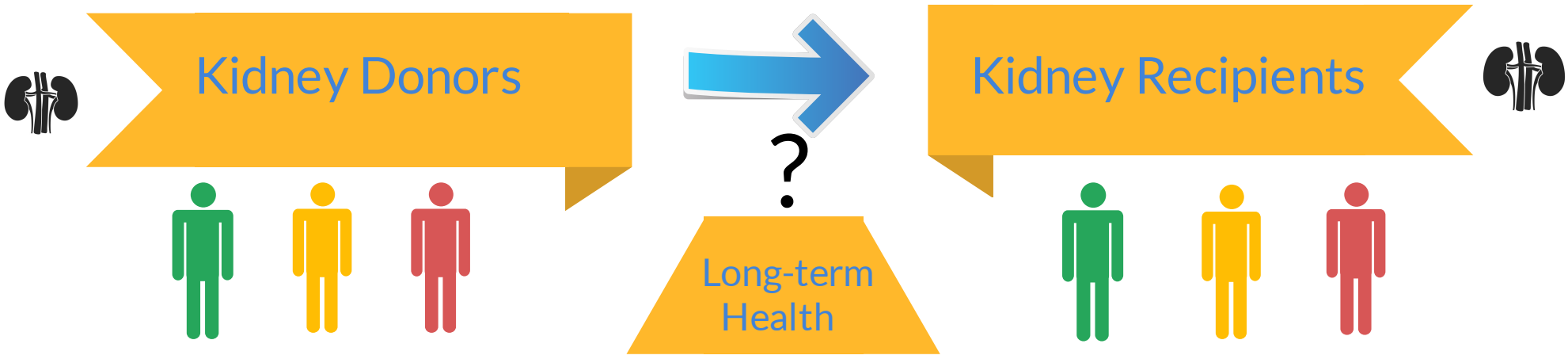
To learn more about preventing kidney disease, please talk with your doctor.

APOL1 Long-term Kidney Transplantation Outcomes Consortium

APOLLO

Mission: To improve the lives of those who donate or receive a kidney by learning more about genetic variations that are found in some people of African descent.

www.TheApolloNetwork.org



Who?

Kidney doctors and surgeons and the APOLLO Community Advisory Council designed APOLLO.

The Community Advisory Council is a group of kidney donors and recipients and their families from groups who are more likely to have the higher risk forms of the APOL1 gene.

Those who donate and receive eligible kidneys will be invited to participate.

How?

Those who donate or receive a kidney will get the same medical care whether or not they are in APOLLO.

Collect a small amount of blood and urine.

Find out what forms of the APOL1 gene those who donate or receive kidneys have.

See how healthy they are over many years.

When and where?

APOLLO will start in the fall of 2018 everywhere in the United States, including Puerto Rico.

Why?

To improve the lives of those who donate or receive a kidney.

APOLLO
APOL1 Long-term Kidney Transplantation Outcomes

APOL1 Gene

- 3 forms: G0, G1, G2
- Everyone inherits 2 copies of the gene

G0 - most common; no increased risk of kidney disease

G1 and G2 - can increase risk of kidney disease

G0/G0

- No increased risk of kidney disease

G0/G1 or G0/G2

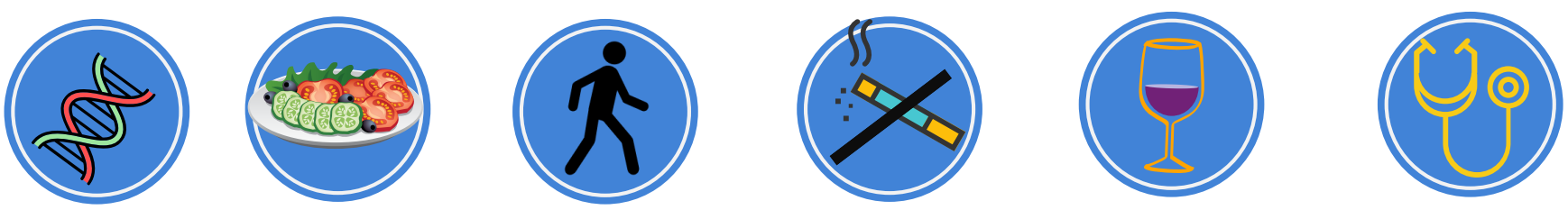
- No increased risk of kidney disease
- Carrier: Might pass higher risk form to children

G1/G1 or G2/G2 or G1/G2

- Higher risk of kidney disease
- Will pass 1 copy of higher risk form to children

4 out of 5 people who have 2 copies of the higher risk forms of APOL1 DO NOT get kidney disease

Kidney Disease
It's NOT all in our genes



Thinking about getting your APOL1 research results?

The choice is yours. The information is yours.

If you choose to get your results, you decide whether to share your results.

Reasons some people might not want their results:

- The results might make them worry
- Afraid others will find out
- Afraid of discrimination
- Don't want other people asking for their results
- Don't think it will be useful

Reasons some people might want their results:

- Results might be a relief
- Want to share information with family
- Just want to know
- Curious
- Think it might be helpful

APOLLO Website:

www.TheApolloNetwork.org

If you would like to obtain your APOL1 research results, please see the APOLLO website for further information.

To learn more about preventing kidney disease, please talk with your doctor.

Thank you for participating in APOLLO.

APOLLO
APOL1 Long-term Kidney Transplantation Outcomes

APOL1 Gene

- 3 forms: G0, G1, G2
- Everyone inherits 2 copies of the gene

G0 - most common; no increased risk of kidney disease

G1 and G2 - can increase risk of kidney disease

G0/G0

- No increased risk of kidney disease

G0/G1 or G0/G2

- No increased risk of kidney disease
- Carrier: Might pass higher risk form to children

G1/G1 or G2/G2 or G1/G2

- Higher risk of kidney disease
- Will pass 1 copy of higher risk form to children

4 out of 5 people who have 2 copies of the higher risk forms of APOL1 DO NOT get kidney disease

Kidney Disease
It's NOT all in our genes

Genes | Healthy Diet | Exercise | No Smoking | Limit Alcohol | Get check-ups

Thinking about getting your loved one's APOL1 research results?

The choice is yours.
If you choose to get your loved one's results, you decide whether to share the results with anyone else.

Reasons some people might not want the results:

- The results might make them worry
- Afraid others will find out
- Afraid of discrimination
- Don't want other people asking for the results
- Don't think it will be useful

Reasons some people might want the results:

- Results might be a relief
- Want to share information with family
- Just want to know
- Curious
- Think it might be helpful

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To learn more about preventing kidney disease, please talk with your doctor.

Thank you for giving the gift of life and allowing your loved one's information to be used in APOLLO.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym *APOL1* Long-term Kidney Transplantation Outcomes Network (APOLLO): Design and Rationale
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry APOLLO is registered in clinicaltrials.gov as NCT03615235
	2b	All items from the World Health Organization Trial Registration Data Set N/A
Protocol version	3	Date and version identifier October 6, 2019; R1 version

Funding	4	Sources and types of financial, material, and other support	

NIH	5U01DK116041	FREEDMAN, BARRY REBOUSSIN, DAVID STRATTA, ROBERT BOWDEN, DONALD	Wake Forest
NIH	5U01DK116043	HSU, CHI-YUAN PARK, MEYEON	UCSF
NIH	5U01DK116099	PASTAN, STEPHEN NEWELL, KENNETH	Emory
NIH	5U01DK116040	REEVES-DANIEL, AMBER FREEDMAN, BARRY GBADEGESIN, RASHEED	Wake Forest & Duke
NIH	5U01DK116093	BIRDWELL, KELLY	Vanderbilt
NIH	5U01DK116042	BRENNAN, DANIEL LENTINE, KRISTA	Johns Hopkin & SLU
NIH	5U01DK115997	JULIAN, BRUCE MANNON, ROSLYN	UAB
NIH	5U01DK116095	BROMBERG, JONATHAN WEIR, MATTHEW	U. Maryland
NIH	5U01DK116097	POGGIO, EMILIO DOSHI, MONA	Cleveland Clinic & U. Michigan
NIH	5U01DK116066	MOHAN, SUMIT SAWINSKI, DEIRDRE	Columbia & U. Pennsylvania
NIH	5U01DK116092	ASTOR, BRAD	U. Wisconsin
NIH	5U01DK116101	FORNONI, ALESSIA GUERAA, GISELLE GOGGINS, MARIELLA	Miami
NIH	5U01DK116102	ROSAS, SYLVIA	Joslin Diabetes Center
NIH	5U01DK116100	MURPHY, BARBARA DADHANIA, DARSHANA	Mount Sinai & Weill Cornell
NIH	R01 DK120551*	HSU, CHI-YUAN PARK, MEYEON LENTINE, KRISTA	UCSF & SLU
NIH	R01 MD014161*	DUBOIS, JAMES MOHAN, SUMIT	Washington U. & Columbia

Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors Page 1-3 in the manuscript lists contributors, affiliations and contact information. All co-authors contributed to development of the protocol.
	5b	Name and contact information for the trial sponsor National Institutes of Health (NIH): NIDDK Paul Kimmel, MD (KimmelP@extra.niddk.nih.gov) NIAMS Jonah Odim, MD, PhD (odimj@niaid.nih.gov) NIMHD Nishadi Rajapakse, PhD, MHS (chandima.rajapakse@nih.gov)

	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities. The study sponsor has one vote on the APOLLO Steering Committee. They did not contribute to the study design, data collection, management, analysis or interpretation of data in this report. They approved the final manuscript prior to submission.
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee). The Wake Forest APOLLO Coordinating Centre developed the protocol in concert with the APOLLO Steering Committee. This manuscript reviews the protocol and does not contain data or results.
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention Retrospective studies demonstrated that kidneys transplanted from African American deceased-donors had shorter renal allograft survival than kidneys from European American deceased-donors. African American living-kidney donors also develop ESKD more often than European American living-kidney donors. The National Institutes of Health-sponsored "*APOL1* Long-term Kidney Transplantation Outcomes Network" (APOLLO) is prospectively assessing kidney allograft survival from donors with recent African ancestry based on donor and recipient *APOL1* genotype. APOLLO will also assess kidney function after donation in African American living-kidney donors based on *APOL1* genotype.
	6b	Explanation for choice of comparators The presence of two *APOL1* renal-risk variants (RRVs) in kidney donors (*e.g.*, autosomal recessive pattern of inheritance) is associated with earlier allograft failure after deceased donor transplantation and poorer post-donation kidney function in living kidney donors. The observational APOLLO study will assess time to kidney allograft failure after transplantation and post-donation kidney function based on *APOL1* renal-risk genotypes. Kidney donors and transplant recipients with two RRVs (high-risk genotypes) will be compared with those who have zero or one RRV (low-risk genotypes).

Objectives	7	Specific objectives or hypotheses The primary objective of APOLLO is determining whether the presence of *APOL1* high-risk genotypes in deceased-donors is associated with death-censored renal allograft survival. Secondary objectives include: • defining whether the presence of *APOL1* high-risk genotypes in kidney donors is associated with poorer kidney function or greater proteinuria after transplantation. • defining whether the presence of *APOL1* high-risk genotypes is associated with poorer kidney outcomes in living-kidney donors after nephrectomy. • identifying modifying factors that increase susceptibility to shortened allograft survival, reduced kidney allograft function or association with greater proteinuria in recipients of kidneys from *APOL1* high-risk genotype donors, under the assumption that donor *APOL1* high-risk genotypes are associated with poorer kidney function in recipients of renal allografts.
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) Parallel group comparing transplant outcomes from kidney donors with *APOL1* high-risk genotypes versus low-risk genotypes.

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained All U.S. kidney transplant programs.
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) APOLLO inclusion criteria include kidney donors with self-reported or family-reported African American, Hispanic black, Afro-Caribbean or African ancestry. Recipients of APOLLO kidneys are eligible regardless of their ancestry.
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered There is no intervention. This is an observational study assessing time to renal allograft failure based on *APOL1* genotypes.
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) N/A

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) Outcomes data will be provided by United Network for Organ Sharing (UNOS) and engaged kidney transplant programs. APOLLO will analyse the data that is available from clinic visits. There are no specific APOLLO study visits.
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended The APOLLO primary outcome is whether *APOL1* high-risk genotypes in deceased-donors are associated with time to death-censored renal allograft survival in transplant recipients. Secondary outcomes include estimated glomerular filtration rate (eGFR), serum creatinine concentration and proteinuria in recipients of APOLLO kidneys, and eGFR and proteinuria in living kidney donors based on *APOL1* genotype.
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) APOLLO initiated “rolling” recruitment in May 2019 when U.S. Organ Procurement Organizations (OPOs) and HLA labs began collecting samples from eligible deceased kidney donors and transplant programs began collecting samples from recipients of APOLLO kidneys and living kidney donors.

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations APOLLO is designed to detect an *APOL1* high-risk genotype (two *APOL1* RRVs) effect on the hazard for time to allograft failure of 1.7 with power between 50% and 94% depending on length of recruitment, recruitment yield, the correlation between two outcomes from a single donor and observed failure rates. It was initially anticipated that follow-up of recipients would be approximately 3 years; however, if follow-up can be extended by one year beyond the current study timeline and the proposed recruitment yield of 2,614 deceased donor-recipient pairs is obtained within 18 months, the minimum power to detect a 15% failure rate would be 80%. The analysis estimating the increased hazard attributable to high-risk *APOL1* genotypes will include African American deceased-donor kidney transplant recipients, allowing for correlation between outcomes from two recipients receiving kidneys from a single deceased-donor.
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size The NIH study sponsor is considering extending the enrolment and follow-up phases to ensure adequate power for the primary outcome.

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial N/A

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol *APOL1* genotyping will be performed in a CLIA laboratory at the Wake Forest Coordinating Centre once enrolment is complete. Kidney transplant outcomes will be provided by UNOS using UNOS ID numbers for donors and TRR ID numbers for recipients. Data collection forms are included in on-line supplementary materials.
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols Complete follow-up is anticipated using data provided by UNOS and participating kidney transplant programs.
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol Data entry will be done for information abstracted from participants' Electronic Health Records using a secure, web-based system. The system will include range and consistency checks. Further details will be available in the Manual of Procedures.
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol These are detailed in the manuscript and on-line supplementary materials.
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) These are detailed in the manuscript and on-line supplementary materials.
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) There is no protocol for participants after they have been consented: all follow-up is done using Electronic Health Records.

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed Along with the central IRB at Wake Forest School of Medicine, the APOLLO External Expert Panel (EEP) is monitoring the study. Because APOLLO is observational and usual medical care is provided, there is no DMC. The EEP is comprised of physicians, statisticians and ethicists with expertise in African American health, kidney disease and genetic analyses. They review and approve study protocols and monitor unanticipated events during the performance of APOLLO. The EEP meets with the APOLLO Coordinating Centre and study sponsor at least annually and is contacted by the Coordinating Centre on an "as needed" basis for questions or concerns.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct The Coordinating Centre will notify the central IRB and EEP of concerns with trial conduct. No adverse events are anticipated in this observational trial.
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor Annual review with the EEP.

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval APOLLO employs a central IRB located at the Wake Forest School of Medicine. Communications between all research institutions and the central IRB are via the web-based IRB Reliance Exchange (IREx).
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) Via central IRB using IREx.
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) CITI-certified research personnel at engaged transplant programs.
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable APOLLO Protocol and Publications Committee.

Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial Personal information on the study website is secured by access control. Other research records are kept in secured space with access limited to authorized persons.
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site The consent form lists financial interests and competing interests for principal investigators.
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators No contractual agreements will limit access to the final dataset apart from terms in Data Use Agreements with UNOS.
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions After publication, results will be disseminated via relationships between the media and members of the APOLLO Steering Committee and Community Advisory Council.
	31b	Authorship eligibility guidelines and any intended use of professional writers Manuscripts will be drafted solely by APOLLO study team members. Professional writers will not be used.
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code Final trial dataset will be made available in de-identified form through the NIDDK Data Repository.
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates Participant informational materials and consent forms are included in on-line Supplementary materials with the main manuscript.

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable DNA (and available urine and serum samples) from APOLLO deceased kidney donors are collected by OPOs and processed at HLA laboratories before shipment to the APOLLO Coordinating Centre. DNA (and available urine and serum samples) from living kidney donors and recipients of APOLLO kidneys are collected by transplant programs and shipped to the APOLLO Coordinating Centre. Samples are stored at -80°C and a portion will be sent to the NIDDK Biorepository, with the remainder stored at the APOLLO Central Lab at Wake Forest School of Medicine.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.