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1. PURPOSE

The purpose of this document is to outline the steps for receiving kits for a study. Also described here is what is contained in each of the kits for this study.

2. SCOPE

This Standard Operating Procedure (SOP) will describe what is contained in each of the kits that we will be receiving for this study and also cover how to receive them properly.

3. DEFINITIONS

- NaHep – Sodium Heparin

4. RESPONSIBILITIES

- Project Manager – The role of the project manager is to oversee the work in the laboratory and deal with any deviations from the protocol.
- Research Assistants – The role of the research assistants is to perform the physical tasks of the lab bench

5. MATERIALS

PPE:



- Lab Coat
- Gloves
- Closed toe shoes
- Face shield/ goggles

Equipment:

- Laptop
- Scanner
- Tube racks
- Box cutter
- Binders for paperwork
- Biohazard trash bin
- Centrifuge

6. ENVIRONMENTAL HEALTH AND SAFETY

- 6.1 Always treat all blood samples as though they are infectious.
 - 6.2 Always wash hands before and after contact with blood
 - 6.3 Always wear gloves and protective clothing
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7. PROCEDURE

7.1 Process Flow

TBD

7.2 Procedure

7.2.1 Overview

This is what we are expecting from each participant:

- Participants in this arm are collecting:
 - Whole Blood
 - Urine samples.
- We are expecting the participants to send back 3 or 4 – NaHep blood tubes and 1 – 20 mL urine vial. There is the possibility that a participant will send 4 NaHep tubes back because we provide an extra blood tube to the participants in case one breaks.
- The participants will ship one kit to us that has a kit ID in this format T1234567-BU-01.

7.2.2 OPENING KITS

- There are 4 taped off areas in the lab's Receiving Area
- Separate kits by placing kits from each study into its corresponding area.
- The priority for opening the kits is from the left to the right.
- Line up all the kits in alias ID order beginning from the smallest to the largest number.
- Score open the first kit using the box cutter.
- A complete kit should contain one envelope containing completed paperwork and 1 biohazard bag with the blood tubes and Urine container.
- First remove the envelopes. Open the envelopes.
 - Check the alias ID on the envelope against the label on the outside of the kit to make sure they match.
 - If they do not match, please notify project manager.
- Next take out the samples from their packaging. Verify that the labels on all the samples match both the labels on the envelope with the paperwork and the kit.

7.2.3 DATA ENTRY: PAPER LOG

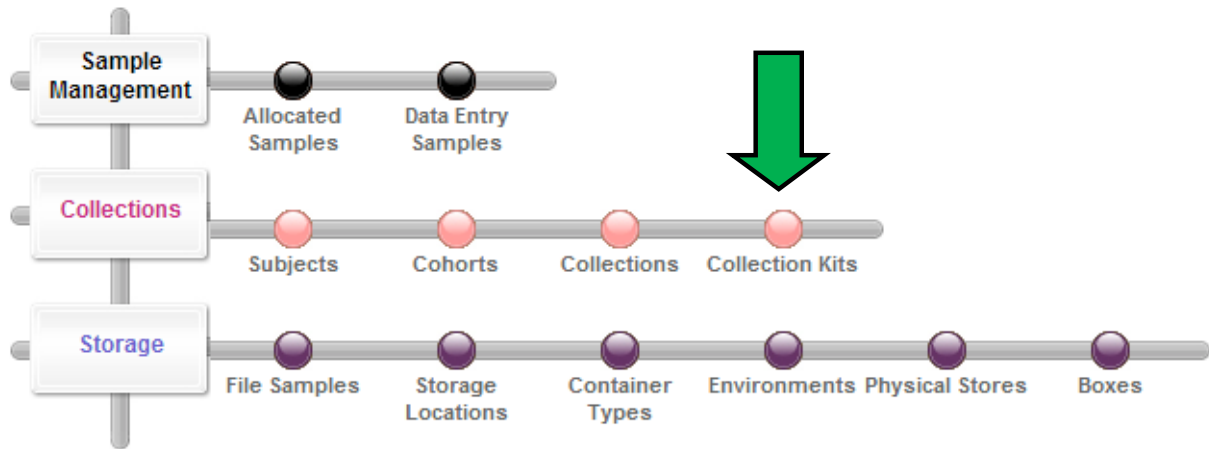
- Once you have verified that all the labels match, record the information on the paper log shown in the picture below.
- A paper log of kit receipt is maintained in addition to the electronic records in LIMS.
- Here below is screen shot of the log:

Arrival Date	KitID	Ship Date	Arm 1	Arm 2	Arm 3	Arm 4	Paperwork received?		Sample received?								Delays?	Comments	Physical Log RA	LIMS RA
							F	L	F				L							
							Whole blood	Plasma	Urine	DBS	Whole blood	Plasma	Urine	DBS						

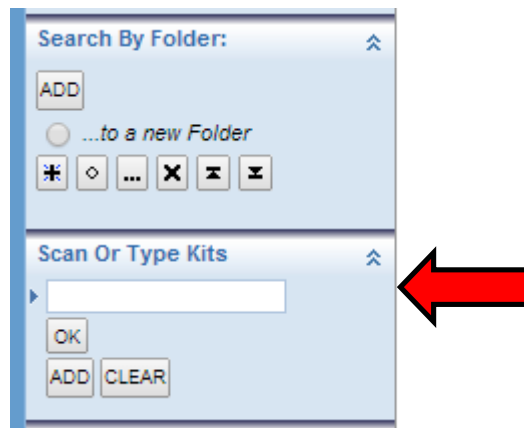
- The following information is recorded on the paper log:
 - Arrival date – Record the date samples are received into the lab
 - Kit ID – This is on the outside of the kit, the envelope, the consents and the samples. They should all match
 - Ship date – This information is found on the FedEx airbill and also on a barcoded label that Fedex fixes onto the package. Use the ship date on the barcoded label as this is the most accurate.
 - Arm – Put a check mark under the appropriate arm for the kit being received.
 - Paperwork - Record receipt of the paperwork by putting a check mark on the paper log. If not received, write “No” on the log.
 - Next, record the number of samples received.
 - Record how many Whole Blood and Urine samples are received
 - If the samples are arriving more than a day later after they were shipped, mark them as delayed by putting the number of hours they were in transit. E.g. 24 hours, 48 hours...
 - Physical Log RA – to record the initials of RA doing the paper log
 - LIMS RA – to record the initials of RA logging the kit into LIMS
 - Comment field to log any issues or deviations
 - The RA completing the physical log of samples must initial in the Physical Log RA column and the RA performing the data entry in LIMS must initial in the LIMS RA column.

7.2.4 DATA ENTRY: LIMS

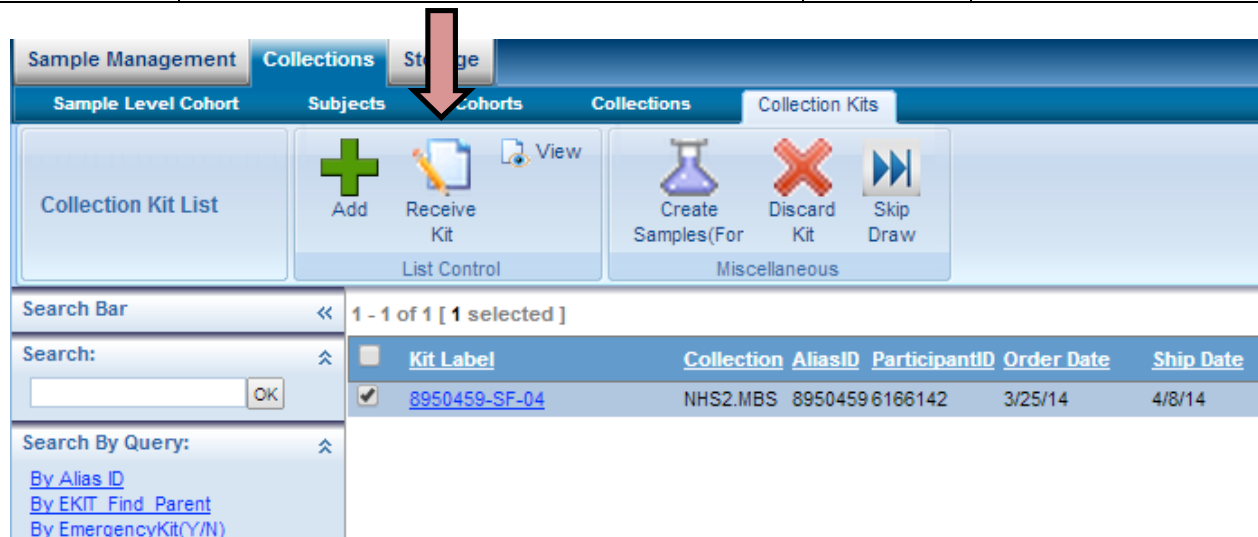
- Log into LIMS.
- On the Collection tramline, click on Collection Kits shown with green arrow below.



- At the bottom of the page that opens, there is a field that says “Scan Or Type Kits”
- Scan the barcode on the envelope in this field shown by the red arrow below:



- Click OK.
- The kit ID will populate on the right side of the page. Click on the little box in front of the kit label.
- Click on the Receive kit icon at the top of the page to enter the kit receiving screen as shown by the pink arrow below



- On the kit receiving screen, fill in the following fields:
 - **Kit receipt date:** type in “n” (stands for now). A time stamp will be added after saving.
 - **Status:** This is pre-populated as “Sent.” Below is a description of each Status option:
 - **Sent:** This is the default status of a kit in LIMS and it indicates that the kit has been shipped to the participant by Therapak.
 - **Received:** This indicates that the kit has been received in the lab and processed. Change to this status during this receiving process if samples will be processed and stored.
 - **Discard:** Indicate this if all the samples in a kit are unusable (please ask project manager if unsure of whether samples are usable or not)
 - **Any Mismatch:** If any of the barcoded labels did not match when you were opening the kit, select “Yes” and notify project manager. If they all matched select “No”
 - **Paperwork scan:** Yes if an envelope has been returned.
 - **Cold pack status:** The options for this are cool, warm, NA or missing.
 - **qx:** Record whether a questionnaire was received by choosing from the options Yes, No or N/A.
 - **Consent Form:** Record whether a signed and dated consent form has been received by choosing from the options Yes, No or N/A. The signature is on the last page of the consent form.
 - **Notes:** Use this field to add extra notes or make note of any deviations, such as late arrivals and if the samples are destroyed in any way.
- Here is a screen shot example of this page:

Sample Level Cohort	Subjects	Cohorts	Collections	Collection Kits
Edit Collection Kit NHS3.-T000001- 127464 Details		 Save	 Return	
		Maintenance	Page Control	

<input type="checkbox"/> Collection Kit			
Collection Kit			
Barcode/Kit ID	T0000013-PBU-02		
Participant Id	T1002360	Collection	NHS3.1PILOT
Participant Alias Id	T0000013	Collection Start Date	9/1/13
Collection End Date	9/30/14	Any Mismatch	<input type="text"/>
Order Date	4/15/14	Paperwork scan	<input type="text"/>
Kit Ship Date	<input type="text" value="5/5/14"/>	Cold Pack Status	<input type="text"/>
Kit receipt Date	<input type="text"/>	qx	<input type="text"/>
Tracking#	580864941395	Consent Form	<input type="text"/>
Status	<input type="text" value="Sent"/>	Complete	
Notes			
<input type="text"/>			

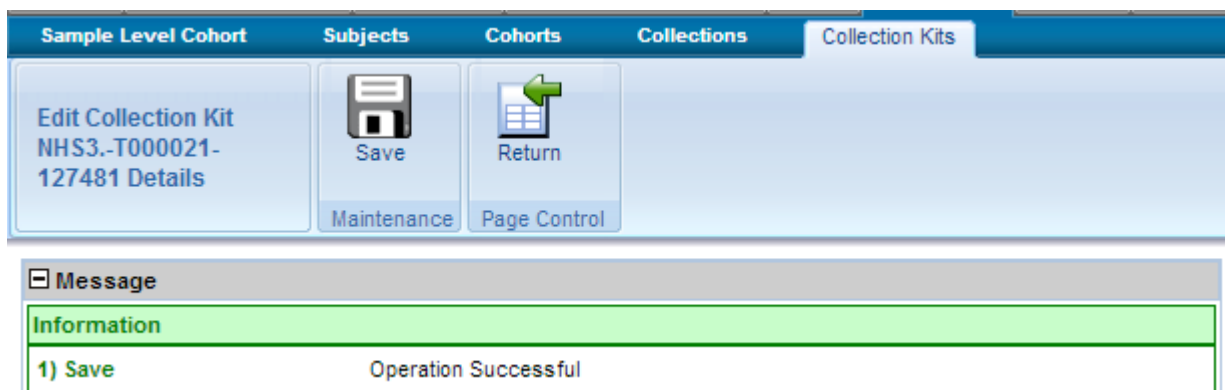
- Next fill in the kit details section as follows:
 - **Exp:** This is the number of samples expected back; this is autopopulated by LIMS
 - **Date rec'd:** type “n” for Now; a time stamp will be added after saving.
 - **Rtn:** number of actual samples returned for each sample type. If none, fill in 0.
 - **Brk:** number of samples destroyed in transit. If none, fill in 0.
 - **Ctm:** number of samples contaminated. If none, fill in 0.
 - **Lkd:** number of samples leaked in transit. If none, fill in 0.
 - **Lost:** number of samples lost after receipt (eg. Dropped while processing). Any loss of sample after arrival in the lab should be marked here. Please notify project manager as well. If none, fill 0.
 - **Arrv Delay:** note delays in sample receipt. Determine this by using the ship date written on the FedEx label. 24h= 1 day late, 48h= 2 days late, and so on.
 - **Sub-C:** “subcollection.” This field is pre-populated by LIMS and should match the last two digits of the kit ID.
 - **Low Vol:** If the volume of the samples received is less than the amount we are anticipating mark this field
 - **Status:** Log the status of each sample type received.
 - **Ok:** sample received and good to process

- **Discard:** sample cannot be processed
- Here is an example of what the kit details section looks like:

Kit Details

<input type="checkbox"/>	Type	Treatment	TimedType	Exp	Date Rec'd	Rtn	Brk	Ctm	Lkd	Lost	Arrv Delay	Sub-C	Emergency	Low Vol	Status	Timed Samples#
<input type="checkbox"/>	Blood	NaHep	Follicular	3	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	no delay ...	01	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/>	Urine	No Treatment	Follicular-Spot	1	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	no delay ...	01	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>

- Once all this information is entered, click on the save icon at the top of the page. A message saying Save – Operation Successful should appear as shown below:



Sample Level Cohort Subjects Cohorts Collections **Collection Kits**

Edit Collection Kit
NHS3.-T000021-
127481 Details

Save Return

Maintenance Page Control

Message



Information

1) Save Operation Successful

- Click on the Return icon to return to the Collection Kits home page
- Repeat steps 7.2.2 – 7.2.4 to receive all the kits.
- Once this is completed, under the “Search by query” click on the “By Kit Received Date” shown by the pink arrow below.
- The “Received Date” field will populate below the queries as show by the green arrow below.
- Enter the current date when all the receiving is being performed on and click OK.



- All the samples that have been received that day will populate on the right.
- Verify that they match the number of kits received on that day.
- If they do, select them all and click on the “Create Samples” icon. This will generate a csv file with all the aliquot sample information.
- This csv file is located in the polvs00 drive.
- Retrieve this file and save as Word file in the study folder that is located in the polvs00 drive.
- Add a line at the top of this document and put your initials and the date. Also add a comments column at the end.
- Print this document. This is the Aliquot Sheet that you will use to record the volume of sample aliquoted into each vial.

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8. APPLICABLE REFERENCES

List of applicable reference documents.

9. QUALITY RECORDS

List of applicable Quality records.

APPROVALS

<i>Approver</i>	<i>Approval Date</i>
<i>S. Sawyer</i>	<i>5/30/14</i>

REVISION HISTORY

<i>AUTHOR</i>	<i>REVISED SECTION/PARAGRAPH</i>	<i>REV</i>	<i>RELEASED</i>
Gakii Masunga	Initial release	1	5/30/14

Draft and Archived/Obsolete revisions are not to be used.