Title: Procedure for Outside Project Sample Check-In

Purpose: To record the arrival and storage location of clinical research samples, assign box numbers to the samples in order to aid in identification and record the date and method in which samples were returned to the appropriate Investigator/study staff.

Procedure:
1. Investigators/study staff should have been instructed to notify CLASS of a shipment and receive a CLASS confirmation statement prior to sending a shipment. Upon receiving a message from a site indicating their intention to send a shipment, the intended carrier and the tracking number, kindly state that CLASS will be on the lookout for the shipment in an email entitled “received shipment message.” Should the site omit the carrier or the tracking number, request this information in the text of the message. Post this email communication on the sample check-in corkboard so that sample check-in personnel will be alerted to incoming shipments.

2. Sample check-in personnel are to check and update the sample check-in corkboard periodically during the day. If an expected shipment has not arrived by 3:00 p.m. track the shipment through the shipping carrier to determine its location and status. If the shipment will be delayed, notify the Lab Manager and the Investigator/study staff member as soon as possible. Mark the email communication with the word “DELAYED shipment.”

3. Regardless if an Investigator notifies CLASS of an arriving shipment, at the time the shipment arrives, send a “notification of receipt” message to the Investigator indicating that the shipment was received, the shipping carrier and the tracking number. Re-read the email communication posted on the sample check-in board and check to ensure the appropriate shipment (or number of boxes) has arrived. At that time please write the words “RECEIVED” on the email message posted on the board. At the end of the day as an extra QC measure, check that all the messages posted on the corkboard are marked “RECEIVED” or “DELAYED.” If a message is marked “RECEIVED,” the message is to be discarded.

4. Visually inspect the tubes at sample preparation station in Room A124 for evidence of thawing. Handle biohazardous materials using the Universal Blood and Body Fluid Precautions. A poster of these precautions is in Room A122 and A124 and it includes wearing a lab coat and gloves at all times; safety glasses are also recommended and they may be found in Room A122 and gloves can be found in multiple rooms. Full precautions are detailed in the Procedure for Universal Precautions. Carry out the following steps before checking in the samples:

   a. Make sure that there are blue pads on the sample preparation station. Blue pads may be found in Room A122 or A124.
b. Obtain styrofoam container and fill with dry ice, or put dry ice on top of a piece of styrofoam. Dry ice may be obtained from the moveable dry ice chest located in Room A124.

c. Remove packing material and dry ice from the shipping container and check that all tubes have been removed from the shipping container.

d. If the tube is not frozen solid, mark the tube unobtrusively with a sharpie or other indelible pen. Mark partially thawed tubes with a 'P' and completely thawed samples with a 'T'. Snap freeze the samples in an upright manner. If the check-in process needs to be delayed at this time, the samples may be left in a backed up, alarmed -80 degree C ultralow freezer at CLASS, however, the samples must be clearly labeled with the Investigator information and the date of receipt.

5. Record the following information in the Outside Project Shipment Log, located on the A124/PC computer: the date the shipment was received, the tech’s initials, the Investigator/Study Staff Coordinator, the carrier and tracking number as well as the storage location and appropriate comments pertaining to the shipment. The shipment ID number is automatically filled in by Filemaker. Record any additional comments, such as number of thawed samples and their specific SIDs for example.

6. It is necessary to assign a box number or multiple box numbers (if there is more than one box) to the samples. Refer to the previous record in order to ascertain the last box number used. Use the next box number(s) for these samples. Write this number with an indelible pen onto the box and record the box number(s) on the record in Filemaker.

7. Place the box or boxes into a backed up, alarmed -80°C freezer and specify the freezer under storage location.

8. File the packing slip, if applicable, in the Outside Project Shipper Binder located in Room A124.

9. When samples are to be returned, open the corresponding record. Record the method by which the samples are to be returned and the date. If the samples are picked up by the Investigator/study staff, record that individual’s name.