

POLICIES AND PROCEDURES

SECTION: Research and Compliance			NUMBER: CLN-19.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 4/14/2009	REV. B: 8/26/2010	REV. C:
TITLE: Specimen Handling			Page 1 of 3	

1. PURPOSE

To standardize specimen handling, storage, and shipping.

2. SCOPE

Applies to all personnel involved in the implementation and coordination of clinical investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is ultimately responsible for all aspects of the study that she/he directs, including the area of the careful handling of body fluids (blood, urine, stool, sweat, saliva, etc.). Great care must then be taken to be sure the laboratory testing the specimens operates at the highest standards.

4. BACKGROUND

The importance of the careful and skillful handling of specimens taken from Study Participants (SPs) over the course of a clinical research study cannot be overestimated. Biologic specimens may be required to perform the analytical and biochemical testing on specimens of human body fluids as documented in the protocol approved by the IRB of record.

5. PROCEDURE

5.1. Specimen Handling

- 5.1.1. The SC reviews with the laboratory staff the protocol for specimen handling instructions, noting specimen stability issues, type of centrifuge needed, speed/time, storage, and special shipping instructions.
- 5.1.2. Specimens are collected according to the approved protocol (or by direction of the sponsor if this information is not in the protocol).
- 5.1.3. Universal precautionary procedures are followed when handling all specimens.
- 5.1.4. Specimens are never handled in office or eating areas.
- 5.1.5. Specimens are not disposed of until there are documented instructions from sponsor.
- 5.1.6. No retained specimens will be used for any research purposes other than that approved by the IRB involved.

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5.2. Specimen Log

- 5.2.1. All specimens should be logged in a specimen laboratory notebook in the research laboratory as either:
 - 5.2.1.1. Ambient (room temperature, ~25 degrees Celsius or as designated by study protocol)
 - 5.2.1.2. Cool-Refrigerated (0-5 degrees Celsius or as designated by study protocol)
 - 5.2.1.3. Frozen (-20 degrees or -80 degrees Celsius or as designated by study protocol)
- 5.2.2. Specimens are also logged onto a specimen location chart or list kept in the lab.

5.3. Specimen Labeling

- 5.3.1. All specimens placed in the research freezer or refrigerator are labeled with:
 - 5.3.1.1. Name of study
 - 5.3.1.2. Date/time drawn
 - 5.3.1.3. Study subject identifier
- 5.3.2. Frozen specimens are shipped to the required laboratory Monday through Thursday, unless receiving laboratory can accept Saturday delivery.
 - 5.3.2.1. The sponsor is notified of the date and time of the shipment, as is the destination lab (if different from the sponsor), as required by the study protocol.
 - 5.3.2.2. The SC or other designee will maintain a shipping log including a copy of shipping requisitions for tracking purposes.

5.4. Shipping

- 5.4.1. The shipment of specimens must follow any applicable guidelines, including, but not limited to:
 - 5.4.1.1. International Air Transport Association (IATA)
 - 5.4.1.2. UN 1333 guidelines
 - 5.4.1.3. Guidelines set forth by the courier used to ship the specimens

6. TERMS & ABBREVIATIONS

GCP	Good Clinical Practice
GLP	Good Laboratory Practice
IATA	International Air Transport Association
IRB	Institutional Review Board
SC	Study Coordinator
SP	Study Participant

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UN United Nations

7. REFERENCES

7.1. GLP Overview

8. ATTACHMENTS

None