



**Nova Southeastern University
Standard Operating Procedure for GCP**

Title: <u>Phlebotomy</u>		Version # 1
SOP Number: OCR-LAB-002	Effective Date: August 2013	Page 1 of 2

PURPOSE: Acceptable phlebotomy practices should be followed with research subjects.

POLICIES:

1. The Center/College should follow it's own policies independent of this manual on the drawing of blood and the issues that surround it which should include but not be limited to the following:
 - 1.1. General Phlebotomy
 - 1.2. Re-stick Policies
 - 1.3. Needle-Stick protocols
 - 1.4. Use of Saline/Heparin Locks and IVs etc.
 - 1.5. Appropriate Training/Licensure of Staff
 - 1.6. Demonstration of Competency
2. In addition to the reporting requirements of adverse events occurring during phlebotomy required by the Center/College's policies, these events may also need to be reported through research-related mechanisms as well (i.e. to the IRB, Sponsor etc).
3. Storage of specimens prior to transport shall be adequate and monitored.

Procedure for Storage of Specimens Prior to Transport

1. Specimen storage shall be in accordance with the Center/Colleges policies on storage of biohazardous materials.
2. In the event sub-ambient temperatures are required for storage,
 - 2.1. The storage medium should be prepared for loss of power to protect the integrity of the specimens in the event of such power loss. Emergency generator back up.

- 2.2. A Temperature Log shall be kept at all times the specimens are stored awaiting packaging (i.e. frozen for batch shipment). The log shall, at a minimum:
 - 2.2.1. Be clearly labeled and proximal to the storage medium (i.e. taped on or above the freezer) so that it is not confused with other logs.
 - 2.2.2. Shall specify the temperature scale as Centigrade (C) or Fahrenheit (F) in either
 - 2.2.2.1. at the top of the page stating something such as "All entries are on the Centigrade (C) temperature scale"; or
 - 2.2.2.2. at each entry.
 - 2.2.3. Documented on daily