Nova Southeastern University
Standard Operating Procedure for GCP

Title: Storage of Investigational Product		Version # 1
SOP Number: OCR-AIP-002	**Effective Date: August 2013**	**Page 1 of 2**

POLICIES:

1. This policy does not apply to radiopharmaceuticals, biologics or genetic therapy vectors, which will be governed under separate policy if utilized.
2. Physical storage requirements include "Double-Lock" conditions
   2.1. Limited access through the first lock by non-research/non-administrative staff
   2.2. Second lock shall be in form of an affixed or substantially constructed container/cabinet/refrigerator etc.
   2.3. Access through the second lock should be limited to the Principal Investigator and study staff.
3. Investigational Products should be stored within the temperature requirements of the Investigator's Brochure, packaging insert or other authoritative document.
4. A Sponsor, NSU IRB, or other relevant organization may impose additional storage requirements and these are also to be documented as to how they will be followed.
5. When relocating Investigational Products, the storage specifications regard to temperature shall be maintained throughout the move.

Procedure for Temperature Logs

1. A Temperature Log shall be kept at all times the specimens are stored, regardless of the temperature range (i.e. even if stored at room temperature, documentation that the room did not get too hot is necessary). The log shall, at a minimum:
   1.1. Be labeled and proximal to the storage medium (i.e. taped on or above the freezer, by the cabinet etc.) so that it is not confused with other logs.

1.2. Shall specify in each case or at the top of the page whether the temperature scale is Centigrade (C) or Fahrenheit (F).
1.3. Documented on regular basis

2. If Investigational Products are to be stored at other than room temperature (i.e. refrigerated), then a backup system should be in place in the event of power failure. Examples of this can be the following:
   2.1. The preferred method is connecting the refrigerator to a "generator" outlet
   2.2. Separate cooler that could maintain the temperature range
   2.3. Moving the Investigational Product to another similarly secure location while maintaining the storage conditions during transport
3. Copies of the relevant Temperature logs can be placed in folders for archiving so that the study documents can be complete.

Procedure for Relocating Investigational Product to Alternate Storage

1. Storage specifications (i.e. temperature requirements) shall be maintained throughout transport. Specific transport containers (use of coolers, dry ice etc) with a thermometer may be used as necessary.
2. During transport, the transporting individual will maintain line-of-sight with the product.
3. Transportation may be accomplished in private vehicle as necessary however, transportation should be directly from the Transport-From Center/College directly to the Transport-To Center/College
4. All of the following should be part of the permanent study record (narrative format is acceptable)
   4.1. Departing inventory and temperature of original storage medium.
   4.2. Time of removal from storage.
   4.3. Internal temperature of transport medium upon placement of Investigational Product.
   4.4. Internal temperature of transport medium upon removal of Investigational Product.
   4.5. Arriving inventory (any discrepancies should follow respective policy).
   4.6. Time of placement in storage and Temperature of such storage.
   4.7. Any significant events that occurred during transport
5. Return to Double-Lock conditions.