Nova Southeastern University
Standard Operating Procedure for GCP

Title: Policies on Standard Operating Procedures ("SOPs") for GCP		Version # 1
SOP Number: OCR-ADM-001	**Effective Date: August 2013**	**Page 1 of 3**

PURPOSE: The best research practices should be in place at all times.

POLICIES:

1. The Center/College has the following SOP for GCP manual in place, which govern the conduct of the best practice in the Center/College.
2. Periodic, but no less than annual, review of this manual shall be performed.
3. Whenever a new policy, a revision to an existing policy or the deletion of a policy is needed, appropriate review of said policy is completed. A historic record is kept so that any given date, it can be easily determined what policy was in place.
4. From time to time, deviations from this policy will either occur or be necessary in "single case" scenarios. If prior written approval for such deviation from the Vice President Research and Technology Transfer is not possible (i.e. emergent need or discovered negligence that occurred in the past), the Vice President Research and Technology Transfer is to be informed as soon as possible when the deviation occurs.

Procedure for Periodic Review of SOPs for GCP

1. The Vice President Research and Technology Transfer, Assistant Vice President Research and Technology and Administrative Director Office of Clinical Research shall review these policies once annually and document such review.
2. The Vice President Research and Technology Transfer, Assistant Vice President Research and Technology and the Administrative Director

Office of Clinical Research shall review and approve amendments and revisions.

Procedure for Additions/Modifications/Deletions to SOPs for GCP

1. Unless initiated by the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research, in the event a particular policy is requested to be generated or modified or deleted, a written request to the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research containing the following information will be sent prior to implementing the change:
   1.1. The reason for requesting the addition/modification/deletion
      1.1.1. Statements such as "required by law/accrediting body/etc" cannot be considered unless accompanied by the relevant citation of such external requirement; AND
   1.2. The relevant policy number (for modification or deletion requests); AND
   1.3. The proposed change (preferably in a redline format) or new policy that molds to the same format as this manual; AND
   1.4. Any other relevant information.
2. Once received, the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research will research the policy request and decide the following:
   2.1. Compliance with relevant federal, state and local laws as well as GCPs
   2.2. Approval "As-Is"; Approval with modifications (and provide modifications); OR Disapproval (with justifications)
   2.3. Appropriateness of the request, regardless of decision at the requesting Center/College, as it may pertain to other Center/Colleges within the scope of their service. If appropriate, the Vice President Research and Technology Transfer and Administrative Director Office of Clinical Research shall initiate the modification.
3. To maintain historic integrity on NEW policies…
   3.1. An Effective Date shall be provided in the policy header.
4. To maintain historic integrity on MODIFIED policies…
   4.1. An Effective Date shall be provided in the policy header
   4.2. The old policy will have an end date and shall be archived on the shared drive.
5. To maintain historic integrity on DELETED policies…
   5.1. The archived policy shall note the date no longer effective.
   5.2. The deleted policy shall be archived on the shared drive and stored in back of binder under appropriate section
6. Please note: Only the current policy will be referenced online.

Reporting SOP for GCP Deviation

1. Criteria for SOP for GCP deviations are as follows:
   1.1. Submit report to Vice President of Research and Technology Transfer within 5 days of discovery.
   1.2. Vice President determines appropriate actions and notifies appropriate persons