Nova Southeastern University
Standard Operating Procedure for GCP

Title: **Monitoring**		Version # 1
SOP Number: OCR-MON-001	**Effective Date: August 2013**	**Page 1 of 4**

POLICY: The Sponsor is required by ICH GCPs to verify that the data collected in the CRFs is verifiable to source documentation. They are also required to verify that essential documentation is being maintained correctly at the site and that the test product is being maintained according to the conditions outlined in the protocol.

A "Monitor" is a person who by training, education and experience is qualified to represent the Sponsor in the verification of materials at the investigational site. The monitor acts as the agent for the Sponsor and is the only party that has access to the true identity of the subjects, which is necessary to verify the data documented in the CRFs and the ICFs. The monitor is bound by confidentiality agreements not to reveal the subject's identity in reporting the activities at the site level. A monitor may be one of the following:

1. Employee of the Sponsor Company.
2. Employee of a Contract Research Organization (CRO) that the Sponsor has employed to run or assist in running the clinical trial.
3. An Independent CRA that has been contracted by either the CRO or by the Sponsor directly.

The monitor should be considered an adjunct to the research site research team and is there to assist the team in the correct and accurate recording of all activities of the clinical trial. He/she should be utilized as a resource person for any questions or concerns about the clinical trial.

A schedule of visits should be established by the site and the monitor, but this schedule may very according to the rate of subject recruitment**.**

PROCEDURE:

Booking a monitoring visit:

1. The monitoring trip is usually initiated by the monitor via a telephone call, e-mail or letter. He/She will request a date and time for the visit.

1.1 Be as flexible as possible in booking monitoring visits.
1.2 Avoid having monitors from competing companies visit on the same day.

2. The monitor should meet with the Principal Investigator at every visit.

3. The visit should be confirmed in writing.

4. If this is the monitor's first trip to the research site offer directions and hotel suggestions.

Preparation for the monitoring visit:

1. Booking a room for the monitor should include:
   1.1 Large desk.
   1.2 Telephone access.
   1.3 Access to photocopier.
   1.4 As quiet as possible.

2. Every 1st time monitor should receive an overview of the research site procedures, charts, etc. by the research site staff and be offered a tour of the facilities.

3. Book a meeting time with the PI (if appropriate).
   3.1. Usually best to book near the end of the day so that findings from that day can be discussed and any applicable CRFs or forms can be signed.
   3.2 The CRC will be available throughout the day to respond to the monitor's questions and complete necessary corrections or clarifications.
   3.3 The P.I. will be available through the visit to respond to questions.

4. Review Investigator Binder to assure that all documents are current and complete.
   4.1 Prepare photocopies of new documentation for the monitor to take.

5. Review all source documentation to be reviewed by the monitor for completeness and accuracy.
   5.1 Insure that all applicable lab reports etc. have been reviewed and signed by the PI.

6. Review all CRFs to be reviewed by the monitor for completeness and accuracy.
   6.1 CRFs should not be signed by the PI until after the monitor's review.

7. Review Study Drug Accountability Records to assure that they are current, complete and accurate.

Day of monitoring visit:

1. Have the appropriate CRFs and Investigator Binder(s) set out prior to the monitor's arrival.
   - 1.1 All completed CRFs.
   - 1.2 Investigator Binder(s.)
   - 1.3 Study drug accountability material.
   - 1.4 Access to study drug cabinet upon request.

2. Greet the monitor and make her/him feel welcome.
   - 2.1 Offer coffee and show location of the washroom.

3. Allow the monitor to review all necessary material without disruption, but make yourself available for questions or corrections. These will include but are not necessarily limited to:
   - 3.1 Original Informed Consent Forms.
   - 3.2 Original source documentation.
   - 3.3 The monitor will be looking for evidence that the subject is real, (does exist) and that the data collected is accurate.
   - 3.4 All procedure results should have been reviewed and signed prior to the monitor arrival.

4. Set aside a designated period of time to complete clarifications/corrections with the monitor.
   - 4.1 Clarifications may include corrections to the CRF or additions/corrections to the source documentation.

5. The Study Coordinator should be prepared to meet with the monitor and PI upon completion of the visit.
   - 5.1 This meeting should include a review of findings, expectations and booking of the next visit.

Monitoring visit follow-up

1. The monitor will be writing a report to the Sponsor as to what he/she found at the site and what was accomplished.
   - 1.1 This will include recommendations for improvement and requested activities.

2. The Monitor will write a letter as a follow-up to the monitoring visit.
   - 2.1 Should contain work accomplished during the visit and requested activities or tasks to be completed prior to the next monitoring visit.

2.2 If the follow-up letter is not received within a reasonable time frame the monitor should be contacted to request the documentation.

2.3 The letter usually includes the mutually agreed upon date for the next monitoring visit.

3. All communications in relation to the monitoring visit need to be filed in the Regulatory Binder under general correspondence.

3.1 Correspondence with the monitor becomes part of the essential documents that are required to be stored for a minimum of 25 years