Nova Southeastern University – Institutional Review Board Standard Operating Procedures		
SOP #5 **Version #1**	**TITLE: Post-Approval Monitoring of Research**	
Date First Effective: January 11, 2018	Revision Date: N/A	Page 1 of 3

OBJECTIVE

To describe policies and procedures for the post-approval monitoring of human participant research.

GENERAL DESCRIPTION

The Institutional Review Board (IRB) at Nova Southeastern University (NSU) leads the university's human participant protection program. In addition to reviewing new research submissions to ensure they adhere to basic ethical principles underlying the acceptable conduct of research involving human participants, the IRB is tasked with monitoring research after the initial approval. The goals of Post-Approval Monitoring Program are to enhance both the protection of human research participants and the quality of research performed here at NSU.

Post-approval monitoring will consist of evaluations conducted by the Post-Approval Monitor (PAM) or their designee. All active and concluded studies involving human participants under the purview of the NSU IRB can be selected for evaluation. Studies may be selected for evaluation randomly as part of the post-approval monitoring program or due to allegations or concerns regarding the conduct of a study. A post-approval evaluation involves a review of study-related documents and/or observation of the consent or research process, either on-site or via webcam conferencing.

The PAM is authorized to, but not limited to, review of the following:

- Protocol file/regulatory documentation
- IRB documentation
- Signed informed consent/assent documents
- Individual Participant Records, all or a random selection may be used
- Interviews with study staff
- Interviews with research study participants
- Observation of the consent process
- Observation of research procedures
- Other study related documentation and materials

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Research Personnel, Institutional Review Board (IRB) Office Staff, IRB Members, IRB Chairs

PROCEDURES

1. Selection of Research for Post-Approval Evaluations may be scheduled or unscheduled, and will fall into one of the following categories:
    a. *Not-for-Cause Evaluation*: Protocols will be randomly selected for a Post-Approval Evaluation by the PAM.
    b. *For-Cause Evaluation*: Protocol selected for a Post-Approval Evaluation due to allegations of or concerns regarding the conduct of a study reported to the IRB Office.

2. Active studies and those that have been concluded may be selected for a post-approval evaluation. Investigators should adhere to the IRB policy regarding the retention of research records. (See Privacy, Confidentiality, and Recordkeeping of Research Records SOP.)

3. The PAM will contact the Principal Investigator and other research personnel (if applicable) via an *Evaluation Selection Memo* to set up an evaluation date/time and to discuss evaluation procedures. The Principal Investigator must respond within ten (10) business days of receiving their selection memo to schedule their evaluation.

4. The *Evaluation Selection Memo* will contain a list of all the required documentation. Requested research documents may include, but are not limited to, the following:
    - New Protocol Submission Form;
    - Initial IRB approval memo & stamped documents;
    - Amendment Forms;
    - Amendment IRB approval memo & stamped documents;
    - Continuing Review Forms;
    - Continuing Review IRB approval memo & stamped documents;
    - Copies of signed Informed Consent/Assent Forms;
    - Documentation of participant eligibility;
    - Documentation of participant compensation;
    - Documentation of participant complaints, adverse events, protocol deviations, or unanticipated problems;
    - Copies of study data files/participants records;
    - Responses to the “Not-for-Cause” Pre-Evaluation Questions”.

5. The Principal Investigator should collect and organize the materials listed in their selection memo in order to expedite the evaluation visit. Additional resources are available on the

Post-Approval Monitoring page of the IRB website that will assist with preparation for an evaluation visit.

6. The PAM will indicate in the selection memo if research personnel or participants will be interviewed. If the evaluation requires observation of the consent process and/or research procedures, that will also be indicated in the selection memo.

7. Evaluations may be conducted at the IRB Office or at a location convenient to the Principal Investigator. Alternately, evaluations may be conducted at the research site to determine adherence to the study procedures as outlined in the approved IRB submission.

8. The PAM will review the investigator's research records to verify that the investigator is conducting the research as approved by the IRB and has made no changes to the protocol. Additionally, the PAM will determine whether the procedures for informed consent are conducted in accordance with federal/state regulations, institutional policy, and the approved IRB protocol submission.

9. As part of the evaluation, the Post-Approval Monitoring Form will be completed by the PAM. To maintain confidentiality, the PAM will not record participants' private identifiable information in the evaluation form.

10. After the evaluation, the evaluation form will be sent to the Principal Investigator for review and sign-off prior to being reviewed and signed by the IRB Director, PAM, and IRB Chair. The Principal Investigator will received a signed copy for their records and a copy will be placed in their study file.

11. After conducting a post-approval evaluation, if the PAM determines that there are deficiencies, they may recommend suspension or termination of the research due to noncompliance. The PAM will present the information to the convened IRB as outlined in the Non-Compliance and the Suspension/Termination of Approved Research SOP.

REFERENCES

45 CFR 46.103(b)(4)(i-iv) and 46.109(e)
21 CFR 56.108(a)(1) and 56.109(a - f) 21 CFR 56.108(a)(1) and 56.109(e)
21 CFR 56.108(a)(2)
21 CFR 56.115(a)(3)