



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

<b>Title: <u>Communications with the IRB</u></b>		<b>Version # 1</b>
<b>SOP Number: OCR-IRB-002</b>	<b>Effective Date: August 2013</b>	<b>Page 1 of 3</b>

**PURPOSE:** The IRB must be fully informed of the research activity to best fulfill their role in human subject protection. The Principal Investigator must be fully informed of the IRB's decisions to aid in his/her protection in human subjects as well.

**POLICY:**

1. No study may begin without having the written approval (or documented waiver) from the IRB. Verbal approval is not acceptable.
2. All information included below, if applicable, and any additional information deemed necessary by the IRB should be submitted in a timely manner.
3. The Center/College/Principal Investigator shall maintain all correspondence to and from the IRB in the Investigator Binder for the study.

**Procedures for Submitting Initial Review**

1. The Principal Investigator will submit the new protocol submission form to the IRB Center/College representative, who is the starting point for IRB process. This individual is charged with reviewing the submission to determine the appropriate level of review for the study as well as assuring that all necessary documents are included
  - 1.1. Instructions for completion of the New Protocol Submission Form can be found on the following NSU website:  
<http://www.nova.edu/irb/manual/forms.html>.
  - 1.2. IRB Center/College Representative approves complete submission application
  - 1.3. PI submits application to NSU IRB

## **Procedures for Submitting Amendment of IRB-approved Studies**

1. Federal regulations and NSU policy require researchers to obtain approval for study modifications before implementing changes to approved research.
  - 1.1. These changes to research include but are limited to:
    - 1.1.1. Changes to research staff, including principal investigator or co-investigators, or changes to the contact information of research staff.
    - 1.1.2. Changes to the types of or number of subjects to be recruited or enrolled in the study.
    - 1.1.3. Changes to study procedures or locations of where the research is going to be conducted.
    - 1.1.4. Changes in instruments or data collection instruments.
    - 1.1.5. Changes in methods of recruitment, advertisement of the study or to the wording of the informed consent.
2. The NSU-IRB Amendment of IRB Approved Studies Form can be found at the following website: <http://www.nova.edu/irb/manual/forms.html>

### **References:**

- 45 CFR 46.103(b)(4)(iii)
- 21 CFR 56.108(a)(3)

## **Procedures for Submitting Continuing Review Report**

1. The NSU IRB conducts **continuing review** of all research, funded or unfunded, in accordance with the policies and procedures outlined in the NSU-IRB manual at intervals appropriate to the degree of risk, but not less than once per year for the life of the project.
2. Federal regulation requires that IRB approved research be reviewed by the IRB by no later than one year from the date of approval—or sooner if the IRB determines that the nature of the research warrants shorter review intervals. No study may continue beyond the one-year approval until the IRB has reviewed the continuation request. Researchers are also reminded that the IRB may conduct audits at intervals sooner than continuing review periods.
3. The NSU IRB Submission Form for Continuing Review of IRB Approved Studies can be referenced for completion at the following website: <http://www.nova.edu/irb/manual/forms.html>

## **Procedures for Submitting Closing Report**

1. As the study progresses, the Principal Investigator shall submit the following to the IRB:

1.1. The NSU IRB Closing Report Form for IRB Approved Studies can be found on the following NSU website:

<http://www.nova.edu/irb/manual/forms.html>

- 1.1.1. This form is to be completed for all studies approved via expedited or full review procedures. The form must be submitted within 30 days of the conclusion of research activities.
2. This information must be submitted in the shorter of the timeframes dictated by the IRB, protocol, or this policy.
3. All correspondence to and from the NSU IRB should be filed in the Investigator Binder.