Nova Southeastern University
Institutional Review Board
Policies and Procedures

Monitoring of Approved Research, Approval Duration, and Continuing Review
Effective 03/08/2007; Revised 10/14/2010; 8/29/2011; 10/17/2012; 5/10/13

Purpose:

To establish policy and procedures for the monitoring of approved research, the approval duration of protocols, and continuing review requirements.

Definitions:

None

Policy:

1. Continuing Review and Approval Duration

   It is the responsibility of the IRB to govern research that has been approved to ensure that research is conducted in accordance with governmental guidelines and regulations and with IRB requirements. In order to effectively do this, the IRB must conduct—as prescribed by regulation—continuing review of approved research not less than once a year. When approving the study, the IRB (or IRB Chair/Designee in the case of an expedited review) will determine if the risks are of a sufficient magnitude that continuing review is required more often than annually. Continuing review is required for any active protocol including those where the only activity that remains is data analysis.

   The factors that shall be considered to determine whether a study requires continuing review more frequently than annually include, but are not limited to;

   - studies that involve experimental therapies or procedures in which a clear potential for significant adverse experiences has been identified at the time of review,
   - the nature, probability and magnitude of anticipated risks to subjects,
   - the medical, psychological, or physical conditions of the proposed subjects,
   - age of subjects,
   - qualifications of the PI and other members of the research team,
   - nature and frequency of adverse events observed in similar research,
   - vulnerability of the population being studied including familiarity with the language on consent forms and other documents, and other facts the IRB deems relevant.

2. Audits of Research/Monitoring of Informed Consent Procedures

The IRB and the institution have the right to conduct audits of approved research to ensure that all requirements have been met—in particular, the manner in which informed consent has been conducted. The IRB is authorized to monitor or to have a third-party monitor the informed consent process. Voting members, members, alternate members, and designated IRB staff may audit approved research for adherence to study procedures as outlined in the approved IRB submission. Additionally, governmental agencies may also review research records. The university may randomly audit approved studies and may elect to target audit studies.

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)

Procedures:

1. For Continuing Review:
   a. PIs who require continuation of study approval must request continuation with sufficient time to allow for continuing review without a lapse in approval. As a result, the IRB recommends that investigators submit for continuing review at least two months prior to the continuing review date. Federal regulations and university policy do not allow for any form of grace period. As a result, research with human subjects and/or their data must end should approval of continuing review not be obtained before the end of the approval period and may not begin again until the study has been approved for another continuing review period. A lapse in IRB approval of research occurs whenever an investigator has failed to provide continuing review information to the IRB or the IRB has not conducted continuing review and re-approved the research (with or without conditions) by the expiration date of the IRB approval. In such circumstances, the activities involving human subjects and/ or their data must stop after IRB approval expired, unless it is determined to be in the best interests of already enrolled subjects to

continue participating in the research. Enrollment of new subjects cannot occur after the expiration of IRB approval. If the investigator has failed to submit the required documentation for continuing review by the expiration date of the IRB approval, the IRB office will send the investigator, via electronic mail,

b. notification that the research study has been closed and that no further work with human subjects or analysis of data may take place. The determination regarding whether it is in the best interests of already enrolled subjects to continue to participate in the research after IRB approval has expired may be made initially by the investigator, and if applicable in consultation with the subject's treating physician (if the researcher is not the subject's treating physician), but the investigator should submit request for confirmation that the IRB agrees with this determination within one business day of receipt of the protocol closure notification. The determination by the IRB may be made by the IRB chairperson, by another IRB member or group of IRB members designated by the IRB chairperson, or at a convened meeting of the IRB. Furthermore, this determination may be made for all enrolled subjects as a group or for each individual subject. If the investigator or the IRB determines that it is not in the best interests of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities including intervening or interacting with subjects and obtaining or analyzing data.
c. When IRB approval of an ongoing research project lapses and the investigator wants to continue the project, the investigator should submit the required documentation to the IRB office as soon as possible. The investigator may resume the human subjects research activity once continuing review and approval by the IRB has occurred. The IRB will document why the lapse in IRB approval occurred, and, if appropriate, any corrective actions that the investigator, institution, or IRB is taking to prevent any such lapse of approval of the project from occurring.
d. When IRB approval of ongoing research project lapses and the IRB subsequently re-approves the research project, the IRB may approve the project for one year and establish a new anniversary date for the expiration date of subsequent approval periods.
e. The Submission Form for Continuing Review (attachment) will be reviewed at the appropriate level (expedited or full review). Typically, studies are reviewed at the same level for continuing review as for initial review. For studies originally reviewed by the full Board, the PI will submit 2 copies and one original of the submission form for continuing view, the current informed consent and any newly proposed consent document and the complete protocol including any

modifications previously approved by the IRB.. In some instances, continuing review of full reviewed protocols may be conducted at the expedited level; however, this will be determined by the IRB office in keeping with the expedited categories enumerated by the OHRP and FDA. The policy Level of Review and Decision describes the situations in which a renewal/revision of a study, initially receiving Full Review, qualifies for an expedited approval. For studies involving FDA regulated products, if there is a sponsor protocol and/or clinical investigator brochure then the investigator must submit three copies of the current document(s) for distribution as follows: the IRB Chair, the IRB Director and the study file The sponsor protocol and/or the clinical investigator brochure will be made available to the members of the adverse events subcommittee and the lead reviewer(s) via the password protected area of the IRB website or an equally secure area.

f. In circumstances where an IRB at a convened meeting approves a research study without any conditions, the effective date of IRB approval is the date of the convened meeting. The date by which the first continuing review must occur is one year following the day prior to the approval date of the research study unless it has been determined that continuing review should occur more frequently than on an annual basis

g. In circumstances where an IRB at a convened meeting approves a research study with conditions, the effective date of IRB approval is the date on which the IRB chairperson or any other individual(s) designated by the IRB chairperson has reviewed and accepted as satisfactory all changes to the protocol, consent forms, and any other responsive materials, required by the IRB from the investigator. The date by which the first continuing review must occur is one year following the day prior to the date on which the IRB chairperson or any other individual(s) designated by the IRB has determined that the conditions of approval have been satisfied unless it has been determined that continuing review should occur more frequently than on an annual basis.

h. For all subsequent continuing reviews of a research study, the date of the convened IRB meeting when the IRB conducts continuing review and approves the study (with or without conditions) determines the latest permissible date of the next continuing review.

i. The effective date of IRB approval and the date by which the continuing review must occur is communicated to the Principal Investigator in his/her approval memo which is delivered electronically.

j. The PI and Center Representative are notified in writing by electronic mail. Additionally, in the case of student investigators, faculty sponsors are also included in the electronic communication.

k. The IRB maintains all records of continuing review within the respective protocol's file. For continuing review conducted at convened meetings, the minutes also reflect any discussions related to the continuing review process and list the items submitted for review by the investigator or his/her staff.

2. For audits of research:

a. The university will contact the PI in writing to request delivery of research records within thirty (30) days to the Institutional Official (IO).
Audits may also be conducted at the research site to determine adherence to the study procedures as outlined in the approved IRB submission. On-site audits may be conducted by voting members, members, alternate members, and designated IRB staff.

b. Studies that have been concluded may also be reviewed by the institution, IRB, or governmental agencies, and as a result the investigator should retain research-related (including informed consent) documents for a minimum of three years from the date the study was concluded or in the case of funded research, the time specified in the award document if longer than three years. For multi-site studies, researchers are reminded that the date of conclusion of the study is the date when the sponsor closes the research and/or the last research site had concluded research activity—not the date research activities ended at the local site.

c. Informed consent documents must state that the university, the IRB, and regulatory agencies are permitted to review research records which may contain personal/confidential information.

d. Researchers may be asked to meet with the individuals conducting the audit. Prior to submitting the audit report to theIO, feedback will be solicited from the researchers.

e. At the conclusion of the audit, the final report will be reviewed by the convened IRB and submitted to the IO.

Attachment

NSU-IRB Submission Form for Continuing Review of IRB Approved Studies

Version: 01/29/2013

Instructions: In order to comply with federal regulations requiring **continuing review,** as well as to conform to guidelines of the university's Institutional Review Board (IRB), the principal investigator is required to complete all of the following items for projects that will continue beyond the period of approval granted by the IRB. Continuation of a study includes data analysis, even if no further subject interaction occurs. Investigators are advised to submit this form and all necessary documents at least three months before the expiration date of the study's approval. For further information, refer to the *Monitoring of Approved Research, Approval Duration, and Continuing Review* policy available on the IRB Web site (http://www.nova.edu/irb/manual/policies.html). Please contact your center representative for information regarding submitting this form. This form should be sent directly to the IRB Office at NSU, Office of Grants and Contracts, 3301 College Avenue, Fort Lauderdale, FL 33314, ATTN: IRB.

Please download this document and fill in the BLUE sections using a word processor. You may expand the size of sections if needed to answer the questions. Do not be concerned about where page breaks fall. Fill in all questions; if not applicable, write NA.

I. General Information
Project Title
Insert Principal Investigator's (PI) Last Name and Date of Submission in the footer.

IRB Protocol #	Initial IRB Approval Date
Previous Reapproval Date(s)	Current Continuing Review Due Date

II. Principal Investigator (PI) Information			
Name		Relationship to NSU (Check Applicable)	
Mailing Address (for students)		Faculty	
		Staff	
		Student	
Daytime Phone		NSU Center/College/Dept	
Alternate Phone			
NSU Email Address			
Alternate Email Address		PI CITI Completion Date*	
Principal Investigator's Signature: _____ Date: _____			

III. Co-Investigators (Co-I) Information (including faculty advisers)

	Co-Investigator 1	Co-Investigator 2	Co-Investigator 3
Name			
Mailing Address			
Contact Phone Number			
Email Address			
Degree/Academic Information:			
CITI Completion Date*			

If the PI is a student, the thesis adviser/dissertation chair must also sign this form.

Chair/Adviser's Signature: _____ Date: _____

IV. Research Assistant Information (if applicable)

	Research Assistant 1	Research Assistant 2	Research Assistant 3
Name			
Mailing Address			
Phone Number			
Email Address			
CITI Completion Date*			

*NOTE: CITI must have been completed by all investigators and research assistants within the last 3 years. If a member of the research team is affiliated with another institution, please include a copy of that individual's training certification.

V. Management of Conflict of Interest

Read the financial conflict of interest policy at http://www.nova.edu/irb/manual/forms/significant-financial-interest.pdf

I certify that I, as PI, have read this policy, and have verified that my co-investigators and research assistants also have read this policy.

PI Initials	

For studies that are funded by a governmental agency (any federal, state or local governmental entity that has promulgated regulations or policies requiring investigator financial disclosure or requiring institutional conflict of interest policies relating to award of grants or contracts) read the Office of Sponsored Research's Financial Conflicts of Interest policy.

I certify that I, as PI, have read these guidelines, and have verified that my co-investigators and research assistants also have read these guidelines.

PI Initials	

Do any investigators have a significant financial interest (as defined by the above referenced policy) in relation to this study?

Yes	No
☐	☐

If yes, please describe the nature of the conflict of interest below

VI. Status of the Research

If the study's last approval was a continuing review for data analysis only and no other amendments have since been approved, please skip to section XV.

Please provide a summary of the methods and procedures of the study.

Please describe any changes to the risks or benefits associated with the study.

Has there been any lapse in IRB approval for this study? Yes ☐ No ☐

If yes, please describe the reason for this lapse in approval

VII. Subject/Participant Information and Study Timelines

Types of Subjects/Participants (complete all that apply)							
	Fetus/ abortuses	Newborns/ Infants	Children (2-7)	Children (8-12)	Adolescents (13-17)	Adults (18+)	Pregnant Women
Total # Originally Approved							
# Entered in Study to Date*							
# Of Screen Failures**							
# Completing Study to Date							
# Who Withdrew							
# Currently Active							
# to Enroll in the Future***							

*By Entered the IRB means any subjects who consented to participate in the study and began study activities.
**By Screen Failure the IRB means individuals who signed the consent form, but later proved not to qualify for the study during screening procedures.
***Please remember that your future number of subjects cannot exceed the total number of subjects originally approved by the IRB. If you need to exceed that number, please submit an amendment as well.

Subject Selection Information

	Subjects by Gender	Subjects by Race						Hispanic or Latino
	Gender	White	Black or African American	Asian	American Indian or Alaska Native	Native Hawaiian	Other Pacific Islander	If any of the individuals listed to the left also identify themselves as Hispanic or Latino please provide that information here.
# Recruited for the Study								
# Actually Entered into the Study*								

If the design of your study did not allow you to collect this information, please describe how you assured equitable subject selection.

*By Entered the IRB means any subjects who consented to participate in the study and began study activities.

Please provide a detailed description as to why the subjects withdrew or were withdrawn.

Anticipated end date of subject recruitment	
Anticipated end date of subject participation	
Anticipated end date of data analysis and interpretation	

VIII. Changes

Please describe below any substantive amendments since the protocol was initially and approved by the IRB.

IX. Summary of Results to Date

Please describe significant findings to date in the box below.

X. Participant Complaints

Were there any complaints from subjects? Yes ☐ No ☐

If "Yes," please provide a detailed description of the subjects' complaint(s). If more than one subject complained, please provide the information by subject. For example, "Subject 1: Nature of complaint. Nature of resolution."

Is this study multi-site? Yes ☐ No ☐

If "Yes," please attach any related reports from the other sites.

XI. Unanticipated Problems/Adverse Events

List ALL adverse events or unanticipated problems (for multi-center studies, from NSU researchers only) and their resolution. (If none, state none). Attach copies of all adverse reaction reports, even if previously reported.

Unexpected/Adverse Reaction and Resolutions

Do the results of the study to date suggest that the study risks differ from what was originally described in the research submission? Yes ☐ No ☐

If "Yes," please describe.

XII. Consent Forms

Are you seeking approval to continue to enroll new subjects? Yes ☐ No ☐

If "Yes," then please review and complete the following.

ATTACH CURRENT CONSENT FORM(S) (STAMPED)
ATTACH CLEAN CONSENT FORM(S) FOR STAMPING

Please see http://www.nova.edu/irb/manual/forms.html for instructions regarding consent forms.

Please note: If your study also requires changes/amendments please use the NSU-IRB Submission Form for Amendment of IRB Approved Studies. Amendments include, but are not limited to, changes in funding source, number of subjects to be enrolled, methods, procedures, or the content of the consent documents or recruitment materials.

If you will not be enrolling new subjects, only provide a copy of the current consent form(s).
If you have completed all work with human subjects and your submission for continuing review involves data analysis only, you are not required to submit a copy of the consent form(s).

As IRB and legal requirements continually evolve, all consent forms must be reviewed using current IRB guidelines as found on the IRB website. Have you reviewed and confirmed that the attached consent forms have been modified as necessary to meet current IRB guidelines.

Yes ☐ No ☐

If "No," please explain (e.g., requirement of grantor, the study is conducted at another site and their consent forms are used, or other reason).

Did the consent forms require translation?

Yes ☐ No ☐

If "Yes," please attach the original English version along with all translations, and submit the consent forms to be used during the study continuation.
If you have completed all work with human subjects and your submission for continuing review involves data analysis only, you are not required to submit a copy of the translated consent forms.

Were subjects enrolled whose primary language was not English?

Yes ☐ No ☐

If "Yes," and consent forms were not translated into that language, please explain how it was determined that subjects could understand the informed consent process and form.

XIII. Recruitment Materials

Are you continuing to recruit subjects?	Yes ☐ No ☐
Are you using flyers or other recruitment materials to continue to recruit?	Yes ☐ No ☐

Please attach the most current recruitment materials. Please include a copy of the previously approved (and stamped) materials and a clean unstamped version.
If you have completed all work with human subjects and your submission for continuing review involves data analysis only, you are not required to submit a copy of the recruitment materials.

XIV. Research Protocol

If your study was approved at the expedited level, you must submit a copy of the complete protocol including any modifications previously approved by the IRB incorporated into the protocol. It is recommended that you also include a brief overview of the amendments approved.

If your study was approved at the full review, you must submit 23 copies and one original of the complete protocol including any modifications previously approved by the IRB incorporated into the protocol. It is recommended that you also include a brief overview of the amendments approved.

If you have completed all work with human subjects and your submission for continuing review involves data analysis only, you are not required to submit a copy of the complete protocol.

XV. Data Analysis Only

Complete this section if the study's last approval was a continuing review for data analysis only AND no other amendments were submitted.

Anticipated end date of data analysis and interpretation

Summary of Results to Date
Please describe significant findings to date in the box below.

List any adverse events, unanticipated problems (for multi-center studies, from NSU researchers only), and subject complaints that occurred in the past year. In addition, state their resolution. (If none, state none). Attach copies of all adverse reaction reports for the past year, even if previously reported.

Unexpected/Adverse Reaction/subject complaint and Resolutions

Has there been any lapse in IRB approval for this study? Yes ☐ No ☐

If yes, please describe the reason for this lapse in approval