

SOP: 301
RESEARCH SUBMISSION REQUIREMENTS

1. POLICY

IRB members often rely solely on the documentation submitted by Investigators for initial and continuing review. Therefore, this material must provide IRB members with enough information about a study to assess whether it adequately meets the IRB's criteria for approval.

All materials submitted to the IRB for review must include the appropriate documentation and information necessary for adequate review. IRB staff will be responsible to check each submission for the appropriate materials.

Specific Policies

1.1 Submission Requirements for Initial Review of a New Research Project

1.1.1 Investigators applying for initial approval of a proposed biomedical or social behavioral research protocol must submit:

- IRB Application Form signed and dated by the Investigator
- Research Protocol: Investigators are encouraged to use the Research Protocol Outline for investigator-initiated studies.
- Informed consent document or waiver of informed consent document indicated on the IRB application.

1.1.2 Additional required items if applicable:

- Investigator Brochure or device specifications (if study involves an investigational drug or device)
- Questionnaires and assessment instruments
- Recruitment advertising materials
- Copy of the grant (required for federal granting agencies)
- Participant Study Instructions or Participant Diary
- Documentation that the study has been reviewed and approved by other committees charged with oversight of research at the University or at outside sites
- Documentation that the study has been reviewed and approved by the Cancer Center Scientific Review Committee
- HIPAA Authorization or Waiver of Authorization, if applicable
- The DHHS-approved sample consent document (when one exists)
- The complete DHHS-approved protocol (when one exists)

1.2 Submission Requirements for Continuing Review

Investigators requesting renewal of an approved research project must submit:

- Completed Application for Continuing Review

- Additional documents specified on the Continuing Review Application

Submissions must be received by:

HSC Campus: Seventy-five (75) calendar days before the IRB approval expiration date.

Norman Campus: Forty-five (45) calendar days before the IRB approval expiration date.

For specific policy details, see SOP 404, Continuing Review.

1.3 Submission Requirements for Amendments to Currently Approved Research Projects

Investigators requesting approval of revisions to previously-approved research projects must submit:

- Completed Protocol Modification Form indicating revisions, signed by the Investigator
- Copies of all documents being revised with changes indicated. (i.e., protocol, informed consent document, advertisement)

For specific policy details, see SOP 405, Amendments.

1.4 Submission Requirements for Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations

Investigators informing the IRB of Unanticipated Problems Involving Risks to Participants or Others and/or Protocol Deviations must submit:

- Unanticipated Problem Report Form must be completed, signed, and dated by the investigator.
- Protocol Deviation Report Form must be completed, signed, and dated by the investigator.
- For specific policy details, see SOP 407, Unanticipated Problems Involving Risks to Participants and Others and Protocol Deviations.

1.5 Action Taken If Documentation is Not Adequate or Additional Information is Required

If the IRB or IRB staff determines that the submitted documents are not adequate, Investigators may be required to submit additional information, or the Investigator may be required to answer questions or explain the details of the study in person to the IRB. The IRB will not review incomplete submissions.

1.6 IRB Submission Forms

All IRB forms can be accessed from the respective IRB websites. The IRB forms shall not be altered by the Investigator or member of the research team.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. RESPONSIBILITY

The HRPP Director or designee is responsible for maintaining current research project submission requirements for interested Investigators and for preliminary review of non-routine submissions.

The IRB Administrator is responsible for reviewing the submission materials for completeness and preparing review materials for members.

The IRB Administrator is responsible for receipt, tracking, and acknowledgement of all correspondence to and from Investigators.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.115

21 CFR 56.108 (a)

21 CFR 312, 812

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 404, Continuing Review

SOP 405, Amendments

SOP 406, Determination of Human Research

SOP 407, Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations.

6. ATTACHMENTS

301-A Application for New Research Project

301-A-1 Institutional Review Board Application-Norman Campus

301-A-4 Description of Study Protocol-Norman Campus

301-A-5 International Research Review Form–Norman Campus

301-A-2 FDA IND Worksheet

301-A-3 FDA IDE Worksheet

301-B Application for Continuing Review or Final Closure Report

301-B-1 Continuing Review of Approved Research

301-C Protocol Modification Form

301-C-1 Request for Modification of Approved Research

301-D Research Protocol Outline

301-E Report of Emergency Use of a Test Article

407-A Unanticipated Problem Report Form

407-A-1 IRB Form for Reporting Unanticipated Problems in Human Subjects

407-B Protocol Deviation Report Form

407-B-1 Protocol Deviation Report Form-NC

7. PROCESS OVERVIEW

7.1 Submission of a New Research Project

- 7.1.1 Upon receipt of a New Research Project, IRB Staff review the submission for completeness of required documents and confirm education requirement status of key personnel.
- 7.1.2 Investigator will be notified if education requirements are incomplete. See SOP 102B, Key Personnel Education for specific education requirements.

The IRB does not accept for review a study submitted by an investigator who has not completed the HRPP education. The Investigator is notified and the study is not processed.
- 7.1.3 The receipt of a New Research Project submission is recorded in the database, assigned to an appropriate IRB, and forwarded to IRB staff to make a preliminary determination regarding whether the information and materials submitted by the Investigator present an adequate description of the proposed research.
- 7.1.4 The IRB Administrator evaluates claims for exemption from IRB review and presents the study to the IRB Chair or designee for review and final determination.
- 7.1.5 The IRB Administrator evaluates submissions that fit the requirements for expedited review and presents the study to the IRB Chair or designee for review and final determination.
- 7.1.6 Studies that involve more than minimal risk are forwarded for convened IRB review.
- 7.1.7 The IRB Administrator reviews the consent form for inclusion of required elements.
- 7.1.8 The IRB Administrator adds the new study submission for convened IRB review to the next appropriate agenda.
- 7.1.9 If the documents submitted for initial review are not adequate, a pre-review letter or email is sent to the Investigator describing the required additional information. It may also be determined that the Investigator may be required to attend the IRB meeting to answer questions or explain the details of the study.

7.2 Submission of a Continuing Review, Amendment, Unanticipated Problem Involving Risks to Participants or Others and Protocol Deviations

- 7.2.1 Submission materials for Continuing Reviews, Amendments, Unanticipated Problems Involving Risks to Participants or Others, and Protocol Deviations must provide IRB members with enough information

for them to assess whether the submission adequately meets the IRB's criteria for continuation of study approval.

- 7.2.2 For Continuing Reviews, Amendments, Unanticipated Problems Involving Risks to Participants or Others, and Protocol Deviations, the receipt of each item of the submission is recorded in the database and forwarded to the appropriate IRB Administrator for processing.
- 7.2.3 Before a Continuing Review is scheduled for IRB review, the IRB Administrator conducts a preliminary review to determine if information and materials submitted by the Investigator present an adequate description of the proposed research. If deficiencies are noted, the IRB Administrator contacts the Investigator for resolution.
- 7.2.4 The IRB Administrator evaluates Continuing Reviews that fit the requirements for expedited review and presents the study to the IRB Chair for review and final determination.
- 7.2.5 The IRB Administrator evaluates Continuing Reviews that fit the requirements for convened Board review and adds the item to the next appropriate agenda.
- 7.2.6 Unanticipated Problems Involving Risks to Participants or Others and Protocol Deviations are reviewed and evaluated by the IRB Chair to determine if they should be reviewed by expedited procedure or reviewed by a convened Board.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012