SOP 301: Research Submission Requirements

1. POLICY

IRB members rely on the documentation submitted by Investigators to review all submissions. Therefore, this material must provide IRB reviewers with enough information about a research project for them to assess whether it adequately meets the IRB's criteria for approval. All IRB submissions must include the appropriate documentation and information to be forwarded to the appropriate Board for review.

Specific Policies

1.1 Each IRB submission will include a combination of IRB forms generated by the electronic information system and uploaded documents the research team has created using IRB-provided templates. There are other documents that the research team may create, or that the research team must secure from another person or organization, that are required for the IRB review of the submission. These may include the following, as applicable:

- Investigator’s Brochure or device specifications (if research project involves an investigational drug or device)
- Data collection instruments (for example: questionnaires, surveys, assessments, field observation forms, chart/records abstracting forms)
- Recruitment and/or advertising materials
- Copy of the grant (required for projects with external funding)
- Participant Study Instructions or Participant Diary
- Documentation that the research project has been or will be reviewed by other committees charged with oversight of research at the University or at outside sites, such as Radiation Safety or Institutional Biosafety Committee
- Documentation that the research project has been approved by the Cancer Center Scientific Review Committee
- HIPAA Authorization or Waiver of Authorization form
- The DHHS-approved sample consent document
- The complete DHHS-approved protocol
- Letters of Support from external research project sites
- Documentation of approval from external IRBs
- Curriculum vitae of Non-OU investigators (NC only)

1.1.1 Certificates of Confidentiality: Some research projects may require that the investigator obtain a certificate of confidentiality to protect the privacy of research participants. Investigators generally may not be compelled to release data covered by a certificate of confidentiality in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings.

Even though a Certificate of Confidentiality has been issued by a federal agency, Oklahoma law may require disclosure of certain information, such as child abuse or intent to harm self or others. In these situations,
additional information to advise research participants of the legal reporting obligations of the members of the research team is included in the Informed Consent Documents.

Investigators may obtain certificates of confidentiality only if a determination is made by the investigator, the IRB, or the research sponsor that the research is of such a sensitive nature that protection is necessary to perform the research.

OHRP has determined that research may be considered sensitive if it involves the collection of any of the following types of information:

- Information related to sexual attitudes, preferences, or practices
- Information related to the use of alcohol, drugs, or other addictive substances
- Information pertaining to illegal conduct
- Information that if released, could reasonably be damaging to an individual's financial standing, employability, or reputation in the community
- Information that would normally be recorded in the patient’s medical record, the disclosure of which could reasonably lead to social stigmatization or discrimination
- Information pertaining to psychological well being or mental health
- Genetic information

Other Federal agencies may evaluate IRB research projects for certificates of confidentiality using different criteria.

OHRP does not issue Certificates of Confidentiality. The NIH and other federal agencies issue these to protect identifiable information from forced or compelled disclosures.

The IRB website provides additional information on how Investigators can obtain a Certificate of Confidentiality. In the IRB submission, the investigator will indicate that a Certificate of Confidentiality is needed. The IRB will hold the official approval letter but will issue a contingent approval letter for the research project in order for the investigator to obtain the Certificate of Confidentiality. However, no research activities can begin until the Certificate of Confidentiality is received by the IRB. At this time, the IRB will release the research project approval letter and stamped consent documents to the investigator.

**1.2 Submission Requirements for Review of a New Research Project**

1.2.1 Investigators applying for approval of a new research project must complete and submit the Study Application and IRB submission materials through the IRB’s electronic information system and upload all related research project documents. At a minimum, the following documents must be included with the IRB submission:
• Protocol- (Investigators are encouraged to use the Research Protocol Outline (HSC) or Research Protocol Form (NC) available from the IRB website for investigator-initiated studies).

• Informed consent documents or information supporting a request for waiver of informed consent.

• Norman Campus – Student as Principal Investigator form approved by the designated Faculty Sponsor for graduate student who wishes to serve as Principal Investigator.

• Norman Campus – Staff as Principal Investigator form approved by the designated Supervisor for the staff member who wishes to serve as Principal Investigator.

1.3 Submission Requirements for Continuing Review

Investigators requesting renewal of an approved research project must complete and submit the Continuing Review/Final Report form in the IRB’s electronic information system and must upload all related research project documents specified on the Continuing Review/Final Report form.

Investigators will be notified electronically that a Continuing Review/Final Report must be received by the specified date to allow sufficient time for IRB review.

For specific details, see SOP 404: Continuing Review.

1.4 Submission Requirements for Modifications to Currently Approved Research Projects

Investigators requesting modifications to previously-approved research projects must 1) complete and submit the Modification/Notification form in the electronic information system 2) upload the additional documents specified on the Modification/Notification form, and 3) upload all related research project documents. When uploading these documents, the Investigator shall provide updated versions with the modifications noted using the track changes function to highlight the investigator-requested changes (i.e., protocol, informed consent documents, recruitment flyers, data collection instruments).

For specific policy details, see SOP 405: Modifications

1.5 Submission Requirements for Continuing Review with Modifications

Investigators requesting modifications at the time of renewal of an approved research project must complete and submit the Continuing Review form in the IRB’s electronic information system. In addition, investigators must upload the additional documents specified on the Continuing Review form and all related research project documents. When uploading these documents, the Investigator shall provide updated versions with the modifications noted using the track changes function to highlight the investigator requested changes (i.e., protocol, informed consent documents, recruitment flyers, data collection instruments).

For specific policy details, see SOP 404: Continuing Review, and SOP 405: Modifications

1.6 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 complete and submit the Unanticipated Problem Report and/or Protocol Deviation/Violation Report forms in the electronic information system. In addition, investigators must upload relevant supporting documents.

For specific policy details, see SOP 407: Protocol Deviations and Unanticipated Problems.

1.7 Submission Requirements for Human Research Determinations

Investigators requesting an IRB review to determine if proposed research does constitute human participant research must complete and submit the Determination of Human Research worksheet in the IRB’s electronic information system. In addition, investigators must upload relevant supporting documents.

For specific policy details, see SOP 406: Determination of Human Research and Protocol Development.

1.8 Submission Requirements for Protocol Development (Norman Campus only)

Norman Campus Investigators who will need evidence of IRB review of research protocols in order to have external funding released from ORS for research activities must complete and submit the Norman Campus Protocol Development form in the IRB’s electronic information system. In addition, investigators must upload relevant supporting documents.

For specific policy details, see SOP 406: Determination of Human Research and Protocol Development.

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

If the IRB, IRB reviewer, or IRB staff determines that the submitted documents are not adequate, Investigators may be required to submit additional documents or may be required to answer questions or explain the details of the research project to the IRB. The IRB will not review incomplete submissions.

All IRB forms can be accessed in the IRB’s electronic information system. Templates for many of the supporting documents are available on the respective campus IRB websites. The Investigator or members of the research team shall not alter the IRB forms.

2. SCOPE

This SOP applies to all research projects submitted to the IRB.

3. RESPONSIBILITY

The HRPP Director or designee is responsible for maintaining research project submission requirements.

The IRB Administrator is responsible for conducting the pre-review and assigning the submission to the IRB reviewer for evaluation.
The IRB Administrator is responsible for documenting in the IRB’s electronic information system any investigator communication that occurs outside of the electronic information system.

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 102b: Key Personnel Education
- SOP 404: Continuing Review
- SOP 405: Modifications
- SOP 406: Determination of Human Research and Protocol Development
- SOP 407: Protocol Deviations and Unanticipated Problems

6. ATTACHMENTS

- 301-A-1 Research Protocol Outline (HSC)
- 301-A-2 Protocol Description Form (NC)
- 301-B Continuing Review/Final Report
- 301-C Modification/Notification
- 407-A Unanticipated Problem Report
- 407-B Protocol Deviation/Violation Report
- 501-A Determination of Human Research Determination and Protocol Development
- 502-B Protocol Development

7. PROCESS OVERVIEW

7.1 Submission of a New Research Project

7.1.1 Upon receipt of a new submission, IRB Staff review the submission to make sure required documents have been submitted and to confirm that key personnel have met all education requirements.

7.1.2 The IRB Staff will notify the Investigator if additional documents are required or education requirements are incomplete for any key personnel. See SOP 102B: Key Personnel Education, for specific education requirements.

The IRB will not accept a new research project submission until required documents are submitted and all key personnel have completed the HRPP education.

7.1.3 Once the education requirements are met, the IRB Staff assigns the new research project submission to an appropriate IRB and forwards to the
IRB Administrator for pre-review to determine whether the information and materials submitted by the Investigator contain an adequate description of the proposed research. The IRB Administrator reviews the consent documents for inclusion of required elements. If deficiencies are noted, the IRB Administrator contacts the Investigator for resolution.

7.1.4 The IRB Administrator evaluates the research project to determine if it will require IRB review, and, when appropriate, posts the research project to the next appropriate IRB meeting agenda.

7.15 The IRB Administrator assigns all other new submissions to the IRB Chair or IRB designee for review.

7.1.6 If the documents submitted for IRB review are not adequate, stipulations will be sent to the Investigator describing required changes or requesting additional information. The IRB reviewer may also request that the Investigator attend the IRB meeting to answer questions or to explain the details of the research project.

7.2 Submission of a Continuing Review, Modification, Protocol Deviations, Unanticipated Problems

7.2.1 Submission materials for Continuing Review, Modification, Reporting Unanticipated Problems Involving Risks to Participants or Others, and Protocol Deviations must provide the IRB with enough information for the IRB to approve continuation of the research project.

IRB Staff will review submissions for Continuing Review and Modification to confirm the education requirement for key personnel has been met.

7.2.2 The IRB Staff will notify the Investigator if additional documents are required or education requirements are incomplete for any key personnel. See SOP 102B: Key Personnel Education, for specific education requirements.

7.2.3 Once the education requirements are met, the IRB Staff assigns the submission to the appropriate IRB Administrator for processing.

7.2.4 The IRB Administrator conducts a pre-review to determine whether the information and materials submitted by the Investigator provide adequate information and documentation for IRB review. If deficiencies are noted, the IRB Administrator contacts the Investigator for resolution.

7.2.5 The IRB Administrator evaluates the research project to determine if it will require convened IRB review, and, when appropriate, posts the research project to the next appropriate IRB meeting agenda.

7.2.6 The IRB Administrator assigns all other submissions to the IRB Chair or IRB designee for review.

7.2.7 If the documents submitted for IRB review are not adequate, stipulations will be sent to the Investigator describing required changes or requesting additional information. The IRB reviewer may also request that the Investigator attend the IRB meeting to answer questions or to explain the details of the research project.
7.3 Human Research Determination

7.3.1 Upon receipt of a Human Research Determination request, IRB Staff review the submission and assign to an IRB Chair or IRB designee to make a determination.

7.3.2 If the documents submitted for IRB review are not adequate, stipulations will be sent to the Investigator describing required changes or requesting additional information.

APPROVED BY:________________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016