1. POLICY

All research projects that include human participants must meet the criteria specified in Section 1.1 below. These criteria are based on the principles of respect for persons, beneficence, and justice, as discussed in the Belmont Report. In addition, certain other criteria that are unique to the University of Oklahoma may apply and must be met when applicable.

No investigator has a right to conduct research within the University. Rather, it is a privilege granted by society as a whole and the Board of Regents of the University of Oklahoma in particular.

The IRB shall evaluate each project on an individual basis in order to assess whether the investigator is providing adequate resources to protect the participant. Such resources may include research staff, social support services, counseling, ancillary care, equipment, and training provided by the investigator to external or internal entities involved in the research project.

This evaluation shall be based on the investigator’s initial IRB submission, which includes the protocol, outside IRB approval letters, letters of support, advertisements, and all other supporting documents. The IRB shall consult the investigator for additional information regarding necessary services.

The IRB will systematically review the IRB submission, research protocol, consent document, and the HIPAA documents that address the proposed arrangement for protecting privacy and confidentiality of research participants and their information during and after the conduct of the research.

The IRB will also systematically review the IRB submission, research protocol, consent documents, and the HIPAA documents that address the proposed arrangement for storage of identifiable data during and after the conclusion of the research project.

Specific Policies

1.1 Minimal Criteria for Approval of Research

In order for a human research project to be approved, the IRB must find that:

A. Risks to participants are minimized:
   - By using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and
   - Whenever appropriate, by using procedures already being performed by or on the participants for diagnostic or treatment purposes.

B. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and to the importance of the knowledge that may be expected to result.

In evaluating risks and benefits, the IRB shall consider those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that participants would receive even if not participating in the research).

C. Selection of participants is equitable:
The IRB shall take into account the purpose(s) of the research, the setting in which the research will be conducted, and the inclusion/exclusion criteria so that fair and equitable burdens and benefits are maximized. The IRB shall evaluate the recruitment and enrollment practices and the amount and timing of any payments to participants. The IRB should also be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

D. The investigator will obtain informed consent/assent from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by appropriate local, state, and federal laws and regulations.

E. Informed consent/assent will be appropriately documented or appropriately waived as required by local, state, and federal laws and regulations.

F. If the protocol is more than minimal risk, the research plan includes adequate provisions for monitoring the data collected to protect participants.

G. Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of identifiable data.

H. When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, or participants enrolled at international sites, additional safeguards have been included in the research project and in the IRB review process to protect the rights and welfare of these participants.

1.2 Other Criteria

The IRB will review the plan for data and safety monitoring when the protocol is submitted for initial review. The investigator is required to provide a Data and Safety Monitoring Board (DSMB) report at the time of continuing review or as available for studies that are overseen by a DSMB. The IRB may suggest a data safety monitoring plan (DSMP) to the investigator, if applicable, to protect participants.

The IRB shall determine the time period for continuing review of research projects at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. Additional guidelines for Continuing Review can be found in SOP 404: Continuing Review.

For VA Research:
The IRB has the option to require the medical record be flagged to protect the participant's safety by indicating participation in the research project and the source of more information on the research project. Additional guidelines for initial review of research projects involving the VA can be found in SOP 603A: Veterans Affairs Health Care System.

1.3 Reliance on Other IRBs for Review and Approval of Research Conducted at the University of Oklahoma.

For collaborative research projects that involve investigators who are not affiliated with the University of Oklahoma, the IRB may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon modification of the institutional Federal-wide Assurance agreements (FWAs).
Guidelines for determining the IRB of record can be found in SOP 602J: Use of Single IRB (sIRB) in Multicenter Research.

1.4 Reciprocal Review and Approval of Research Conducted at One of the University of Oklahoma Campuses.

When a human research project involves both University campuses, a reviewing campus shall be designated in accordance with SOP 602G: Determination of Reviewing OU Campus IRB.

1.5 Review of Research Conducted by Persons with University of Oklahoma Appointments at Non-University Facilities.

Human research carried out by persons with University of Oklahoma affiliations impacts the University, even if the research is not conducted at University facilities. Any individual who has a University appointment, whether full- or part-time, salaried or voluntary, staff or faculty, is required to notify the appropriate IRB of his/her plans to conduct human participant research, regardless of location of the research. The IRB Chair or IRB designee shall review such proposed activities and determine whether the rights and safety of the participants have been adequately considered by another IRB. If no IRB review has taken place, or if the IRB Chair or IRB designee has sufficient concerns about the research project, the research shall not proceed until those concerns have been adequately addressed by the IRB Chair or the convened IRB (per SOP 801: Investigator Qualifications and Responsibilities) or review by another IRB has occurred.

1.6 Length of Approval Period

The approval period for research is based on the date of the convened meeting at which the IRB approved the protocol or approved the research with modifications. When continuing review is required by law or regulations, length of IRB approval period is typically one year. However, the IRB may require more frequent reviews.

A. If any of the following are true, the IRB will require review more often than annually:
   • There is a high degree of risk to the participant.
   • The stage of the research is such that many of the risks are unknown.
   • Any other reason an IRB member believes that warrants more frequent review.

B. The IRB will consider review of research more often than annually when any of the following are true:
   • Proposed procedures have not been used in humans.
   • The nature of and any risks posed by the clinical investigation.
   • The degree of uncertainty regarding the risks involved.
   • More than minimal risk to special populations exists, with no prospect of direct benefit.
   • A high likelihood exists that participants will die due to the research procedures.
   • The vulnerability of the participants.
   • The experience of the clinical investigator in conducting clinical research.
• The IRB’s previous experience with the researcher or sponsor (e.g. compliance history, previous problems with the researcher obtaining informed consent, prior complaints from participants about the researcher).
• The projected rate of enrollment.
• Whether the study involves novel therapies.
• Any other reason for which the IRB requests closer monitoring.

1.7 Scientific Review
The IRB shall evaluate proposed research for scientific and scholarly validity. The scientific/scholarly review is documented on the Reviewer Checklist. The IRB shall evaluate the following:
• Whether the research uses procedures consistent with sound research design and that do not unnecessarily expose participants to risk.
• Whether the research is designed to answer the proposed question.
• The importance of the knowledge reasonably expected to result from the research.

1.8 Multi-Site Management of Research
Refer to SOP 801: Investigator Qualifications and Responsibilities, Section 1.5, for information regarding multi-site management of research projects.

1.9 Pre-review of Research
The IRB may elect to conduct a pre-review of research prior to review at the convened meeting. All changes resulting from this pre-review may be reviewed and approved by the convened IRB.

1.10 Transfer of Research
The investigator must submit human participant research for IRB review and approval when transferring research from another institution to the University. The research submission shall include all the documents reviewed by the original IRB. Note: The research is considered ongoing if the investigator is in the process of data analysis, and this activity requires IRB approval.

The investigator is responsible for obtaining a memorandum of understanding or other similar agreement from the transferring institution allowing the investigator to remove the data and any source documents from the previous institution and continue the research at OU.

2. SCOPE
This SOP applies to all IRB staff and IRB members and to researchers submitting protocols to the IRB.

3. RESPONSIBILITY
3.1 The IRB Administrator is responsible for initial identification of submissions that may qualify for review by the convened IRB. The Administrator will coordinate with the IRB Chair or IRB designee to assign Primary and Secondary reviewers and forward these assignments to those reviewers to complete their reviews.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting one Primary and one Secondary
reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select Primary and Secondary reviewers with the relevant expertise, the IRB Chair or IRB designee shall defer the review to another IRB with Primary and Secondary reviewers with the relevant expertise, or obtain that expertise through a special consultant.

3.3 The IRB Chair or IRB designee and the IRB Administrator are responsible to check each item on the agenda to determine whether a special consultant is needed for additional expertise, such as scientific or scholarly expertise in a particular field, expertise regarding the local context, or knowledge or experience in working with special populations.

3.4 Primary and Secondary reviewers are responsible to conduct an in-depth review of all materials and present their findings at the convened IRB.

3.5 All other IRB members are responsible to review all provided materials in enough depth to be prepared to discuss the information at the convened meeting.

3.6 The HRPP Education Coordinator is responsible for the initial and continuing education of the IRB members.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111
21 CFR 56.108, 56.111
VHA Directive 1200.05

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 402: Expedited Review
SOP 404: Continuing Review
SOP 602G: Determination of Reviewing OU Campus IRB
SOP 602J: Use of Single IRB (sIRB) in Multicenter Research
SOP 603A: Veterans Affairs Health Care System
SOP 801: Investigator Qualifications and Responsibilities

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist

7. PROCESS OVERVIEW

7.1 The IRB Staff will verify that all necessary documents are received per SOP 301: Research Submission Requirements.

7.2 The IRB staff will conduct pre-review of the submission, assign the appropriate Board, and forward the item to the IRB Administrator for processing. The IRB Administrator will check the new research project submission for accuracy of information and to verify that all required documents are submitted. The staff will conduct an initial assessment of the research project to determine if the project requires review by expedited procedures or a convened IRB and will
either assign the project to the next appropriate agenda or to the IRB Chair or IRB designee for review.

7.3 The IRB Chair or IRB designee will review the content with respect to the risk/benefit analysis, research project design, selection of participants, and the inclusion of required elements in the informed consent according to applicable federal law and regulations, the Belmont Report, and applicable local and state requirements. If the research project requires convened IRB review, the IRB Chair or IRB designee will forward the submission to the IRB Administrator, who will assign the research project to the next appropriate IRB agenda.

7.4 The IRB Chair may require verification of information submitted by an investigator. This information may be obtained from third parties such as the sponsor, other institutions participating in the research, and other IRBs reviewing the research. The IRB Chair or IRB designee will document this verification in the IRB’s electronic information system.

7.5 Prior to the meeting, the IRB Chair will designate the Primary and Secondary reviewers for each submission on the agenda. The IRB Administrator will assign the Primary and Secondary reviewers which is reflected in the agenda.

7.6 The IRB Administrator will provide to IRB members the agenda and previous IRB meeting minutes prior to each convened IRB meeting.

7.7 The IRB Primary and Secondary reviewers will summarize their findings on the reviewer checklists provided in the electronic information system. All IRB members are encouraged to use the IRB’s electronic information system to provide information arising from their review of agenda items. The IRB reviewers will determine whether special considerations exist that may influence the review of a submission and whether evidence exists for third party verification of submitted information or is needed. The IRB reviewers will present a summary of findings and recommendations at the convened IRB meeting. The IRB Administrator will record the conclusions in the IRB meeting minutes.

7.8 All submissions eligible for expedited review shall follow the expedited review process outlined in SOP 402: Expedited Review.

7.9 For DOE research projects, the IRB Chair shall send a letter to the investigator indicating that the research has been approved in accordance with DOE expectations and will be monitored and tracked by the IRB.

APPROVED BY:________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020