1. POLICY

Each IRB shall be composed of members who are able to ascertain the acceptability of proposed human participant research in terms of University commitments (including policies and resources), regulations, applicable law, and standards of professional conduct and practice. Each IRB shall also be composed of members able to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

Each IRB shall consist of at least five regular voting members. Qualified persons from multiple professions shall be considered for membership. IRB membership shall not consist entirely of members of one profession. Each IRB has at least one member who represents the perspective of research participants.

The University shall make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise needed to conduct IRB functions.

Individuals who are responsible for University business development or raising funds or garnering support for research are prohibited from serving as IRB members and/or carrying out the day-to-day operations of the review process.

Specific Policies

1.1 Membership Selection Criteria

1.1.1 The members of the IRB shall be sufficiently qualified, through experience and expertise (professional competence), to review human research proposals in terms of regulations, applicable law, standards of professional conduct and practice, and University commitments. The IRB shall include persons knowledgeable in these areas.

The membership shall be diverse, so selection shall include consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience, and sensitivity to such issues as community attitudes to assess the human research submitted for review.

There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no affiliation with the University, either self or family member. For research involving an FDA-regulated article, at least one member who is a licensed physician must be included in the quorum.

1.1.2 VA Research

The HSC IRBs 1, 2, 3, and 4 have been designated as the IRBs of record for the Oklahoma City Veterans Affairs Medical Center. The HSC IRB 4 has been designated as the IRB of record for the Eastern Oklahoma VA Healthcare System (EOVAHCS), Muskogee, Oklahoma. The HSC IRB membership for IRBs 1, 2, 3, and 4 shall include two or more VA employees as voting members.

The Norman Campus IRB shall not review VA research.

The VA members shall serve as full members of the IRB and review both VA and non-VA research matters presented to the IRB. The members must hold a minimum of 1/8th VA-compensated appointment unless a waiver is obtained from the VA’s chief research and
development officer. Consideration will be given to including a veteran or veteran’s representative as an IRB member. At least one of the VA members of the IRB must have scientific expertise. Examples include, but are not limited to: physicians, dentists, nurses, pharmacists, social workers, other clinicians, statisticians, and allied health professionals. At least one VA voting member of the IRB must be in attendance when VA research is discussed at a convened meeting. Alternate members must have qualifications similar to the member they replace. Alternate members may not serve for a class of members (for example, a physician may not serve for all physician regular members, but must be designated to serve for a specific physician member). The individual the alternate is serving for must be referenced specifically by name, in the minutes and in the IRB roster.

VA Research and Development administration officials, including but not limited to the Associated Chief of Staff for Research and Development and the Administrative Officer for Research and Development, are prohibited from serving as voting members of the IRB.

The facility director, administrative staff, chief of staff, other senior administrators such as associate or assistant directors, and the chief nurse may observe meetings but may not serve as voting or non-voting members of the facility’s IRB. VA Research and Development office staff, including but not limited to the associate chief of staff for Research and Development, the administrative officer for Research and Development, and IRB administrative staff, may not serve as voting members of the IRB.

The facility director appoints the VA privacy officer and information security officer as non-voting members or consultants of the IRB or Research and Development committee.

The VA’s research compliance officer may serve as a non-voting consultant, as needed, to the VA facility’s IRB. The VA research compliance officer may not serve as a voting or non-voting member of the IRB. The VA research compliance officer may attend meetings of the IRB when requested by the IRB or as specified by local procedure.

Individuals working without compensation (WOC) appointments from the VA facility and those with intergovernmental personnel act (IPA) appointments cannot be VA representatives.

Veterans whose only relationship with the VA facility is receiving care at a VA facility or receiving benefits from the Veterans Benefits Administration are not considered to be affiliated for the purpose of being an IRB member. Individuals who perform occasional volunteer activities without compensation are not considered affiliated. However, those who hold a WOC appointment for volunteer activities other than IRB service are considered to be affiliated. Individuals who have retired from the VA and who are receiving VA retirement benefits are considered affiliated.

The non-affiliated voting member must be given a VA WOC appointment if the non-affiliated voting member is performing the duties and responsibilities of an IRB voting member.

Officials in Research and Development administration, including but not limited to the Associate Chief of Staff for Research and Development, the Administrative Officer for Research and Development, and IRB administrative staff, do not serve as voting members of the IRB.
1.2 Composition of the IRB

IRB members: The backgrounds of the IRB members shall be varied in order to promote complete and adequate reviews of the types of human participant research activities commonly reviewed by the IRB. Regular members shall include:

1.2.1 Nonaffiliated member(s): The nonaffiliated member(s), who can be either scientific or nonscientific reviewers, shall be knowledgeable about the local community and be willing to discuss issues and research from that perspective. The HRPP Director shall give consideration to recruiting individuals who speak for the communities from which the University will draw its human research participants. The nonaffiliated member(s) shall not be vulnerable to intimidation by the professionals on the IRB, and their services shall be fully utilized by the IRB.

1.2.2 Scientific members: Most IRBs include physicians and Ph.D. level physical, social, or biological scientists. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 45 CFR 46.107(f) and 21 CFR 56.107(f). When research involving an FDA-regulated article is reviewed, at least one member who is a licensed physician must be included in the quorum; therefore, at least one (1) member of each IRB shall be a physician licensed in the State of Oklahoma.

1.2.3 Nonscientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, at least one nonscientific member whose education, work, and interests are not solely in medical or scientific areas shall be on each IRB.

1.2.4 Representatives of special groups of research participants: The IRB may require members or consultants who are knowledgeable about the concerns of certain groups, especially those who are vulnerable to coercion or undue influence. For example, if an IRB reviews research involving prisoners, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group, must be included on the IRB.

1.2.5 IRB Chairs: The individual IRB Chairs shall be highly respected individuals from within or outside the University, fully capable of managing the IRB and the matters brought before it with fairness and impartiality.

1.2.6 Special Consultants: The IRB Chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB, including review of the scientific merit of a study. The IRB Chair may invite consultants to either attend the IRB meeting or provide a written report so that IRB members are made aware of and provided with information concerning the consultants’ review. Special consultants shall not vote with the regular and alternate members of the IRB, and their presence or absence shall not be used in establishing a quorum for an IRB meeting. Special consultants shall be used at the IRB Chair’s discretion or if requested by the convened IRB. All special consultants shall be asked to sign an IRB Guest Confidentiality Agreement. The consultant may be asked to participate via a teleconference or attend the IRB meeting to lend his/her expertise to the discussions. Special consultants shall not vote.

Documentation of key information provided by special consultants shall be summarized in the IRB minutes and, if available, the special consultant’s written report shall be stored in the IRB file.
1.2.7 **Alternate members:** The IRB shall appoint an alternate member for each primary member. The IRB roster shall identify the primary member(s) for whom each alternate member may substitute. To ensure an appropriate quorum is maintained, the alternate's qualifications shall be comparable to the primary member to be replaced. The IRB minutes shall document when an alternate member replaces a primary member. When an alternate serves for a primary member, the alternate member shall have received and reviewed the same material that the primary member received or would have received. If both the primary and alternate members attend the meeting, only one may vote. The non-voting member is specified in the minutes.

1.3 **Conflict of Interest**

See SOP 104B: Conflicts of Interest for IRB Members, for information regarding an IRB member’s participation in the IRB’s review of any project in which the IRB member has a conflicting interest.

2. **SCOPE**

This SOP applies to the primary and alternate membership of the IRB.

3. **RESPONSIBILITY**

The HRPP Directors and IRB Chairs are responsible for the composition of the IRB.

4. **APPLICABLE REGULATIONS AND GUIDELINES**

- 45 CFR 46.107
- 21 CFR 56.107
- VHA Handbook 1200.05

5. **REFERENCES TO OTHER APPLICABLE SOPS**

SOP 104B Conflict of Interest for Board Members.

6. **ATTACHMENTS**

- 201-A IRB Roster Template
- 201-B HSC Campus IRB Membership Rosters
- 201-C Norman Campus IRB Membership Rosters
- 201-D HSC Campus IRB Meeting Schedules
- 201-E Norman Campus IRB Meeting Schedules

7. **PROCESS OVERVIEW**

7.1 The HRPP Director identifies IRB members with varied backgrounds and experiences to provide optimal review of human participant research, giving consideration to gender, race, ethnicity, community affiliation, and professional experience. The HRPP Director consults with IRB Chairs as needed for selection of IRB members.
7.2 The HSC HRPP Director consults with the VA Medical Center Director as needed for selection of IRB member representation from the VA.

7.3 The HRPP Director considers a number of factors in developing IRB membership. These factors include, but are not limited to: the specialty of the IRB (i.e., Oncology, Pediatrics, and Behavioral), number of members required to fill the IRB and allow for a thorough review of all human participant research, and consideration of the requirements of an IRB as described above in Section 1.2.

7.4 The HRPP Director recommends IRB membership to the Senior Vice President and Provost, in accordance with SOP 202: Management of IRB.

APPROVED BY:_______________________________ DATE: 01/06/2020

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020