Burrell College of Osteopathic Medicine IRB Membership and Responsibilities	SOP #: RSP.005.02
Effective Date	9/30/29 (Converted from BCOM Policy to SOP)
Last Revision/Review	9/30/19, 11/30/2021, 4/1/2023, 4/11/2024

1. Purpose

To document the procedures used by the Burrell College of Osteopathic Medicine Institutional Review Board for membership, appointment and responsibilities of the Institutional Review Board (IRB) to ensure compliance with federal requirements.

2. Related Policy/Authority

Burrell College Policy #B8500 – Authorized Institutional Official for Research
Burrell College Policy # B8530 – Human Research Protection Program Statement of Compliance
45 CFR 46.107 - Public Welfare: Part 46, Protection of Human Subjects
21 CFR 56.107 – Food and Drug: Part 56, Institutional Review Boards
38 CFR 16.107 - Pensions, Bonuses, and Veterans' Relief: Part 16, Institutional Review Boards

3. Faculty/Staff Responsibilities

Execution of SOP: Assistant Dean for Research and IRB Chairperson, IRB Members, ORSP Staff

4. Definitions/Abbreviations

IO – Institutional Official - The Authorized Institutional Official for Research, (IO), serves as the institutional point of responsibility for the oversight of research and research related regulatory compliance which includes the Human Research Protection Program, the Animal Care and Use Program, Institutional Biosafety Program and all other areas of research where state and/or federal oversight is required. Federal guidelines state that the IO should be an official of the institution who has the legal authority to act and speak for the institution, and should be someone who can ensure that the institution will effectively fulfill its research oversight function. The Burrell College President functions in this capacity but may choose to appoint an IO and delegate authority.

- **IRB** – Institutional Review Board - means The Burrell College of Osteopathic Medicine at New Mexico State University Institutional Review Board #1 (IRB). The IRB is recognized as the authorized Burrell College entity that functions to protect the welfare of human subjects used in research conducted by agents, students, and/or trainees of Burrell College. The IRB is registered with the Department of Health and Human Services Office for Human Research Protection as IRBOOO 10422 and has an approved Federal wide Assurance (FWA0002407 l).

5. Procedural Steps

5.1 IRB Membership

5.1.1 Recommendations for membership may be made by Department Chairs, Faculty Council, or by individuals who wish to be considered for membership. Prospective members may also be identified by the IRB Chairperson and staff who are familiar with the nature and demands of the IRB. The IRB Board Members are appointed by the Authorized Institutional Official for Research in consultation with the Dean. The IRB Chairperson is appointed from the Regular IRB Membership by the Authorized Institutional Official. The Vice-Chair is

appointed from the Regular IRB Membership by the Authorized Institutional Official in consultation with the Chairperson and the membership of the IRB. The Authorized Institutional Official for Research may also appoint Alternate Board Members.

5.2 Composition of the IRB

5.2.1 The IRB at minimum shall be composed of:

- At least five members with varying backgrounds to promote complete adequate review of research activities commonly conducted at Burrell College.
- A diverse group of members with consideration given to race, gender, and cultural background.
- Members representing more than one profession.
- Members representing biomedical and behavioral sciences.
- At least one member trained in and licensed to practice osteopathic medicine.
- At least one member whose primary concerns are in scientific areas.
- At least one member whose primary concerns are in nonscientific areas.
- At least one member whose is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- Alternate members who are appointed to assume the responsibilities of regular members in the event that a regular member is unable to attend a meeting of the IRB.

5.3 **IRB Resources and Duties**

5.3.1 IRB Resources

5.3.1.1 The IRB shall have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties. The Assistant Dean for Research and authorized I.O. provides staff support, recordkeeping supplies, and storage space in support of the IRB through the ORSP budget. Lunch is provided at IRB meetings held during the noon hour.

5.3.1.2 The I.O. shall prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution. The roster should also include term of appointment to the board.

5.3.2 IRB Duties

5.3.2.1 The IRB shall establish written procedures for protocol review that include:

5.3.2.1.1 Conducting initial review of new research proposals involving human subjects, continuing review of approved human subjects research, and for communicating IRB findings and actions to the investigator and the College.

5.3.2.1.2 Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

5.3.2.1.3 Ensuring prompt reporting by the investigator(s) to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

5.3.2.2 The IRB shall establish written procedures for oversight of human subjects research that include:

5.3.2.2.1 Establishing and following written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of: (1) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with federal regulations or the requirements of the IRB; and (2) Any suspension or termination of IRB approval.

5.3.2.2.2 Having authority to suspend or terminate approval of research that is not in compliance with the IRB's determinations or has been associated with unexpected serious harm or risks to subjects.

5.3.3 Discharge of Duties

5.3.3.1 Except when an expedited review procedure is used, the IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

5.3.3.2 IRB members are expected to attend and participate in convened meetings of the IRB. Members who are not able to attend a scheduled meeting shall inform the IRB Chair of her/his absence in advance of the meeting. Excessive absences could result in replacement of the member.

5.4 **IRB Membership Categories and Responsibilities**

The term or appointment for the committee members will be three (3) years in order to establish a rotational membership with approximately one-third of the membership renewing each year. Subsequent terms of appointment are for three years. If a member resigns prior to the end of her/his term, an individual with comparable expertise should be appointed to complete the term of the member who vacated the position. Appointments are renewable without term limits. The IRB shall recognize the following categories of membership: Regular Members (i.e., Chairperson, Vice-Chairperson, Voting Board Members); Alternate Members; *Ex Officio* Members (non-voting); and *Ad Hoc* IRB Consultants (non-voting).

5.4.1.1 The IRB Regular Members are appointed by the Authorized Institutional Official (Section 5.1.1). Regular members responsibilities include: completion of required IRB training, attendance and participation in meeting deliberations, review of protocols, and assisting the IRB chair with development and/or review of IRB policies and procedures.

5.4.1.2 The IRB Chair is a voting member of the IRB and assumes the duties of IRB members. The IRB Chair is appointed from the Regular Membership by the Authorized Institutional Official (Section 5.1.1). The term of appointment as chair is one-year and renewable. In addition to her/his responsibilities as an IRB member, the IRB Chair convenes regular meetings of the IRB, convenes special meetings of the IRB when necessary, assigns primary and secondary reviewers on protocols, conducts review of all protocols discussed at convened meetings, and conducts expedited review of research studies. The IRB Chair is responsible for providing written communication to investigators of deliberations and concerns regarding

specific protocols reviewed by the IRB. The IRB Chair is also responsible for reviewing policies and procedures on an ongoing basis and recommending revisions to the IRB as necessary.

5.4.1.3 The IRB Vice-Chairperson is appointed from the regular membership by the IO from the regular membership in consultation with the Chairperson and membership of the IRB. The Vice-Chairperson shall perform duties of the chairperson in her/his absence, preside over meetings when the chairperson has reason to recuse her/him-self from meeting deliberations and assist the IRB Chairperson and IRB staff as needed.

5.4.1.4 The IRB Alternate Members shall have qualifications comparable to the applicable regular member for whom he/she is serving as a replacement (scientific to scientific; non-scientific to non-scientific). The alternate member(s) attending the meeting will assume all responsibilities of the member for which he/she is substituting. Alternate Members may attend IRB meetings without serving as a replacement for a regular member, however, may not serve as a voting member unless they have been designated by the IRB chair as a replacement for a regular member. IRB meeting minutes will reflect who is in attendance as a voting IRB member.

5.4.1.5 *Ex Officio* Members (non-voting) are Individuals from among the academic or administrative staff of the College are appointed to aid the IRB in conducting its duties. These members may take part in all meetings of the IRB, participate in discussions and make recommendations, but they may not vote on the decisions. *Ex-Officio* Members are not included in determining or establishing a quorum at the meetings. IRB meeting minutes reflect the attendance or absence of *Ex-Officio* Members. While not required by federal regulations, it is recommended by the NIH Office of Human Research Protection (OHRP) that the Institutional Official not serve as chairperson or voting member of an IRB holding a federal wide assurance.

5.4.1.6 The IRB at their discretion may invite individuals with particular expertise to serve as an *ad hoc* consultant when expertise is needed to assist in reviews that are deemed to require expertise beyond or in addition to that which is available on the IRB. Particular expertise needed may include scientific or discipline-specific knowledge, as well as knowledge about and/or experience working with, certain research topics or research populations. Consultants may be used for all aspects of IRB function including but not limited to initial protocol review, continuing review, reportable incidents, and protocol modifications. The IRB Chair and Institutional Official are responsible for identifying individuals with specific expertise and selecting the consultant when a consultant is deemed necessary by the IRB. Consultants to the IRB may not be selected if they have a conflict of interest with the protocol under review. No compensation is provided to the consultants. Consultants are only allowed to provide information to the committee and are not allowed to vote on the protocol decision.

5.6 Conflict of Interest Disclosure

5.6.1 No IRB member or consultant may participate in the IRB review of any project in which he/she has a conflict of interest, except to provide information requested by the IRB. Members must indicate conflicts of interest as soon as possible after meeting materials are distributed by notifying the IRB Chairperson and must recuse her/him-self from the meeting or abstain from deliberation and voting on the outcome of the protocol. The IRB Chairperson will ask members to disclose any conflict of interest at the beginning of each convened meeting. Examples of conflict of interest may include but are not limited to: a member of the IRB who serves as an investigator or researcher on the protocol under review, or a member of the IRB who serves as an investigator or researcher on the protocol under review, or a member of the IRB who holds a financial conflict of interest in a sponsor or product under study. The minutes of the meeting shall reflect the fact that member(s) were recused.

5.7 Member Confidentiality

5.7.1 Deliberations of the IRB are confidential. Actions of the IRB are reflected in the meeting minutes. Members, consultants, and guests will be appropriately noticed on confidentiality.

6. Reports/Charts/Forms/Attachments/Cross References

Applicable Rules and Regulations:

7. Maintenance

The S.O.P. was developed by the Office of Research & Sponsored Programs in consultation with the IRB Chairperson and Vice-Chairperson. The S.O.P. is reviewed at least once every three (3) years by the I.O., IRB Chairperson, and IRB Vice-Chairperson.

8. Signature

Signature on File	4/11/2024
Department Head of Research	Date

9. Distribution List

Internal/External

10. Revision History

Updated and converted from BCOM Policy to a Standard Operating Procedure. Revision Date	Subsection #	Summary of Changes	New/Cancellation/ Replacement Procedure? (if applicable)	Approval Date
1			Replaces previous BCOM Policy	9/30/19
11/30/2021		Removed reference to BCOM and replaced with Burrell College		12.6.2021
4/11/2024		Updated information about the IO		4/11/2024