

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

STANDARD OPERATING PROCEDURES

Burrell College of Osteopathic Medicine IRB: Voting and Actions	SOP #: RSP.006.02
Effective Date	10/4/19
Last Revision/Review	10/4/19, 11/30/2021, 04/04/2023

1. Purpose

Federal regulations state that *“The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all BCOM research activities involving human subjects, including exempt research activities for which limited IRB review is a condition of exemption.”* The purpose of this SOP is to document the procedures used by the Burrell College of Osteopathic Medicine Institutional Review Board for the voting process and actions that the IRB may take on research protocols.

2. Related Policy/Authority

45 CFR 46.109 IRB Review of Research

3. Faculty/Staff Responsibilities

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

4. Definitions/Abbreviations

4.1 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 Burrell College IRB is registered with the Department of Health and Human Services Office for Human Research Protection as IRBOOO 10422 and has an approved Federalwide Assurance (FWA0002407 I) valid through October 4, 2022 (10/4/22).

4.2 Research - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this SOP, whether or not they are conducted or supported under a program that is considered research for other purposes.

4.3 Human Subject - a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

5. Procedural Steps

- 5.1** The IRB makes an independent determination to approve, require modification in order to secure approval, or disapprove a human subjects research protocol based upon whether or not human subjects are adequately protected. Approved research is subject to continuing IRB review and must be re-evaluated at least annually. IRB jurisdiction applies to all Research involving Human Subjects at Burrell College. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of Burrell College. However, those officials may not approve research if it has been disapproved by the IRB. Actionable items by the IRB must be voted on and the vote recorded in the meeting minutes along with the motion as approved.

5.2 IRB Actions

5.2.1 IRB review of a new research protocol and amendments to an approved protocol result in various outcomes, which are communicated in writing to the investigator by the IRB Chairperson after the IRB meeting. The IRB is limited to three actions with respect to review of new protocols and amendments to approved protocols

5.2.1.1 Approval - A vote to approve an initial or continuing protocol or amendment indicates that all IRB concerns have been satisfactorily addressed and that the research may begin as soon as the investigator receives written documentation of IRB approval.

5.2.1.2 Deferral - A vote for "Deferral" occurs when the IRB is unable to approve initial or continuing research because it cannot make the determination required for approval. In such instances, the IRB may defer the decision pending receipt of modifications or additional information that is needed in order to secure approval. If the IRB votes for deferral of a decision on a research protocol, the research may not proceed until the IRB reviews the revised research project and approves it. The IRB may choose to review the investigator's response using the expedited review process or choose to review the response at a convened meeting of the full committee. The IRB chair will communicate the reasons for "Deferral" to the investigator and request specific modifications or additional information based on the IRB deliberations. The minutes of the IRB meeting will reflect the committee recommendation.

5.2.1.3 Disapproval - A vote for "Disapproval" occurs if the IRB determines that the study has major problems involving risks to participants or other significant concerns. In cases of "Disapproval", the investigator may attend a future convened meeting of the IRB to defend the protocol if he/she wishes to pursue the study. When the IRB votes "Disapproval" of a project, the research may not go forward.

5.3 Other Actions of the IRB

5.3.1 Suspension - The IRB Chairperson or the convened IRB may suspend a study at any time if it is determined that further review or evaluation of the research is required. The Institutional Official is notified immediately when a study is suspended. Suspension may be made on the basis of an adverse event, noncompliance or other danger to human subjects. Once a study has been suspended, the IRB must review the study at a convened meeting. The IRB may either remove the suspension or terminate the research project.

5.3.2 Termination - Although the IRB chairperson may suspend a study, only the IRB is authorized to terminate a study. Decisions of the IRB to terminate a research study are made at a convened meeting of the IRB. The Institutional Official is informed of the IRB decision and is the responsible party for all required reports to federal agencies and funding organizations.

5.3.3 Expired Protocols - IRB Protocols that are not renewed by the date of expiration are automatically closed and the investigator is informed in writing. The IRB is

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informed of protocol expirations at a convened meeting. All research on the expired protocol must cease.

- 5.3.4 Project Completion** - The investigator may elect to close a project prior to the protocol expiration date by completing an IRB closure form. Upon receipt of the completed IRB closure form, the IRB office is authorized to administratively close the research project. The researcher will not be permitted to have any further interaction with research subjects or their data in ways that would require ongoing IRB approval. The researcher may continue to analyze aggregate de-identified data sets following study closure but may not enroll new subjects or further examine identified datasets.

5.4 Non-IRB Administrative Action

- 5.4.1 Administrative Termination of Approved Protocol** - Other Burrell College Officials as well as certain state and federal agency officials may, in certain cases, decide that a research study that has been approved by the IRB may not be conducted. Reasons for such an action may relate to research that is viewed as inappropriate or research that is underfunded. In such instances, the Burrell College Officials must notify the Investigator and IRB of the action in writing. The notification should indicate the reason for the institutional action. While Burrell College Officials may terminate approved protocols, under no circumstances are Burrell College Officials, state or federal officials authorized to approve or reinstate research activities that have been disapproved, suspended or terminated by the IRB.

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

Applicable Rules and Regulations:

7. Maintenance

Identify if the organizational unit/staff who developed the procedure; when it will be reviewed and updated.

8. Signature

Signature on File

Joseph Benoit, PhD

4/4/2023

Date

9. Distribution List

Internal/External

10. Revision History

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Revision Date	Subsection #	Summary of Changes	New/Cancellation/Replacement Procedure? (if applicable)	Approval Date
1	[e.g., 3.1]			
11/30/2021		Removed reference to BCOM and replaced with Burrell College		12.6.2021
4/04/2023		Updated definitions adding section 4.3		4/4/2023