

# BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

## STANDARD OPERATING PROCEDURES

<b>IRB Protocol Modifications and Amendments</b>		<b>RSP.030.00</b>
Effective Date	May 2016	
Last Revision/Review	July 25, 2023	

### 1. Purpose/Scope

**Purpose:** This SOP defines the process for seeking approval for modifications or amendments to approved research protocols.

**Scope:** Burrell faculty, staff, and students involved in human subjects research, IRB Committee.

### 2. Related Policy/Authority

45 CFR 46

Policy: B8530

**Responsible Official (S):** Institutional Official, IRB Chairperson, IRB Committee, IRB coordinator.

### 3. Faculty/Staff Responsibilities

Assistant Dean of Research & Authorized Institutional Official for Research

Institutional Review Board Chair

IRB Administrative Coordinator

Principal Investigator / Study Personnel

### 4. Definitions/Abbreviations

a.

### 5. Procedural Steps

#### 5.1 Guidance:

A modification to an IRB protocol refers to any proposed changes or revisions made to an approved research protocol after it has been reviewed and approved by the IRB. These modifications can include changes to study procedures, recruitment methods, consent forms, data collection instruments, or any other aspect of the research that affects the protection of human subjects or the scientific integrity of the study. The researcher shall not modify a protocol without approval of the IRB except in emergent situations where modification of the protocol is necessary to eliminate immediate hazards to the research subjects. In such emergent situations, the IRB must be notified as soon as possible, and appropriate amendments submitted to the IRB for review. The IRB Chairperson may choose to suspend the research pending further review by the convened IRB. Modifications or Amendments include various changes to the research study, such as but not limited to:

1. **Changes to study procedures or methods:** This might involve altering the recruitment process, modifying the data collection methods, or adjusting the intervention approach.
2. **Modifications to informed consent:** If there are changes to the consent process or forms, such as adding new information or revising the language, an amendment is required.
3. **Updates to study materials:** This may involve changes to questionnaires, surveys, or other research instruments used in the study.

4. **Addition or removal of study sites, collaborators, or study personnel:** If new sites, research partners, or research personnel are involved or existing ones are discontinued, it requires an amendment.
5. **Changes to the study population:** If the researchers want to include or exclude certain groups of participants, an amendment is necessary.
6. **Safety concerns:** If new safety information emerges or there are adverse events related to the study, the researchers must submit an amendment to address these concerns.

### **5.1.1 Exempt Status Studies:**

Modifications or Amendments to Exempt Study Protocols: Federal regulations do not require continuing review for approved exempt research. However, any proposed and/or anticipated change(s) to an exempt protocol requires submissions to the Burrell IRB for review and approval as an exempt study. Certain changes may disqualify the research from exempt status.

If information comes to the attention of the IRB suggesting that there are factors increasing the sensitivity and/or potential risk to human subjects in research that otherwise would appear to qualify for exemption under the criteria listed above, the IRB may, at its sole judgement, deem the protocol to be subject to expedited or full IRB review.

The IRB action on proposed amendments is communicated to the researcher in writing. Implementation of the amendments by the researcher can only begin after receiving notification of approval.

### **5.1.2 Non-Exempt Status Studies:**

Modifications or Amendments to Non-Exempt Studies: Minor amendments to previously approved protocols may be approved by expedited review or by full committee review. Minor amendments are defined as changes in the protocol that do not significantly alter the risk/benefit relationship or other study elements. The IRB, in reviewing the amendment(s), should determine if the changes have the potential to affect the research subjects' willingness to continue participation in the study. In such instances, the IRB may require the investigator to obtain re-consent from study participants.

The IRB action on proposed amendments is communicated to the researcher in writing. Implementation of the amendments by the researcher can only begin after receiving written notification of approval.

Major Modifications or Amendments to previously approved protocols represent substantive changes that might increase the risk to human subjects enrolled in the study. Major modifications or amendments must be reviewed and acted on at a convened IRB using the Full Committee Review process. The IRB, in reviewing the amendment(s), shall assess risks and benefits of the proposed modification or amendment to the study participant and determine if the changes have the potential to affect the research subjects' willingness to continue their participation in the study. In such instances, the IRB may require the investigator to obtain re-consent from study

participants. The IRB action on proposed amendments is communicated to the researcher in writing. Implementation of the amendments by the researcher can only begin after receiving written notification of approval.

### 5.2 Investigator Responsibilities

1. **Changes to Study Procedures or Methods:** The Principal Investigator shall submit the modification or amendment for IRB review. Requests should clearly state the requested modification or amendment, provide justification for the requested modification or amendment, as well as any risks or benefits associated with the amendment. Applicable changes to the consent document should also be submitted. Changes to the protocol must be highlighted.
2. **Modifications to Informed Consent:** The Principal Investigator shall submit a revised consent document for IRB review with changes highlighted and a justification that clearly states what changes in the consent process are being made and why. Changes to consent process include translation of the documents as well as oral communication of consent into a language other than English.
3. **Updates to Study Materials:** The Principal Investigator shall submit revised materials for IRB review with changes highlighted as well as explanation and justification of the changes.
4. **Change in study sites, collaborators, or study personnel:** The Principal Investigator shall submit a memo for IRB review detailing the changes. Where appropriate a site letter for new locations may be required. It is the Principal Investigator's responsibility to ensure that new study personnel have been properly trained. Failure to do so may result in delays in the approval process.
5. **Changes in the Study Population:** The Principal Investigator must submit an amendment for IRB review that explains changes in the exclusion or inclusion criteria for study subjects. Instances where changes involve vulnerable populations will require full committee review.
6. **Safety Concerns:** Modifications or amendments to protocols involving safety concerns must undergo full committee review.

### 5.3. IRB and Office of Research Responsibilities

1. The IRB coordinator acknowledges receipt of the modification or amendment to the Principal Investigator and logs receipt of the request within two (2) business days of receipt. If the administrative coordinator is absent or if submission falls on a college holiday, the addition to the study file will be added within two business days after returning to work.
2. The IRB coordinator will conduct a pre-review of the request.
3. The IRB coordinator will deliver the request, with comments and the results of the prereview to the IRB chair for initial review.
4. The IRB chair will determine the next actions and may assign reviewers. Typically, the IRB chair should return the action items to the IRB coordinator within three business days of receipt but not later than nine business days before the next scheduled meeting. Depending on the nature and complexity of the modification or amendment, the IRB may conduct an

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## **STANDARD OPERATING PROCEDURES**

- expedited review or a full committee review to assess the proposed modifications. In emergent situations, the IRB chair may convene the IRB in a special meeting.
5. The IRB coordinator prepares a draft letter describing the expedited or committee findings to the principal investigator and submits it to the IRB withing five (5) business days of the expedited decision or committee meeting.
  6. The IRB chair edits and returns the action letter to the IRB coordinator within
  7. three (3) business days of receipt of the draft.
  8. The IRB coordinator prepares the final letter for the IRB chair signature and
  9. distributes the letters to investigators. Letters will be signed using Adobe Sign. Only after receiving IRB approval can the researchers proceed with implementing the changes to the study.
  10. The IRB coordinator files the letter to the principal investigator in the study file.

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

1. Sample Forms and Templates
2. IRB Amendment Approval Letter
  - IBR Amendment Modification Letter
  - IRB Amendment Disapproval Letter

### **7. Maintenance**

The SOP will be reviewed no less than annually. The review will be conducted by ORSP in consultation with the IRB Chair.

### **8. Signature**

Approved by	8/9/2023
Assistant Dean for Research	Date

### **9. Distribution List**

Internal/External

Revision Date	Subsection #	Summary of Changes	New/Cancellation/Replacement Procedure? (if applicable)	Approval Date
7/25/2023		Converted from May 2016 policy		8/9/2023

### **10. Revision History**



### BURRELL COLLEGE OF OSTEOPATHIC MEDICINE Institutional Review Board

**TO:** [Principal Investigator]  
[Title]

**FROM:** [IRB Chair]  
Chairperson, Burrell College Institutional Review Board

**Cc:**

**DATE:** [DATE]

**RE:** BURRELL IRB# [NUMBER]\_[YEAR], [PROTOCOL TITLE]

The IRB reviewed your amendment to proposal BURRELL IRB [NUMBER]\_[YEAR] entitled, "[PROTOCOL TITLE]." I am pleased to inform you that the amendment request to [DEFINE MODIFICATION OR AMENDMENT] to your project proposal has been approved. Receipt of this notice grants you permission to begin the data collection and research described in your proposal.

Please note that as Principal Investigator, you are responsible for promptly reporting any changes to the study protocol and reporting any injuries, adverse events, or unanticipated events that affect research subjects to the following email address: [irb@burrell.edu](mailto:irb@burrell.edu).

Please be aware that the BURRELL IRB will be conducting routine audits of active protocols as a means of ensuring compliance with federal policies and protection of human subjects in research. Your project may be audited at any time as part of these procedures.

The IRB thanks you for your cooperation and wishes you well on the conduct of your research. Please direct any questions or concerns to [irb@burrell.edu](mailto:irb@burrell.edu).



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**TO:** [Principal Investigator]  
[Title]

**FROM:** [IRB Chair]  
Chairperson, Burrell College Institutional Review Board

**Cc:**

**DATE:** [DATE]

**RE:** BURRELL IRB# [NUMBER]\_[YEAR], [PROTOCOL TITLE]

The IRB reviewed your amendment(s) to proposal BURRELL IRB [NUMBER]\_[YEAR] entitled, "[PROTOCOL TITLE]." The IRB voted for "Deferral" of a decision pending receipt of additional information. Specifically, the IRB has determined that the following items need to be addressed prior to any further action on the protocol:

- [LIST IRB STIPULATIONS]

Please provide the requested information to the IRB at your earliest convenience, but no later than 60 days from the date of this correspondence. Please include the following information with your responses:

1. Cover letter detailing the changes that were made.
2. Revised protocol with the changes highlighted.
3. Revised protocol without any highlighting or marks.

Your responses will be reviewed by the IRB and you will be notified of further actions. However, the research may not begin until you are notified of approval of study. Please direct any questions or concerns to [irb@burrell.edu](mailto:irb@burrell.edu).



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**TO:** [Principal Investigator]  
[Title]

**FROM:** [IRB Chair]  
Chairperson, Burrell College Institutional Review Board

**Cc:**

**DATE:** [DATE]

**RE:** BURRELL IRB# [NUMBER]\_[YEAR], [PROTOCOL TITLE]

The IRB reviewed your proposal BURRELL IRB [NUMBER]\_[YEAR] entitled, “[PROTOCOL TITLE]”. The IRB voted for “Disapproval” of the study. The board has considered various factors during the review process, and there are certain concerns and areas that require further clarification before granting approval.

- [REASON(S) FOR DENIAL:]

Option to Appeal: You may disagree with the IRB's decision. As per Burrell's policy, you have the right to appeal this decision if you believe that the IRB has overlooked critical aspects of your proposal or if you can address the concerns raised during the review.

If you choose to appeal, please follow the steps outlined below:

- Submit a written appeal letter within 30 days from the date of this letter.
- In your appeal letter, clearly state the grounds for your appeal, addressing the specific issues raised by the IRB in the denial letter.
- Include any additional documentation or evidence that supports your case and helps address the concerns mentioned by the IRB.
- Send the appeal letter and supporting materials to [irb@burrell.edu](mailto:irb@burrell.edu).
- The IRB will thoroughly assess the additional information provided and reconsider the decision made on your proposal.

Please be aware that the appeal decision will be final and cannot be further contested. Should you have any questions or concerns please contact the IRB at [irb@burrell.edu](mailto:irb@burrell.edu).