Office of Research Procedures for Managing IRB and IBC Protocols	SOP #: RSP.010.02
Effective Date	11.20.19
Last Revision/Review	07.02.2020, 11/30/2021

1. Purpose

To document the procedures used by the Office of Research & Sponsored Programs for managing the Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC) protocols.

2. Related Policy/Authority

Include a link to the organization's authority (its policy and/or federal citation).

- B8530 Human Research Protection Program Statement of Compliance
- 45 CFR 46 Protection of Human Subjects
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

3. Faculty/Staff Responsibilities

Assistant Dean for Research & Authorized Institutional Official for Research
Institutional Review Board Chair
Institutional Biosafety Committee Chair
ORSP Administrative Coordinator

4. Definitions/Abbreviations

4.1 **IBC** – means Burrell College Institutional Biosafety Committee
4.2 **IRB** – means Burrell College Institutional Review Board

5. Procedural Steps

5.1. The Principal Investigator submits the protocol to the Office of Research.
5.2. The Administrative Coordinator acknowledges receipt of the protocol to the Principal Investigator.
5.3. The Administrative Coordinator creates a file containing the protocol and related materials within two (2) business days of receipt. If the administrative coordinator is absent or if submission falls on a College holiday, the file will be created within two business days after returning to work.
5.4. The Administrative Coordinator will deliver the file to the committee chair for an initial action. A protocol assignment sheet will accompany the file (Section 6).
5.5. The committee chair will determine next actions and assign reviewers. Typically, the IRB or IBC chair should return the file to the administrative coordinator within three (3) business days of receipt but not later than nine (9) business days in advance of the next scheduled meeting.
5.6. The administrative coordinator compiles and distributes the meeting packet eight (8) business days in advance of the scheduled meeting along with notification of reviewer responsibilities.

5.7. The IRB or IBC formally review the protocols according to the category of review assigned. Actions on exempt and expedited review may be communicated to the principal investigator when the review is complete. Actions on full committee review will be communicated to the Principal Investigator after the committee action at a convened meeting. The administrative coordinator serves as the recording secretary for the meeting.

5.8. The administrative coordinator prepares a draft of meeting minutes that capture the essence of the meeting deliberation and committee actions. The draft of the meeting minutes is submitted to the committee chair for review and revision within three (3) business days of the meeting.

5.9. The committee chair prepares wording describing the committee findings for incorporation into the action letter to the principal investigator and submits them to the administrative coordinator within five (5) business days of the meeting. The findings will be written in the "What, Why, What" format. Specifically, each item should address the questions: *What is the problem or concern identified by the committee?; Why is it a problem?; and What is the committee requesting?* The Administrative Coordinator will insert the supplied wording supplied by the Chair into a final draft of the standardized action letter and forward the letter draft to the committee chair for final review.

> *Sample format: (What is the problem?)* The proposed study involves more than minimal risk and the informed consent document does not provide an explanation regarding compensation in the event of injury. *(Why is it a problem?)* The basic elements of informed consent 46 CFR 116 requires "an explanation as to whether any compensation and an explanation as to whether medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained." *(What is the committee requesting?)* The IRB requests that the informed consent document be revised to incorporate sufficient information to address the basic elements of informed consent.

5.10. The committee chair edits and returns the action letter to the administrative coordinator within three (3) business days of receipt of the draft.

5.11. The Administrative coordinator prepares the final letter for the committee chair signature and distributes the letters to investigators. Letters will be signed using Adobe Sign.

5.12. The Administrative coordinator files the letter to the investigator in the protocol file.

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

Sample Forms and Templates

- IRB Protocol Assignment
- IRB Full Approval Letter
- IRB Protocol Revision Letter
- IRB Continuing Review Letter
- IRB Continuing Review Non-Compliance
- IBC Protocol Assignment
- IBC Full Approval Letter
- IBC Protocol Revision Letter

7. Maintenance

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

8. Signature

Signature on File	12.6.2021
Assistant Dean for Research	Date

9. Distribution List

Internal

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/ Replacement Procedure? (if applicable)	Approval Date
1	5 and 6	Minor Procedural changes, addition of sample wording to section 5.9, addition of sample templates in section 6.		07.02.2020
11/30/2021		Removed reference to BCOM and replaced with Burrell College		12.6.2021

Institutional Review Board Protocol Assignment

ORSP Office Use Only

Protocol Submission Number	
Date Received	
Protocol Title	
Principal Investigator	

Investigator	CITI Training Status
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete

Administrative Coordinator Checklist

Protocol	☐ Complete ☐ Not Complete
Mountain View Site Letter (Required for all MVMC Protocols)	☐ Yes ☐ No ☐ Not Applicable
Consent Form	☐ Yes ☐ No ☐ Not Applicable

IRB Chair Action:

Category of Review (Check One)			
☐ Exempt	☐ Expedited	☐ Full Committee Review	☐ Limited Review

Reviewer Assignment	
Primary Reviewer (Check One)	**Secondary Reviewer (Check One)**
Harald M. Stauss, PhD	Harald M. Stauss, PhD
Pastor Jared Carson	Pastor Jared Carson
Jennifer Eastwood, PhD	Jennifer Eastwood, PhD
Michael Frederich, MD	Michael Frederich, MD
Adrienne Kania, DO	Adrienne Kania, DO
Robert Ketchum, PhD	Robert Ketchum, PhD
Norice Lee, MLIS	Norice Lee, MLIS
Tanya Martinez, C-TAGME	Tanya Martinez, C-TAGME
Justin McHorse, MS	Justin McHorse, MS

Assign ALTERNATES by writing in only if alternates will be attending in place of absent member.

Deborah Whitson, DO
David Osborne, PhD
Elizabeth Howard, PhD

Comments or Special Instructions: _____

Institutional Review Board

DATE: [DATE]

TO: [Principal Investigator]
[Title]

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

Cc:

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

The Institutional Review Board (IRB) has reviewed your proposal #BCOM IRB [NUMBER]_[YEAR] entitled, "[PROTOCOL TITLE]." I am pleased to inform you that your project proposal has been granted "Full Approval" for implementation at the Burrell College of Osteopathic Medicine, Las Cruces, NM. 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 also reporting any injuries, adverse events, or unanticipated events that affect research subjects to the IRB Chairperson at the following email addresses: [IRB CHAIR EMAIL ADDRESS] or research@bcomnm.org or by phone [IRB CHAIR OFFICE NUMBER].

Federal Guidelines dictate that IRB-approved research must be reviewed no less than once a year. Your Continuation Review/Progress Report will be due on [DATE]. Please contact the Office of Research & Sponsored Programs for necessary forms. Please be aware that the BCOM 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 directly to me or our IRB Administrative Coordinator, Ms. Martha Enriquez.

Institutional Review Board

DATE: [DATE]

TO: [Principal Investigator]
[Title]

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

Cc:

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

The Institutional Review Board (IRB) has reviewed your proposal #BCOM IRB [NUMBER]_[YEAR] entitled, "[PROTOCOL TITLE]."The IRB has determined that the following items need to be addressed prior to any further action on the protocol:

- Please include an itemized list of findings or concerns from the IRB. The findings will be written in the "What, Why, What" format. Specifically, each item should address the questions:
  What is the problem or concern identified by the committee? Why is it a problem? What is the committee requesting?

Please provide the requested information to the IRB at your earliest convenience. Please include the following information with your responses.

1. Cover letter providing a point by point response to the concerns.
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.

Institutional Review Board

DATE: [DATE]

TO: [Principal Investigator]
[Title]

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

Cc:

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

The IRB reviewed your response to proposal #BCOM IRB [NUMBER]_[YEAR] entitled, "[PROTOCOL TITLE]." The IRB voted for "Disapproval" of the study. The decision of the IRB was based on the several concerns, which are summarized as follows:

- Please include an itemized list of findings that led to the vote of disapproval of the protocol. The findings will be written in the "What, Why, What" format. Specifically, each item should address the questions:
  What is the problem or concern identified by the committee? Why is it a problem? What is the committee requesting?

The proposal in its present form was considered to be not acceptable and was "Disapproved" by the IRB. "*A vote for "Disapproval" occurs if the IRB determines that the research cannot be conducted at BCOM, or by employees or agents of BCOM, or otherwise under the auspices of BCOM. When the project as proposed is disapproved, the research may not go forward. Disapproval usually indicates that a proposal requires major changes that are not likely to be feasible without complete reassessment of the protocol by the investigator and/or sponsor*." Submission of a new protocol will be subject to full committee review as a new project. Please contact the IRB should you need more information.

Institutional Review Board

DATE: [DATE]

TO: [Principal Investigator]
[Title]

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

Cc:

RE: Notification of Continuing Review Approval for *BCOM IRB# [NUMBER]_[YEAR],* [*PROTOCOL TITLE*]

The Institutional Review Board (IRB) has reviewed the information that you provided as part of the protocol Continuing Review process. The IRB approved your continuing review submission and has no further questions. Receipt of this notice authorizes to continuation of data collection and research described in your proposal.

Federal Guidelines dictate that IRB-approved research must be reviewed no less than once a year. Your next Continuation Review/Progress Report will be due on [DATE]. Please be aware that the BCOM IRB may conduct 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.

Please continue to inform the IRB of any changes and/or modifications to your protocol.

The IRB thanks you for your cooperation and wishes you well on the conduct of your research. Any questions or concerns may be directed to me or our IRB Administrative Coordinator, Ms. Martha Enriquez.

Institutional Review Board

DATE: [DATE]

TO: [Principal Investigator]
[Title]

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

Cc:

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

The IRB is required to conduct regular monitoring of approved protocols as part of its oversight responsibilities. In a notice from the IRB dated, [DATE], you were informed that a Continuing Review submission for your protocol was due on [DATE]. The IRB did not receive your Continuing Review submission.

At the IRB meeting on [DATE], the IRB voted to suspend your protocol pending receipt and review of the Continuing Review submission. All research activities involving human subjects must cease including, but not limited to, enrollment of new subjects, analysis of individual identifiable data, and research interventions or interactions with currently participating subjects, except where stopping such interventions or interactions could be harmful to those subjects.

The IRB is requesting that you complete the continuing review questionnaire for your protocol BCOM IRB [NUMBER] by 12PM, [DATE]. Failure to respond by the required submission date may result in a non-compliance action and the administrative termination of your project by the IRB. No extensions will be granted. Additionally, the IRB reserves the right to conduct an audit of non-compliance matters as a means of ensuring compliance with federal policies and protection of human subjects in research.

In order to complete the review, please click on the following link to access the form. [QUALTRICS LINK]
To complete the submission process you will need access to your approved protocol, all amendments to the approved protocol, applicable consent forms, and demographic information on the subjects that you have enrolled to date. The total time required to complete the continuing review form is estimated at 30 minutes.

Once submitted, the IRB will review your continuing review submission at a convened meeting and communicate the outcome of IRB review to you.

Please direct any questions regarding the continuing review process to either Ms. Martha Enriquez or me. Thank you in advance for your assistance with this process.

Institutional Review Board

DATE: [DATE]

TO: [Principal Investigator]
[Title]

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

Cc:

RE: Notification of Study Closure for *BCOM IRB# [NUMBER]_[YEAR],* [*PROTOCOL TITLE*]

On [DATE], the Institutional Review Board (IRB) reviewed your Continuing Review. In your submission, you indicated that the study [GIVE STATUS BASED ON INFORMATION PROVIDED IN CONTINUING REVIEW]. I am writing to notify you that the IRB has voted to close the protocol.

Please note that you shall not enroll additional subjects or collect any new data from previously enrolled subjects. Analysis of data that has already been collected may continue.

Institutional Biosafety Protocol Assignment

ORSP Office Use Only

Protocol Submission Number	
Date Received	
Protocol Title	
Principal Investigator	

Investigator	Training Status
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete
	☐ Complete ☐ Not Complete

Administrative Coordinator Checklist

Protocol	☐ Complete ☐ Not Complete

IRB Chair Action:

Category of Review (Check One)			
☐ Exempt	☐ Expedited	☐ Full Committee Review	☐ Limited Review

Reviewer Assignment	
Primary Reviewer (Check One)	**Secondary Reviewer (Check One)**
Michael Woods, PhD	Michael Woods, PhD
Joseph N. Benoit, PhD	Joseph N. Benoit, PhD
John Byrd, PhD	John Byrd, PhD
Erin Martin, RN, BSN, MHA	Erin Martin, RN, BSN, MHA
Kalli Martinez, MS	Kalli Martinez, MS
Jon Jackson, PhD	Jon Jackson, PhD
Steven J. Ontiveros, MBA, PhD	Steven J. Ontiveros, MBA, PhD

Assign ALTERNATES by writing in only if alternates will be attending in place of absent member.

Comments or Special Instructions: _____

Institutional Biosafety Committee

DATE: [DATE]

TO: [Principal Investigator]
[Title]

FROM: [IRB Chair]
Chairperson, Burrell College Institutional Biosafety Committee

Cc:

RE: *BCOM IBC# [NUMBER]_[YEAR],* [*PROTOCOL TITLE*]

The Institutional Biosafety Committee (IBC) has reviewed your proposal #BCOM IRB [NUMBER]_[YEAR]. "[PROTOCOL TITLE]." I am pleased to inform you that your project proposal has been granted "Full Approval" for implementation at the Burrell College of Osteopathic Medicine, Las Cruces, NM. 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 also reporting any exposures or accidents that effect to the IBC Chairperson at the following email addresses: [IBC CHAIR EMAIL ADDRESS] or research@bcomnm.org or by phone [IBC CHAIR OFFICE NUMBER].

We will ask you to sumbit a Continuation Review/Progress Report that will be due on [DATE]. Please contact the Office of Research & Sponsored Programs for necessary forms. Please be aware that the BCOM IBC will be conducting routine audits of active protocols as a means of ensuring compliance with federal policies in research. Your project may be audited at any time as part of these procedures.

The IBC thanks you for your cooperation and wishes you well on the conduct of your research. Please direct any questions or concerns directly to me or our IBC Administrative Coordinator, Ms. Martha Enriquez.

Institutional Biosafety Committee
Michael E. Woods, PhD
Chairperson

TO: [Principal Investigator]
[Title]

FROM: [IRB Chair]
Chairperson, Burrell College Institutional Biosafety Committee

Cc:

DATE: [DATE]

RE: *BCOM IBC# [NUMBER]_[YEAR],* [*PROTOCOL TITLE*]

The Institutional Biosafety Committee (IBC) reviewed your proposal #BCOM IRB [NUMBER]_[YEAR] entitled "[PROTOCOL TITLE]." The IBC has determined that the following items need to be addressed prior to any further action on the protocol.

- Please include an itemized list of findings or concerns from the IBC. The findings will be written in the "What, Why, What" format. Specifically, each item should address the questions:
  What is the problem or concern identified by the committee? Why is it a problem? What is the committee requesting?

Please provide the requested information to the IBC at your earliest convenience. Please include the following information with your responses.

1. Cover letter providing a point by point response to the concerns.
2. Revised protocol with the changes highlighted.
3. Revised protocol without any highlighting or marks.

Your responses will be reviewed by the IBC and you will be notified of further actions. However, the research may not begin until you are notified of approval of study.

Institutional Biosafety Committee

DATE: [DATE]

TO: [Principal Investigator]

Re: Continuing Review of Approved BCOM IBC [NUMBER] _ [YEAR]

Dear [Principal Investigator],

The IBC conducts regular monitoring of approved protocols as part of the committee's oversight responsibilities. In order to fulfill these responsibilities, the IBC is requesting that you complete the continuing review questionnaire for your currently approved protocol BCOM IBC [NUMBER] _ [YEAR]. To complete the submission process you may need access to your approved protocol and all amendments tothe approved protocol. The total time required to complete the continuing review form is estimated at 30 minutes.

Your completed continuing review form must be submitted by [TIME] on [DAY], [MONTH DATE, YEAR]. No extensions will be granted. Failure to respond by the required submission date will result in administrative suspension or termination of your project's approval by the IBC. The IBC will review your continuing review submission at the [UPCOMING MEETING MONTH] meeting and communicate back to you shortly after the meeting regarding the outcome of IBC review.

In order to complete the review, please click on the following link to access the form.
[QUALTRICS LINK]

Please direct any questions regarding the continuing review process to either me or Ms. Martha Enriquez. Thank you in advance for your assistance with this process.

Sincerely,

Michael E. Woods, PhD
Chairperson, BCOM Institutional Biosafety Committee

Institutional Biosafety Committee

DATE: [DATE]

TO: [Principal Investigator]

Re: Continuing Review of Approved BCOM IBC [NUMBER] _ [YEAR]

Dear [Principal Investigator],

The IBC conducts regular monitoring of approved protocols as part of the committee's oversight responsibilities. In order to fulfill these responsibilities, the IBC is requesting that you complete the continuing review questionnaire for your currently approved protocol BCOM IBC [NUMBER] _ [YEAR]. To complete the submission process you may need access to your approved protocol and all amendments tothe approved protocol. The total time required to complete the continuing review form is estimated at 30 minutes.

Additionally, the Office of Research & Sponsored Programs notes that the following researchers have not completed the required continuing/refresher courses. The following trainings must be completed prior to the approval of your continuing review submission.

[NAME]:

- [TRAININGS REQUIRED]

Your completed continuing review form and trainings must be submitted by [TIME] on [DAY], [MONTH DATE, YEAR]. No extensions will be granted. Failure to respond by the required submission date will result in administrative suspension or termination of your project's approval by the IBC. The IBC will review your continuing review submission at the [UPCOMING MEETING MONTH] meeting and communicate back to you shortly after the meeting regarding the outcome of IBC review.

In order to complete the review, please click on the following link to access the form.
[QUALTRICS LINK]

Please direct any questions regarding the continuing review process to either me or Ms. Martha Enriquez. Thank you in advance for your assistance with this process.

Sincerely,

Michael E. Woods, PhD
Chairperson, BCOM Institutional Biosafety Committee