Institutional Biosafety Committee	SOP #: RSP.023.00
Effective Date	3/10/2022
Last Revision/Review	

1. Purpose

Biological safety is the discipline that addresses the safe handling and containment of biohazardous materials in order to protect humans, animals, plants and the environment. The Biosafety policy describes the College's stance on the regulation, handling, containment and disposal of biohazardous material.

The National Institutes of Health (NIH) requires the existence of an Institutional Biosafety Committee (IBC) for research involving recombinant and synthetic nucleic acid molecules. The Burrell College of Osteopathic Medicine IBC reviews, approves and oversees projects in accordance with the responsibilities defined in Section IV-B-2 of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. Burrell has expanded the scope of the IBC to include oversight, administration and review of College policies and research involving any microorganism, biologic toxin, or other biologic material which may pose a threat to humans, animals, plants or the environment. The IBC is charged with providing institutional assurance to the Dean that research is conducted in accordance with current local, state and federal guidelines and regulations relating to the use and disposal of biohazardous material. To this end, the IBC assists and advises researchers in meeting their responsibilities to ensure that all biological aspects of research are conducted in a safe manner using established biosafety standards, principles and practices.

The IBC is empowered to withhold authorization of any studies that do not adhere to Centers for Disease Control and Prevention (CDC) and NIH Guidelines until containment requirements are established.

2. Related Policy/Authority

Burrell College Biosafety Policy

Section IV-B-2 of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Biosafety in Microbiological and Biomedical Laboratories, 6th Edition

3. Faculty/Staff Responsibilities

Assistant Dean for Research

Chair, Institutional Biosafety Committee: The IBC Chair is responsible for implementing College policies and procedures set forth by the committee; monitoring compliance; reporting problems; investigating incidents; assisting laboratory directors and principal investigators in training of personnel; and providing technical advice on biosafety and biosecurity matters. The IBC Chair also provides guidance in current biosafety practices to non-research related areas such as teaching and clinical laboratories.

4. Definitions/Abbreviations

Biohazardous materials: Any material of biologic origin that is potentially hazardous to humans, animals, plants and the environment including but not limited to:

Known pathogenic agents: bacteria, viruses, fungi, parasites and prions.

Nucleic acids used in genetic manipulations (recombinant DNA technology, synthetic biology).

Cell lines: human or non-human primate derived; lines deliberately infected with a pathogen or exposed to a biologic toxin; any recombinant cell line.

Animals including research and wild animals that are known or suspected to harbor pathogenic organisms.

Toxins of biologic origin.

Plant materials including those that are known or suspected to harbor plant pathogens or plant pests; transgenic plants; and exotic plants.

Animal materials including transgenic animals; blood, blood components, body fluids, tissues or organs from animals known or suspected to harbor pathogenic organisms.

Human materials including human blood, blood components, body fluids, tissues or organs.

Vectors including arthropods that are known or suspected to harbor pathogenic organisms.

Select agents are agents that have been determined by the federal government as being capable, if released, of causing a serious public health crisis or are high consequence agricultural pathogens. The select agent lists can be found in 42 CFR Part 73 (human and overlap), 7 CFR Part 331 (plant), and 9 CFR Part 121 (animal).

Containment refers to the safe work practices, equipment and facility design used to protect personnel, the environment and the community from exposure to biohazardous materials.

The Centers for Disease Control's publication Biosafety in Microbiological and Biomedical Laboratories (BMBL, 6th Edition) defines four biosafety levels (BSL-1, -2, -3, and -4) that describe increasing levels of containment.

Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

5. Procedural Steps

1. Functions and Responsibilities of the IBC

1.1 Specific functions and Responsibilities are as follows:

1.1.1 Advise the Assistant Dean for Research on all developments and practices regarding the use of potentially biohazardous materials

1.1.2 Review, approve and monitor all Burrell research projects involving biohazardous material for which BSL-2 or greater containment and practices are required.

1.1.3 Review, approve and monitor all Burrell research projects that fall under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

1.1.4 Ensure administration of the biological safety program at Burrell.

1.1.5 Review IBC procedures annually.

1.1.6 Assess containment levels, facilities, procedures, practices, training and expertise of personnel involved in proposed research in accordance with current biosafety standards.

1.1.7 Notify the Principal Investigator (PI) of the results of the IBC review and approval process.

1.1.8 Review and approve Burrell policies in accordance with federal regulations and guidelines that cover biological safety and make recommendations to the Assistant Dean for Research on relevant biosafety matters. Review and adopt Burrell emergency plans covering accidental spills and personnel contamination resulting from research using potentially hazardous biological materials. Review site safeguards and security plans for biologic materials.

1.1.9 Review incidents and determine level of significance, level of violation, and assess required action. When appropriate, investigate potential violations of the NIH Guidelines or Burrell policies, research-related accidents or illnesses involving hazardous biological materials, and any incidents or problems involving hazardous biological materials. Report results of such investigations to the respective responsible Department Head, and to the Assistant Dean for Research. Report significant problems or violations to the NIH Office of Biotechnology Activities (OBA) as per Section IV-B-2-b-(7) of the NIH Guidelines and as per OBA FAQ guidance document on incident reporting.

1.1.10 Maintain reviews, minutes and reports in an orderly and retrievable fashion.

1.1.11 Submit an annual report to NIH OBA that includes a current membership roster detailing relevant roles and biographical sketches for new members and updated biographical sketches for existing members.

1.1.12 The IBC Chair is responsible for the training of all IBC members.

1.2 Meetings

1.2.1 The meeting format should facilitate the taking of minutes and accommodate open attendance. Acceptable approaches for satisfying the NIH Guidelines include face-to-face meetings and the use of technology such as teleconferencing or videoconferencing. Meetings may be open to the public, and minutes will be provided upon request in accordance with state and federal laws and Burrell policy.

1.2.2 The IBC will hold meetings as needed for the conduct of business. The Chair will develop and distribute a proposed agenda before each meeting. Meetings will proceed and official business be conducted only when a quorum, defined as more than half of the voting members, is present. All research subject to the NIH Guidelines must be reviewed at a convened meeting of the IBC with a quorum present. Meeting minutes will be taken to accurately reflect the topics of discussion. Minutes will be reviewed, approved by the members and maintained on file.

1.3 Confidentiality

1.3.1 All business of the IBC shall be subject to disclosure according to the NIH Guidelines and the Freedom of Information Act. Research reviews and other business of the IBC shall be conducted in compliance with these policies, guidelines and laws in such a

matter as to preserve the academic freedom and confidentiality of the processes, participants and stakeholders to the extent possible.

1.4 Conflicts of Interest

1.4.1 No member of the IBC may review or vote on a project with the following conflicts:

1.4.1.1 Institutional conflict of interest

1.4.1.2 Conflicts of commitment

1.4.1.3 Individual conflicts

1.4.1.4 Financial

1.4.1.5 Competing

2. Procedure for Applicant

The IBC is responsible for reviewing all research projects involving biohazardous materials including laboratory, animal and field studies. In addition, the IBC is responsible for formulating and recommending biosafety policies and establishing procedures for the safe handling of nonradioactive biohazardous waste; reviewing and advising with regard to situations that represent potential biological hazards including dual use research of concern (DURC); and reviewing research personnel, facilities, procedures and proposals involving biohazardous material. The IBC is the only entity with the authority to review all proposed research involving biohazardous materials performed under the auspices of The Burrell College of Osteopathic Medicine. The IBC is authorized to create specific procedures that relate to the operation of the program.

Researchers using any of the following shall complete and submit an IBC application form for review and approval:

- Recombinant DNA
- Agents that are potentially infectious for humans, animals or plants
- Toxins
- Human blood, body fluids, or unfixed tissue
- Tissues, organ or cell cultures of human origin
- Human gene therapy

All research involving biohazardous material must be reviewed and approved by the IBC prior to initiation of the research. The IBC's authority is granted by the President via the Assistant Dean for Research, who is the Institutional Official. The IBC has the authority to act independently to bind all activities falling under their purview.

2.1 IBC Oversight and Approval

2.1.1 Any individual planning to (a) use microorganisms, biological toxins, or other materials which may pose a hazard to humans, animals, plants or the environment, for which biosafety level 2 or greater practices, techniques, equipment, or facilities are required or (b) employ recombinant DNA technology, must not do so without prior IBC approval. All laboratories and animal facilities certified to be biosafety level 2 or higher are to be inspected by the IBC on a periodic basis. Individuals planning to obtain materials referenced above for which biosafety level 2 or greater practices, techniques, equipment, or facilities are required must contact the IBC Chair prior to receipt of such materials.

2.1.2 Consequences of Noncompliance

2.1.2.1 It is imperative that biosafety policies and procedures be strictly followed to ensure the safety of workers and to ensure compliance with government guidelines and regulations. Noncompliance may jeopardize the ability of the College to obtain federal funding or result in suspension of work of all federally funded research. Grantees and contractors must be prepared to demonstrate that proper standards have been put in place or practice.

3. **Review**

3.1 Review by IBC Chair

Biosafety Level 1 or exempt rDNA activity will be reviewed by the IBC Chair. The Chair will notify the PI in writing of the determination of his review and a copy of the determination along with the application will be maintained in the Office of Research & Sponsored Programs for documentation. As long as the activity does not significantly change, no additional action is required by the IBC or the PI.

3.2 Designated Review

Blood draws by fingerstick: At least one member of the IBC, designated by the IBC chair and qualified to conduct the review, will be assigned to review the protocol and be given the authority to approve, request modifications, or recommend full committee review. All IBC members receive a copy of these protocols and have the opportunity to comment. Any IBC member may call for a review of the protocol by the convened IBC.

3.2.1 Designated review for additional protocols may be used under exceptional circumstances, as determined by the IBC chair, as permitted by federal regulations.

3.3 Full Committee Review

Protocols involving non-exempt rDNA activity (as per the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules), or Biosafety Level 2 and higher biocontainment levels (except blood draws by fingerstick) will be reviewed at the next available IBC meeting. Annual continuation and new applications every three years are also required. Blood draws using venipuncture require Full Committee review

3.4 Review Outcomes

3.4.1 Approved: The new protocol submission satisfactorily addresses all issues and the submission is fully approved. No modification is necessary on the part of the principal investigator.

3.4.2 Modifications Required: Minor issues remain that must be addressed by the principal investigator prior to approval. The revised protocol submission is reviewed by the primary reviewer and may be approved outside of the full IBC if changes are deemed satisfactory. Multiple revisions are allowed and may be necessary in some cases.

3.4.3 Deferred: Significant issues remain that require full IBC review upon the principal investigator's response to the requested revisions.

3.4.4 Rejected: The protocol submission is not approved and has not been recommended for further consideration by the IBC.

3.5 Amendments

Minor changes to a protocol, such as a change in personnel (not including the PI), need only notification to the IBC. Major changes, such as a change in previously described procedures, PI, quantity of material, organism or cell lines used, must be submitted to the IBC committee for review before the requested change is implemented.

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

7. Maintenance

Institutional Biosafety Committee – will review annually

8. Signature

Signature on File	3/10/2022
IBC Chair	Date

9. Distribution List

Internal/External

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/ Replacement Procedure? (if applicable)	Approval Date