POLICY & PROCEDURE DOCUMENT

NUMBER: 2.7001

SECTION: Research

TITLE: Institutional Biosafety Committee Policy

DATE: November 6, 2017

REVISED: May 3, 2021

AUTHORIZED BY: Dr. Cheryl Stevens, Provost and Vice President for Academic Affairs

I. Purpose and Scope

Western Kentucky University (WKU) is committed to the safe, responsible, legal, and ethical use of biological materials and technologies in research and instruction. An Institutional Biosafety Committee (IBC) has been created to develop policies and procedures to ensure the health and safety of all faculty, staff, students, patients, and visitors at WKU and to ensure all federal, state and local regulations are followed. WKU Office of Research Integrity (ORI) provides guidance in the protection of the rights, welfare, and security of faculty, staff, and students involved in activities throughout the WKU campus system and supporting communities to ensure compliance with federal, state and local regulations.

The policies and procedures herein apply to all parts of WKU including satellite facilities, regional campuses, and facilities run by affiliated and related foundations.

As a condition for receiving funding from the National Institutes of Health (NIH), institutions must ensure that all research conducted at the institution comply with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. WKU thereby gives assurance that it is in compliance with the National Institutes of Health Office of Biotechnology Activities Policy (OBA policy). The OBA policy is applicable to all research, research training, experimentation, biological testing, instructional, and related activities, involving NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules conducted at WKU, or at another institution as a consequence of the sub-granting or subcontracting of a supported activity by WKU.

The IBC reviews, approves, and oversees projects in accordance with the responsibilities set forth in the OBA policy and in the institutional policy described herein.

II. Policy

A. Institutional Biosafety Committee

1. Western Kentucky University recognizes the importance of investigative research as well as the need for all faculty, staff, students, and visitors to work and meet in an environment free of undue risks to their health and well-being. The Institutional Biosafety Committee (IBC) will, in part, ensure the University meets this goal.

2. Institutional responsibility is delegated from the Provost to the Associate Provost for Research and Graduate Education who oversees the Compliance Manager in the Office of Research and Integrity (ORI). The Compliance Manager works with the Institutional Biosafety Committee (IBC) Chair.

3. The IBC will provide oversight for university research and instructional activities involving recombinant or synthetic nucleic acid molecules, culturing of microorganisms, agents infectious to plants, humans, or animals, cultures of tissues, organs, and cells of human origin, human gene therapy, and Select Biological Agents and Toxins as defined by U.S. federal agencies. If in doubt as to whether a material constitutes a potential biohazard, please contact the IBC Chair.

4. IBC will also provide oversight for instructional activities involving biosafety level 2 methodologies.

5. The IBC will convene a minimum of once per year to conduct committee business.

6. IBC procedures will be reviewed annually, or more frequently as necessary.

7. This committee shall serve as the IBC as defined by the National Institutes of Health.

B. Composition of the Institutional Biosafety Committee (IBC)

1. IBC members will be appointed by the Associate Provost for Research and Graduate Education of Western Kentucky University.

2. The IBC will be collectively capable of assessing the risks to the public or the environment of those activities described above. The IBC must contain persons with expertise in recombinant and synthetic nucleic acid technology, biological safety, and physical containment.

3. The IBC shall include a Chair, who will also serve as the Biological Safety Officer (BSO) and is a full-time faculty member of WKU. Duties of the BSO will be as defined by the National Institutes of Health (NIH) and the IBC. The NIH requires that the IBC shall be composed of no less than five total (5) members.

4. The WKU-Environmental Health and Safety Department (EHS) will have committee membership. One person shall be appointed by the Director of the Environmental Health and Safety Department to serve on the IBC.

5. The IBC must contain no less than one person representing laboratory technical staff.

6. The IBC must contain no less than one WKU faculty member, other than the Chair/BSO.

7. The IBC must contain no less than two (2) members of the general public unaffiliated with the university.

8. The IBC will ensure at least one scientist with expertise in plant, plant pathogen, or plant pest containment principles is on the committee with full voting privileges when experiments utilizing plants are under review.

9. The IBC will ensure at least one scientist with expertise in animal containment principles is on the committee with full voting privileges when experiments utilizing animals are under review. Some applications may also require review by the WKU Institutional Animal Care and Use Committee.

10. The IBC reserves the option of appointing *ad hoc* temporary members to assist in the review of pending applications. Temporary members will be appointed as deemed necessary by the committee. An *ad hoc* member has one vote on the consideration of specific proposals. Proposals on which *ad hoc* members may vote must be specifically identified by the committee prior to the appointment of the *ad hoc* member.

III. Procedure

This institution has established an Institutional Biosafety Committee (IBC), which is qualified through the experience and expertise of its members to provide oversight for university activities, both instructional and research, involving recombinant or synthetic nucleic acid molecules, culturing of microorganisms, agents infectious to plants, humans, or animals, cultures of tissues, organs, and cells of human origin, human gene therapy, and Select Biological Agents and Toxins as defined by U.S. federal agencies.

A. Conflict of Interest

1. No member of the IBC may be involved (except to provide information required by the committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

2. Members of the IBC may not vote on proposals that list the member as the Principal Investigator (PI) or co-PI.

B. Training of IBC Members

All IBC committee members must undergo relevant CITI (Collaborative Institutional Training Initiative) Program training at the time of appointment. Additional training sessions will be offered by WKU on an "as needed" basis. Training sessions should cover, but not necessarily be limited to, technical training of laboratory methodologies, informational presentations of the current scientific understanding of relevant fields, the NIH Guidelines, and instruction on IBC committee structure and function.

C. Public and University Access to IBC Activities

1. The IBC may open its meetings to the public when possible and consistent with the protection of privacy and proprietary interest.

D. Who Must Apply

Researchers or instructors engaged in activities involving any of the following:

- Recombinant and synthetic nucleic acids: In the context of the NIH Guidelines, recombinant and synthetic nucleic acids are defined as:
  (i) molecules that are constructed by joining nucleic acid molecules and can replicate in a living cell;
  (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules; (iii) molecules that result from the replication of those described in (i) or (ii) above.
- Agents known to infect plants, humans, or animals (including but not limited to bacteria, viruses, fungi, rickettsia, protozoa, or parasites)
- Select Pathogenic Agents and/or Toxins : Biological select agents and toxins are a subset of agents that the United States Departments of Health and Human Services (HHS) and Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products.
- All work involving use of human-derived or non-human primate materials, (i.e. blood, body fluids, tissues or cell lines)
- Human gene therapy
- Culturing of microorganisms

E. Researcher/Instructor Responsibilities

1. Researchers and instructors are responsible for the activities conducted within their respective laboratories or research facilities. They are responsible for carrying out all activities in accordance with IBC approved protocols, and in a lab approved for the proposed work. They must promptly report biohazard incidents to the BSO or laboratory safety officer, and if possible, assist in any decontamination, inquiry, and reporting of the incident, as may be required.

2. Researchers and Principal Investigators are ultimately responsible for the instructing and training their staff and students engaging in potentially biohazardous activity.

3. Researchers and instructors are responsible for supervising laboratory staff and students to ensure that appropriate safety techniques and procedures are employed.

F. Procedures for Application and Approval

1. All application materials will be available on the WKU Office of Research Integrity (ORI) website and should be downloaded and completed by the applicant.

2. The IBC actively encourages any submitting applicant to seek input from the IBC members or the Chair-BSO to prevent undue delays prior to submission. The IBC strives to minimize the time and effort required by the applicant to successfully acquire permission for proposed activities.

3. Applications will be submitted to the WKU ORI or the IBC Chair-BSO and reviewed for completeness. If the applications are incomplete, they may be returned to the applicant without review. If the application is complete, it will be reviewed by the IBC and the results of the review communicated to the applicant in a timely manner.

4. Applications will be scored as follows:

    a) Accept: allows the researcher/instructor to begin immediately with experiments

    b) Reject: the researcher/instructor may not proceed with the experimentation

    c) Accept with modification: the researcher/instructor can proceed with experimentation provided he/she accepts modifications provided by the committee.

5. "Fast Track Approval". For applications encompassing only Risk Group 1 organisms and/or Biological Safety Containment Level 1, the Chair-BSO may grant approval without seeking immediate full committee consideration. For this approval all applications must be completed and filed by the applicant. *The full committee reserves the privilege of reviewing the Fast Track Approved Protocols.* It is the intention of the IBC to use Fast Track Approval to ease and simplify application procedures for low risk activities without compromising institutional oversight.

6. The IBC recognizes that much research takes place without external funding sources. Therefore, applications must also be filed to seek approval for all relevant activities conducted without a specific sponsor. Research, in this category is defined as a "Standing Research Initiative".

7. Filing of Applications and Duration of Approval

    a) Applications must be filed when grant proposals are filed with the WKU Office of Sponsored Programs (OSP). IBC applications are directed to the IBC Chair and Compliance Manager for consideration.

    b) Approved applications associated with grant proposals will remain approved for the entire duration of the awarded grant (not to exceed 5 years).

c) Protocols are approved for Standing Research Initiatives and instructional activities involving BSL-2 methodologies, risks groups, or containment for 3 year(s), at which time re-submission is required.

d) The researcher/instructor must submit an addendum if, for any reason, organisms, methodologies, rooms, or protocols are changed or modified on any approved protocol. The researcher/instructor is encouraged to seek guidance from an IBC member or the Chair-BSO, in such instances.

8. Application for Use of Select Agents.

a) All applicants will be directed to Environmental Health and Safety for all matters concerning Select Agents.

G. Noncompliance

Definitions

Noncompliance: Failure (either intentional or unintentional) to comply with applicable federal regulations, state or local laws, the requirements or determinations of the IBC, or university policy regarding institutional biosafety. Noncompliance may be minor (non-serious), serious, and may also be continuing.

Minor or non-serious noncompliance: Noncompliance that does not increase risk to research participants/subjects or affect the integrity of the research/data. Examples of minor noncompliance may include, but are not limited to the following: lapses in continuing IBC approval, minor changes in or deviations from an approved protocol, or administrative errors.

Serious noncompliance: Noncompliance that increases risk to researchers, research participants /subjects or affects the integrity of the research/data. Examples of serious noncompliance may include, but are not limited to the following: conducting or continuing non-exempt research without IBC approval; inappropriate oversight of the research to ensure the safety of researchers, research participants or subjects; inappropriate oversight of the research to ensure the integrity of the research/data.

Continuing noncompliance: Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of IBC requirements. Examples of continuing noncompliance may include but are not limited to the following: repeated failures to obtain IBC approvals for research, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

H. Noncompliance with WKU Institutional Biosafety Policy

A researcher or instructor who is found by the IBC to willfully or negligently be in violation of Federal, State, or WKU guidelines and policies governing the use of biohazardous reagents, potentially hazardous human materials, infectious agents, or recombinant or

synthetic nucleic acid molecules may have his/her IBC approval suspended by the IBC, pending further investigation by the IBC. If the IBC's final action includes revocation of IBC approval of the protocol, the IBC will notify the Associate Provost for Research and Graduate Education, who is in turn authorized to notify the Office of Sponsored Programs, the researcher's dean and department head (or equivalent), the Provost and Vice President for Academic Affairs, and relevant agencies (including granting agencies). Termination of an IBC protocol may require termination of related IACUC or IRB protocols. Any significant problems, violations, or any significant research-related accidents or illnesses must be reported to the Office of Science within 30 days if the activity is supported by federal funds.

I. Procedure for Handling Allegations of Noncompliance

1. Any concerns or allegations of noncompliance are constantly solicited and should be directed to the attention of the Chair of IBC, Associate Provost for Research and Graduate Education, or Compliance Manager without delay.

2. There are no restrictions on who can report alleged non-compliance and there will be no threat of reprisals against those reporting.

3. All allegations will remain confidential to the furthest extent possible.

4. The IBC Chair, in consultation with the Compliance Manager, will conduct an initial inquiry to determine if further investigation and review by the full IBC is warranted. The Compliance Manager will notify the Associate Provost for Research and Graduate Education when an inquiry is initiated.

5. Persons named in the complaint/allegation will have the opportunity to respond in writing. If a researcher/instructor is contacted for a response during an initial inquiry, a written response will be requested by a specific date.

6. If further investigation or convened IBC review is not warranted (e.g. dismissal of the allegation or referred to another University process), the allegation will be considered resolved. The IBC will be informed of all allegations and outcomes of any initial inquiry at the next convened meeting and the Office of Research Integrity.

7. If further investigation is deemed warranted, the allegation will be reviewed by all members of the IBC. Any individual with a potential conflict of interest may not participate in the investigation.

8. In all cases, researchers/instructors will be informed in writing of the further investigation. The Provost and Vice President for Academic Affairs, the Associate Provost for Research and Graduate Education, and the researcher's dean and department head (or equivalent), will also be notified that an IBC investigation will take place. A written response from the researcher will be requested, depending upon the nature of the alleged noncompliance, to facilitate the review and conclusion of the investigation.

9. An activity can be temporarily suspended until such time as a review by a quorum of the IBC committee members, and only if a majority of the quorum votes for suspension.

10. Corrective action(s) will be based on the nature of the noncompliance, extent to which research subjects or research personnel were placed at risk, previous noncompliance, etc. The range of possible corrective actions that the IBC may consider includes, but is not limited to:
    - Modification(s) of the IBC protocol through amendments initiated by the researcher
    - Monitoring of research activities (including audits or assessments of technical abilities)
    - Education or training for the researcher and/or research staff
    - Additional reporting requirements
    - Limitations on research activities, use of research facilities, or use of research data
    - Suspension or termination of IBC approval for one or more of the investigator's protocols
    - Suspension of personnel from working with recombinant or synthetic nucleic acid molecules, culturing of microorganisms, agents infectious to plants, humans, or animals, cultures of tissues, organs, and cells of human origin, human gene therapy, and Select Biological Agents and Toxins

11. When approval is suspended or terminated, an explanation will be communicated to the researcher(s) and their dean and department head (or equivalent), along with any corrective actions required to ensure future compliance with the regulations. A decision by the IBC to suspend or terminate an application or protocol may not be overruled, or reversed by the University, its officials, or other institutional compliance committees.

12. The researcher/instructor will have 14 days to appeal the IBC decision in writing. The appeal will be considered during a scheduled IBC meeting, and the researcher/instructor may be invited to attend or may request to speak at the meeting. The researcher/instructor will be notified of the IBC decision within 14 days. The IBC decision will be final.

13. If the researcher/instructor does not comply with required corrective actions, additional action(s) may be taken, including suspension of IBC approval(s) for ongoing IBC-related activities. The researcher/instructor and the convened IBC will be notified of resolution of corrective actions or the need for additional actions.

14. Consideration for reinstatement of approval for activities will be based on whether there are remaining concerns or continuing noncompliance on the part of the researcher or research staff.

15. Records relating to review and investigation of noncompliance will be retained by the Office of Research Integrity for a minimum of three years.

IV. Resources

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2019)

CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL; 5th Edition)

V. Reasons for Revision

May 2021
Non-substantive changes resulting from fifth-year review in accordance with Policy 0.000V.

VI. Related Policies

Policy 2.730V *Research Misconduct and Non-compliance*