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| Internal Regulation Title | Composition and Governance of the NKU Institutional Biosafety Committee (IBC) | | | | |
| Date Last Revised | 05/01/2018 | Date Created | 10/05/2017 | Revision # | 2.0 |
| Regulation Number | 5 | Required by: | <input type="checkbox"/> OHRP <input type="checkbox"/> Funding Agency <input type="checkbox"/> OLAW | | |
| Applicability | <input type="checkbox"/> RGC Internal <input type="checkbox"/> Researcher | | <input checked="" type="checkbox"/> Institutional | | |
| Subgroup | <input type="checkbox"/> NKU Compliance | <input type="checkbox"/> IRB | <input type="checkbox"/> IACUC | <input checked="" type="checkbox"/> IBC | |

1.0 Purpose

The purpose of this regulation is to describe the composition and governance of the NKU IBC.

2.0 GENERAL INFORMATION AND SCOPE

Northern Kentucky University recognizes the necessity for all faculty, staff, students, visitors and community neighbors to work, meet, and live in an environment free of undue risks to their health. The Institutional Biosafety Committee (IBC) will, in part, ensure that NKU meets this goal. The IBC will provide oversight for university research activities involving recombinant DNA, culturing of microorganisms, agents infectious to plants, humans, and animals, human gene therapy, cultures of tissues, organs, and cells of human origin, and Select Agents as defined by U.S. federal agencies. This committee shall serve as the IBC as defined by the National Institutes of Health and will administer policies and procedures mandated by the document *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* and by NKU regulations and standard operating procedures.

3.0 DETAILS

A. APPOINTMENT OF IBC MEMBERS

IBC members shall be appointed by the Vice President for Graduate Education, Research and Outreach. See the IBC SOP "Appointment and Resignation of Committee Members" for procedures related to appointment or resignation.

B. COMPOSITION OF THE IBC

- Collectively, the committee should have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment.
- The IBC shall be composed of a Chair/Biological Safety Officer (BSO) with no fewer than 6 members
- The IBC shall include:
 - A Chair, who will also serve as the BSO and is a full-time faculty member of NKU. Duties of the BSO will be defined by the National Institutes of Health and the IBC.
 - A NKU Emergency and Safety Management representative
 - No less than one person representing laboratory technical staff.
 - No less than one NKU faculty member, other than the Chair/BSO.

- At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community).
- At least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants*, require prior approval by the Institutional Biosafety Committee.
- At least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals*, require Institutional Biosafety Committee prior approval.

As needed:

- The IBC reserves the privilege of appointing *ad hoc* temporary members to assist in the review of pending applications. Temporary members will not necessarily be appointed by the Vice Provost for Graduate Education, Research and Outreach, but 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.
- When the institution conducts recombinant or synthetic nucleic acid molecule research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the Institutional Biosafety Committee (see Section IV-B-3, of the NIH Guidelines).
- In order to ensure the competence necessary to review and approve recombinant or synthetic nucleic acid molecule activities, it is recommended that the Institutional Biosafety Committee: (i) include persons with expertise in recombinant or synthetic nucleic acid molecule technology, biological safety, and physical containment; (ii) include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment, and (iii) include at least one member representing the laboratory technical staff.

C. TERM LIMITS

Members and the Chair/BSO shall be appointed for three (3) year terms.

D. CONFLICT OF INTEREST

See IR #1 "Conflict of Interest – Institutional Biosafety Committee".

E. TRAINING OF IBC MEMBERS

All IBC members must undergo an initial training upon joining the IBC and refresher trainings every three years while serving on the committee. Training will be offered by NKU's Office of Research,

Grants, and Contracts, NKU’s Department of Safety and Emergency Management, and the NKU Institutional Biosafety Committee. See the NKU Institutional Biosafety Committee website for training information.

F. ADMINISTRATIVE SUPPORT

The NKU Office of Research, Grants & Contracts (RGC) will provide administrative support for the IBC. Duties of the RGC will include but not be limited to: assistance in contacting new members, recording, editing, and distributing the minutes of committee meetings, contacting members or potential members with relevant information concerning the committee, collecting, housing, and distributing committee documents and applications.

G. PUBLIC AND UNIVERSITY ACCESS TO IBC ACTIVITIES

See IR #2 “Public Interest of the Institutional Biosafety Committee”

4.0 REFERENCES

[NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(NIH Guidelines\)](#)

NKU IBC Standard Operating Procedure #1 - Appointment and Resignation of Committee Members

NKU IBC Internal Regulation #2 - Public Interest of the Institutional Biosafety Committee

NKU IBC Internal Regulation #1 - Conflict of Interest – Institutional Biosafety Committee

5.0 FORMS OR ATTACHMENTS

6.0 DEFINITIONS

Approvals

| Title | Approved | Date Approved | Not Applicable |
|--------------------------------|-------------------------------------|---------------|-------------------------------------|
| Manager of Research Compliance | <input checked="" type="checkbox"/> | 04/23/2018 | <input type="checkbox"/> |
| IBC Chair | <input checked="" type="checkbox"/> | 04/23/2018 | <input type="checkbox"/> |
| Institutional Official | <input type="checkbox"/> | | <input checked="" type="checkbox"/> |

Revisions

| Title | Approved | Date Approved | N/A | Summary |
|--------------------------------|--------------------------|---------------|--------------------------|---------|
| Manager of Research Compliance | <input type="checkbox"/> | | <input type="checkbox"/> | |
| IACUC Chair | <input type="checkbox"/> | | <input type="checkbox"/> | |
| Institutional Official | <input type="checkbox"/> | | <input type="checkbox"/> | |