

## **Institutional Biosafety Committee Policies and Bylaws**

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 instructional and 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 DNA Molecules (NIH Guidelines) and by NKU policies.

### **Section I: Composition and Governance of Committee**

- I. Selection of IBC Members
  - A. The IBC shall be appointed by the Associate Provost for Research of Northern Kentucky University.
  
- II. Composition of the IBC
  - A. The IBC will be collectively capable of assessing the risks to the public or the environment of those activities described above.
  - B. The IBC shall be composed of a Chair/Biological Safety Officer (BSO) with no less than 6 members
  - C. 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.
  - D. The NKU-Environmental Health and Safety Department (EHS) will have committee membership of one person.
  - E. The IBC will contain no less than one person representing laboratory technical staff.
  - F. The IBC will contain no less than one NKU faculty member, other than the Chair/BSO.
  - G. The IBC will contain no less than two members of the general public unaffiliated with the university.
  - H. The IBC will ensure at least one scientist expert in plant, plant pathogen, or plant pest containment principles is on the committee with full voting privileges when experiments utilizing plants are under review.
  - I. The IBC will ensure at least one scientist expert in animal containment principles is on the committee with full voting privileges when experiments utilizing animals are under review. Alternatively, the committee reserves the privilege of placing applications under

review of the NKU Institutional Animal Care and Use Committee. In such instances, the recommendation of the NKU Institutional Animal Care and Use Committee will serve as a single vote.

- J. 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 Associate Provost for Research 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.

### III. Term Limits

- A. Members shall be appointed for three (3) year terms.
- B. Members can serve no more than two consecutive terms before reappointment.
- C. Members of the IBC will appoint the Chair/BSO for a three (3) year term. Any person serving as Chair/BSO may serve more than two consecutive terms when appointed as Chair/BSO for the consecutive terms.

### IV. Conflict of Interest

- A. 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.
- B. Members of the IBC may not vote on proposals which list the member as the principal investigator (PI or Co-PI).

### V. Training of IBC Members

- A. All IBC committee members must undergo no less than one training session per one three (3) year term. Training sessions will be offered by NKU and RGC in collaboration with the members of the IBC.

### VI. The Office of Sponsored Project will provide Administrative Support to the IBC

- A. 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.

- VII. Meetings
  - A. The IBC will conduct a face-to-face annual meeting
  - B. Committee members will be deemed present as long as the condition of audio contact is met.
  - C. The on-going business of the committee may be conducted electronically.
  
- VIII. Public and University Access to IBC Activities
  - A. The IBC encourages university personnel and public citizens to participate in IBC activities.
  - B. The RGC will make available all meeting minutes, proposals, and actions on proposals to any person making such requests.
  - C. To inform the public, all IBC meeting times, dates, and locations will be posted on the RGC website no less than three (3) days prior to the meeting.

## **Section 2: Who Must Apply**

- I. Researchers or academic programs engaged in activities involving any of the following:
  - A. Recombinant DNA: Recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.
  - B. Agents known to infect plants, humans, or animals.
  - C. Explicit exposure of any person to potential infectious agents.
  - D. Human gene therapy
  - E. Select Agents
  
- II. Researchers
  - A. Researchers conducting scientific inquiries outside of formal teaching duties shall be held responsible for completion of all necessary applications.
  - B. For the purposes presented here, scientific inquiries outside of formal teaching duties are defined as external grant or university supported research initiatives and/or individual student or student groups research initiatives (i.e. "399 courses", cooperative education courses, etc)

## **Section 3: Procedures for Application and Approval**

- I. All application materials will be available on the NKU-RGC website and should be downloaded and completed by the P.I. or administrative head.

- II. Completed applications will be submitted to the RGC office and reviewed for completeness. If the applications are incomplete they may be returned to the P.I. without review. If the application is complete, it will be reviewed by the IBC and the results of the review communicated to the P.I. in a timely manner.
- III. Applications will be scored as follows:
  1. Accept: allows the researcher to begin immediately with experiments
  2. Reject: the researcher may not proceed with the experimentation
  3. Accept with modification: the researcher can proceed with experimentation provided he/she accept modifications provided by the committee.
- IV. The IBC actively encourages any submitting P.I./administrative head to seek input from the RGC or the Chair-BSO to prevent undue delays prior to submission. The IBC seeks to minimize time and effort required by the P.I./administrative head to successfully acquire permission for the underlying activities.
- V. 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 still be completed and filed by the applicant. The full committee, however, reserves the privilege of reviewing and re-considering such protocols. It is the intention of the IBC to use Fast Track Approval to speed and simplify grant proposal submission of low risk activities without compromising institutional oversight.
- VI. The IBC recognizes that much research and teaching takes place without exterior 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”, similarly a teaching activity, in this category, is defined as a “Standing Teaching Initiative”.
- VII. Filing of Applications and Duration of Approval
  1. Applications must be filed when grant proposal applications are filed with the NKU-RGC.
  2. Approved applications of grant proposals will remain approved for the entire duration of the granting period.
  3. Protocols are approved for the Standing Research Initiatives and Standing Teaching Initiatives for 3 year(s), at which time re-submission is required.

4. The P.I./administrative head must re-submit an application if, for any reason, organisms, methodologies, or protocols are changed or modified on any approved protocol. The P.I./administrative head is encouraged to seek guidance from the Chair-BSO, in such instances.

VIII. Application for Use of Select Agents.

1. All applicants will be directed to Environmental Health and Safety for all matter concerning Select Agents.