

# KENTUCKY STATE UNIVERSITY

---

## USE OF BIOHAZARDOUS MATERIALS IN RESEARCH AND INSTRUCTION

## Administrative Regulation

### PURPOSE:

To ensure safe handling, storage, and disposal of potentially biohazardous materials, as defined below, used in University research or instructional projects. Enforcement of this policy by the University is meant to provide a safe working atmosphere and a well controlled research environment. University Biosafety Committee review also provides compliance with federal regulations on the use of recombinant DNA.

### POLICY:

All University research and instruction activities involving biohazardous materials, as defined below, shall be reviewed and approved by the University Biosafety Committee (UBC) prior to the use of any such reagent. Projects submitted for sponsorship by external agencies should be submitted for UBC reviews and approvals are coordinated by the Office of Sponsored Programs.

### APPLICABILITY

This policy applies to all research and instructional activities, sponsored and unsponsored, conducted under the auspices of the University. This policy is applicable to all University locations. University projects involving the use of biohazardous materials at other institutions should receive University Biosafety Committee approval from the cooperating institution. Copies of UBC approvals from cooperating institutions should be forwarded to the Office of Sponsored Programs.

### DEFINITIONS:

Biohazardous Material--The categories below represent the areas of primary concern with respect to biosafety. Projects involving material(s) included by any of these categories should be submitted for UBC approval.

1. Chemical Carcinogens used in conjunction with animals.
2. Toxic/Infectious agents used in conjunction with animals.
3. Oncogenic viruses used in conjunction with animals.
4. Infectious agents requiring handling conditions above biosafety Level-1. (Biosafety Level determinations are based on the recommendations outlined by the CC-NIH publication Biosafety in Microbiological and Biomedical laboratories.)
5. Recombinant DNA (unless exempted by National Institutes of Health Guidelines).
6. Human blood and blood products, human body fluids, and/or human tissue.
7. Microbial toxins (>1 mg of pure toxin, or solutions with concentrations of >1 mg/ml pure toxin).
8. Whenever a contractual agreement or grant proposal requires Institutional/University Biosafety Committee approval for the safe handling of a biological or chemical product.

The UBC also serves as an advisory committee for University projects that involve possible biohazards that do not appear to fall into one of these eight areas. When it is unclear as to whether a material constitutes a potential biohazard, the UBC should be consulted. Questions should be directed to the Office of Grants and Contracts.

Materials and Methods--A detailed outline of the parts of an experimental procedure that involve the use of the biohazardous material. Sufficient detail is often provided by copying the relevant sections of a grant proposal; however, the principal investigator (PI) should review the document before submission to the UBC and consider whether the use of the biohazardous material is described with appropriate detail.

UBC--the University Biosafety Committee. A committee appointed to review the use of biohazardous agents in research. The membership of this committee includes Kentucky State faculty and staff with expertise in relevant areas to include the Director of Risk Management. In addition, at least one member of the local community is appointed to the committee to represent local concerns. Membership of this committee is consistent with federal regulations on the review of projects involving the use of recombinant DNA.

### **REQUEST FOR BIOHAZARDS REVIEWS:**

UBC review and approval may be obtained by forwarding two copies of a Materials and Methods outline of the use of the potentially biohazardous materials to the Office of Sponsored Programs. Two copies of the completed Review Transmittal Sheet must also be forwarded to the Office of Sponsored Programs. To avoid delays in review, the investigator should clearly identify projects that involve more than one biohazardous material.

### **APPROVAL PROCEDURE:**

Each UBC submission received by the Office of Sponsored Programs will be pre-reviewed by the Director of Risk Management and a member of the UBC committee. The reviewers will either give approval to the proposed Materials and Methods, determine the appropriate biosafety requirements, and recommend full UBC review; or return the request to the Principal Investigator for additional information/ clarification; or deny the request. If the project is to be conducted in a University laboratory, the UBC will contact the PI and schedule an inspection of the sites where the research will be conducted.

Note: When contacted by UBC, the PI should discuss the need for a written Safety Protocol. A written Safety Protocol is required for the projects where the biohazardous material comes in contact with animals.

Upon receiving a positive recommendation from the UBC, the Office of Sponsored Programs then issues a project approval letter to the principal investigator. It is the responsibility of the PI to ensure that approval letters are properly directed to any funding agency or sponsor.

BIOHAZARDOUS MATERIALS

The categories below represent the area of primary concern with respect to biosafety. Projects involving material(s) included by any of these categories should be submitted for UBC approval.

1. Chemical Carcinogens used in conjunction with animals.
2. Toxic/Infectious agents used in conjunction with animals.
3. Oncogenic viruses used in conjunction with animals.
4. Infectious agents requiring handling conditions above Biosafety Level-1. (Biosafety level determinations are based on the recommendations outlined by the CDC-NIH publication Biosafety in Microbiological and Biomedical Laboratories.)
5. Recombinant DNA.
6. Human blood and blood products, human body fluids, and/or human tissue.
7. Microbial toxins (>1 mg of pure toxin, or solutions with concentrations of >1 mg/ml pure toxin).
8. Whenever a contractual agreement or grant proposal requires University Biosafety Committee approval for the safe handling of a biological or chemical product.

The UBC also serves as an advisory committee for University projects that involve possible biohazards that do not appear to fall into one of these eight areas. When it is unclear as to whether a material constitutes a potential biohazard, the UBC should be consulted. Questions should be directed to the Office of Sponsored Programs.

SUBMISSION PROCEDURE

University Biosafety Committee review and approval may be obtained by forwarding two copies of the Review Transmittal Sheet and the Materials and Methods outline of the use of the potentially biohazardous materials to the Office of Sponsored Programs. To avoid delays in review, the investigator should clearly identify projects that involve more than one biohazardous material.

APPROVAL PROCEDURE

Each UBC submission received by the Office of Sponsored Programs will be forwarded to a member of the UBC and the Director of Risk Management for preliminary review. The reviewers will either give preliminary approval to the proposed submission, determine the appropriate biosafety requirements, and recommend full UBC review; return the request to the Principal Investigator for additional information/clarification; or deny the request. If the project is to be conducted in a University laboratory, the UBC will contact the PI and schedule an inspection of the sites where the research will be conducted. (Note: When contacted by the UBC the PI should discuss the need for a written Safety Protocol. A written Safety Protocol is required for projects where the biohazardous material comes in contact with animals.) Upon receiving a positive recommendation from the UBC, the Office of Sponsored Programs then issues the appropriate UBC approval letter to the PI.

**KENTUCKY STATE UNIVERSITY BIOSAFETY COMMITTEE**

**REVIEW TRANSMITTAL SHEET**

TITLE: \_\_\_\_\_

PRINCIPAL INVESTIGATOR: \_\_\_\_\_

DEPARTMENT/UNIT: \_\_\_\_\_

ADDRESS: \_\_\_\_\_ PHONE NUMBER: \_\_\_\_\_

FUNDING SOURCE: \_\_\_\_\_

PROJECT DURATION: START DATE: \_\_\_\_\_ END DATE: \_\_\_\_\_  
(Anticipated)

1a. Will this project use any of the following items? (Check all that apply)  
\_\_\_\_ Oncogenes \_\_\_\_ Toxins \_\_\_\_ Chemical Carcinogens \_\_\_\_ Live Pathogens  
List \_\_\_\_\_

1b. Will any of the items checked in "1a." be used in conjunction with animals?  
\_\_\_\_ Yes \_\_\_\_ No

2. Will any of the following items be used in this project?  
\_\_\_\_ Yes \_\_\_\_ No - Recombinant DNA/Transgenic Animals or Plants (**If yes, please complete ATTACHMENT A.**)  
\_\_\_\_ Yes \_\_\_\_ No - Human Blood, Human Fluids, or Human Tissues  
\_\_\_\_ Yes \_\_\_\_ No - Microbial Toxins (> 1 mg pure toxin or solutions > 1 mg/ml)  
\_\_\_\_ Yes \_\_\_\_ No - Infectious Agents

3. Has this been previously approved by a regulatory agency? Yes \_\_\_\_ No \_\_\_\_  
If yes, what is the **Approval Date** \_\_\_\_\_ and **Approval Number** \_\_\_\_\_.

4. Does a contractual agreement or grant proposal require a review of the proposal by the University Biosafety Committee even if none of the conditions outline in questions 1 and 2 apply? \_\_\_\_ Yes \_\_\_\_ No

5. Have the procedures involving all biohazardous agent(s) that will be used in the proposed project been approved previously by the Kentucky State University Biosafety Committee?  
\_\_\_\_ No. Review is requested.  
\_\_\_\_ Yes. Refer to the previous approval # \_\_\_\_\_.

PI Name: \_\_\_\_\_

Title: \_\_\_\_\_

6. Location where the Biohazardous agent(s) will be used or stored:

Building \_\_\_\_\_ Room(s) \_\_\_\_\_

7. What is the purpose of this study?

7a. Attach 1) a copy of the Materials & Methods from your proposal (or other supporting documentation) or 2) a description of the biohazard(s) being received and/or its intended use.

8. Identify the source from which the biohazardous agent(s) will be obtained-

---

---

**PLEASE RETURN COMPLETED FORM TO**

**Office of Sponsored Programs**

**Room 415 Hathaway Hall**

**ATTACHMENT A**

KENTUCKY STATE UNIVERSITY  
UNIVERSITY BIOSAFETY COMMITTEE  
**RECOMBINANT DNA REGISTRATION DOCUMENT**

Source of DNA \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Nature of Inserted Sequences \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Host - Vector System \_\_\_\_\_  
\_\_\_\_\_

Will the foreign gene be expressed?     Yes     No

If yes, what protein will be produced \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Date

# UNIVERSITY BIOSAFETY COMMITTEE (UBC)

## REVIEW PROCESS

1. For each incoming proposal, the Office of Sponsored Programs will select a committee member with the appropriate expertise to review the proposal. This committee member and the University's Director of Risk Management will serve as co-reviewers. The reviewers will receive the UBC's Review Transmittal Sheet, the purpose and methods, the review sheet, and any other supporting documentation submitted by the investigator. The reviewers will be given ten business working days for the review process. If necessary, the reviewers may contact the researcher for additional information to assist in the review process. A copy of the additional information must be forwarded to the Office of Sponsored Programs for its files.
2. After reading the proposal, the reviewers will complete the review sheet and choose one of the following:
  - a) approve for full UBC review;
  - b) request a second review by another member of the committee;
  - c) deny the request.

Before returning the review sheet to the Office of Sponsored Programs, the reviewers will be required to provide a brief written summary of the review on the review sheet. At the UBC meeting, the reviewers will be asked to provide a **BRIEF** oral overview of this summary and their decision to the committee.

3. Upon receipt of the complete review sheet, the Office of Sponsored Programs will initiate the appropriate paperwork (e.g., approval letter, assigning a second reviewer, etc.) If full approval is granted by the reviewers and the UBC is in agreement, an approval letter will be issued.

All University research and instruction activities involving biohazardous materials, as defined below, shall be reviewed and approved by the University Biosafety Committee (UBC) prior to the use of any such reagent. Projects submitted for sponsorship by external agencies should be submitted to the Office of Sponsored Programs for UBC reviews and approvals.

### APPLICABILITY

This policy applies to all research and instructional activities, sponsored and unsponsored, conducted under the auspices of the University. This policy is applicable to all University locations. University projects involving the use of biohazardous materials at other institutions should receive University Biosafety Committee approval from the cooperating institution. Copies of UBC approvals from cooperating institutions should be forwarded to the Office of Sponsored Programs.

## DEFINITIONS:

Biohazardous Material--The categories below represent the areas of primary concern with respect to biosafety. Projects involving material(s) included by any of these categories should be submitted for UBC approval.

1. Chemical Carcinogens used in conjunction with animals.
2. Toxic/Infectious agents used in conjunction with animals.
3. Oncogenic viruses used in conjunction with animals.
4. Infectious agents requiring handling conditions above biosafety Level-1. (Biosafety Level determinations are based on the recommendations outlined by the CC-NIH publication Biosafety in Microbiological and Biomedical laboratories.)
5. Recombinant DNA (unless exempted by National Institutes of Health Guidelines).
6. Human blood and blood products, human body fluids, and/or human tissue.
7. Microbial toxins (>1 mg of pure toxin, or solutions with concentrations of >1 mg/ml pure toxin).
8. Whenever a contractual agreement or grant proposal requires Institutional/University Biosafety Committee approval for the safe handling of a biological or chemical product.

The UBC also serves as an advisory committee for University projects that involve possible biohazards that do not appear to fall into one of these eight areas. When it is unclear as to whether a material constitutes a potential biohazard, the UBC should be consulted. Questions should be directed to the Office of Sponsored Programs.

Materials and Methods--A detailed outline of the parts of an experimental procedure that involve the use of the biohazardous material. Sufficient detail is often provided by copying the relevant sections of a grant proposal; however, the principal investigator (PI) should review the document before submission to the UBC and consider whether the use of the biohazardous material is described with appropriate detail.

UBC--the University Biosafety Committee. A committee appointed to review the use of biohazardous agents in research. The membership of this committee includes Kentucky State faculty and staff with expertise in relevant areas to include the Director of Risk Management. In addition, at least one member of the local community is appointed to the committee to represent local concerns. Membership of this committee is consistent with federal regulations on the review of projects involving the use of recombinant DNA.

## REQUEST FOR BIOHAZARDS REVIEWS:

UBC review and approval may be obtained by forwarding two copies of a Materials and Methods outline of the use of the potentially biohazardous materials to the Office of Sponsored Programs. Two copies of the completed Review Transmittal Sheet must also be forwarded to the Office of Sponsored Programs. To avoid delays in review, the investigator should clearly identify projects that involve more than one biohazardous material.



## **APPROVAL PROCEDURE:**

Each UBC submission received by the Office of Sponsored Programs will be pre-reviewed by the Director of Risk Management and a member of the UBC committee. The reviewers will either give approval to the proposed Materials and Methods, determine the appropriate biosafety requirements, and recommend full UBC review; or return the request to the Principal Investigator for additional information/ clarification; or deny the request. If the project is to be conducted in a University laboratory, the UBC will contact the PI and schedule an inspection of the sites where the research will be conducted.

Note: When contacted by UBC, the PI should discuss the need for a written Safety Protocol. A written Safety Protocol is required for the projects where the biohazardous material comes in contact with animals.

Upon receiving a positive recommendation from the UBC, the Office of Sponsored Programs then issues a project approval letter to the principal investigator. It is the responsibility of the PI to ensure that approval letters are properly directed to any funding agency or sponsor.