Policy #2204
Policy for Institutional Biosafety

Date: May 1, 1998

THIS POLICY IS CURRENTLY UNDER REVIEW

INTRODUCTION

James Madison University recognizes the importance of conducting a broad spectrum of original problem-solving research which requires the use of recombinant DNA technology. Cognizant that these activities may be accompanied by some risks, the University requires that the activities by this policy be reviewed and approved by an Institutional Biosafety Committee (IBC) to ensure that it is conducted in accordance with the National Institutes of Health Guidelines For Research Involving Recombinant DNA Molecules as published in the Federal Register on 7/5/1995. This policy is in full compliance with the applicable federal and state laws and regulations. In addition, adherence to this policy shall not exempt investigators employing recombinant DNA molecules in their research from compliance with other applicable laws, regulations or policies (e.g. research with human subjects or research with animals).

APPLICABILITY

This policy is applicable to all recombinant DNA research which is conducted at or sponsored by or under the aegis of James Madison University. No activity involving the construction or handling of recombinant DNA molecules or organisms and viruses containing recombinant DNA molecules shall be initiated without the prior notification, and if necessary, review and approval, of the James Madison University Institutional Biosafety Committee.

DEFINITION OF RECOMBINANT DNA MOLECULES

In the context of this policy and in accordance with the NIH Guidelines (section IB), recombinant DNA molecules are defined as either (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i). Synthetic DNA segments likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or pharmacologically active agent) shall be considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide of polypeptide product, it is exempt from this policy.

INSTITUTIONAL BIOSAFETY COMMITTEE

An institutional Biosafety Committee (IBC) comprised of the University faculty and staff and two outside community members appointed by the Vice President for Academic Affairs shall fulfill the responsibilities described in the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules. The Chair shall be elected by the committee members.

A. Committee Membership
See Institutional BioSafety Committee Requirements.
The IBC members shall be selected so that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research experiments and any potential risk to public health or the environment. At least two members shall not be affiliated with James Madison University (apart from membership on the IBC) and shall represent the interest of the community area with respect to the health and protection of the environment. When possible, there shall be at least one member from each department/unit conducting recombinant DNA research. The Associate Vice President for

Research and Program Innovation and the Director of Sponsored Programs shall also be members.

B. Meetings
The IBC shall meet as needed, but at least once per year. A schedule of meetings shall be publicly posted. Meetings will be open to the public whenever possible, consistent with protection of privacy and proprietary interests. A quorum for conducting business shall consist of two-thirds of current members except that at least one member not affiliated with James Madison University apart from serving in the IBC must be present. The meetings will follow recognized parliamentary procedure.

C. Reports
The IBC will report annually to the University community concerning the performance of its assigned functions as described in Section VII B below.

EXPERIMENTAL CLASSES AND PROCEDURES
The different classes of experiments and particular constraints applying to each (e.g., containment requirements) are found in Section III of the NIH Guidelines for Research Involving Recombinant DNA Molecules. As these regulations are modified by subsequent agency action, those modifications shall be incorporated into this policy. A summary description of each class of experiment and the associated required procedures are outlined in the following subsections.

Experiments which require specific Recombinant DNA Advisory Committee (RAC) review and National Institutes of Health (NIH) and IBC approval before initiation of the experiment.

Experiments in this class cannot be initiated without submission of relevant information on the proposed experiment to NIH, the publication of the proposal in the Federal Register for thirty (30) days of comment, review by the RAC, and specific approval by the NIH. Definitions and examples are presented in III A and B of the NIH Guidelines.

Experiments which require IBC approval before initiation of the experiments.

Experiments in this class require submission of relevant information to the IBC for review and approval must be obtained prior to initiation of the experiments. Definitions and examples are presented in III C of the NIH Guidelines.

Experiments which require IBC notification before initiation of the experiment.

Experiments in this class require submission of relevant information to the IBC prior to initiation of the experiments. Definitions and examples are presented in Section III D of the NIH Guidelines. Approval by the IBC is not required UNLESS the IBC determines the investigator has incorrectly classified the experiments.

FORMS AND PROCEDURES
Each investigator using recombinant DNA molecules in his/her research is required to complete a "Registration Document for Recombinant DNA Research" form for each project (or proposed project) involving recombinant DNA being conducted. This form must be completed and approved by the IBC to receive certification for external funding proposals. However, all projects/activities involving recombinant DNA, whether they are part of a grant proposal or not, must be submitted to the IBC. An "Annual Renewal"

form must also be completed for each project. These forms are available from the IBC and are attached as an appendix to this document.

FUNCTIONS OF THE IBC

A. On behalf of James Madison University, the IBC shall review all proposals to assure compliance with NIH guidelines and University policy on biosafety.

B. On behalf of James Madison University, the IBC shall conduct periodic self-studies of the effectiveness of University policy on biosafety and the implementation procedures, reporting the results to the Vice President of Academic Affairs and recommending any needed revisions. This will involve responsibility for:

1. Reviewing the containment levels of experiments;

2. Reporting within 30 days to the Energy and Environmental Awareness Committee and the Office of Sponsored Programs identified with or violations of the guidelines and research-related accidents or illnesses; the IBC along with the Director for Sponsored Programs, under the direction of the Associate Vice President for Research and Program Innovation, has responsibility for communication with external sponsoring and monitoring agencies;

3. Making recommendations to the Energy and Environmental Awareness Committee and Director for Sponsored Programs concerning applications for exemptions within 30 days of their submission, subject to approval Associate Vice President for Research and Program Innovation.

4. Participating with the Energy and Environmental Awareness Committee in the development of emergency plans to deal with accidental spills and personnel contamination resulting from research;

5. Ensuring through periodic inspections that laboratory standards are rigorously followed;

6. Assessing the training in expertise of recombinant DNA personnel in notifying principal investigators and the University community of the results of the assessments. The Chair of the IBC will maintain the files of all the paperwork relating to the Committee; copies of all records will also be on file in the Sponsored Programs Office.

INVESTIGATOR RESPONSIBILITIES

The Principal Investigator is responsible for reviewing this policy and complying with its requirements. Specifically, he/she will:

a. file a "Registration Document for Research Involving Recombinant DNA" and an "Annual Renewal" form for each project and meet all the requirements of the NIH Guidelines;

b. make available to laboratory staff copies of protocols that describe potential biohazards and the precautions to be taken;

c. provide appropriate instruction and training in practices and techniques necessary to ensure laboratory safety;

d. supervise the laboratory staff to ensure that appropriate safety techniques and procedures are employed;

e. report in writing to the IBC any significant problems pertaining to the operation and implementation of containment practices and procedures;

f. submit applications for external funding of recombinant DNA research to the IBC prior to transmittal for external funding.

REGISTRATION DOCUMENT FOR RESEARCH INVOLVING RECOMBINANT DNA

James Madison University Institutional Biosafety Committee

This form must be submitted for all research involving recombinant DNA molecules. Renewal of approval for each project is required every 12 months. In this document Guidelines refers to Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines, June 1994), as published in the Federal Register 7/5/94, 8/5/94.

General Registration Information

1. Principal Investigator:

2. Department:

3. Phone:

4. Building and room number(s) where research is to be conducted:

5. Project title:

6. Project start date:

7. If part of grant proposal, list agency, grant title: (if pending, list requested funding dates; if funded, list number and funding dates)

8. Does this project contain proprietary information?:

If yes, please describe.

Class of Experiments Involving Recombinant DNA and Containment Levels

1. Which class of the Guidelines for covered experiments apply to the proposed experiments (see section III of the Guidelines). Check which one applies:

____ III-A. Experiments that require RAC, NIH, and IBC approval before initiation.

If class III-A is checked, see items III-A-1 through III-A-4 in the Guidelines, indicate all those that apply,

and explain on a separate sheet.

____ III-B. Experiments that require IBC approval before initiation (see items III-B-1 through III-B-5 in the Guidelines). Check all that apply to III-B and explain in detail each check on a separate page.

____ a. Use of other than a class 1 agent as host-vector system. State class

____ b. A viral vector (other than class 1) will be used:

Will less than 2/3 of a genome be used? Yes No

With helper virus? Yes No

May your experiment enhance pathogenicity (e.g. insertion of oncogene, extend host range)? Yes No

____ c. Whole animals or plants will be used as host.

____ d. Experiments will involve more than 10 liters of culture.

____ e. An attempt will be made to obtain expression of a foreign gene.

____ III-C. Experiments that require IBC notice simultaneously with initiation of experiments (experiments not included in III-A, III-B, and III-D).

____ III-D.Exempt experiments (see items III-D-1 through III-D-5 in the Guidelines).

2. Which physical containment level applies to this proposal (Appendix G, section II in the Guidelines)?

Circle one: BL-1 BL-2 BL-3

3. Describe the rationale for selecting class and containment levels chosen and cite appropriate sections of the Guidelines.

Description of Recombinant DNA Experiments

Please answer in detail each of the questions listed below. Use additional sheets if necessary.

1. Summary of project (1 or 2 paragraphs). Include purpose for which recombinant DNA will be used in the project and briefly describe the range of techniques to be employed. Please define any acronyms and abbreviations.

2. Host strain(s) used, including genus, species, parent strains, and class of each agent.

3. Vectors to be used. Include source.

4. Source and nature of inserted DNA sequences. Include size, gene name(s) and function of gene(s), and sequence(s), if known.

ANNUAL RENEWAL FORM FOR PROJECTS INVOLVING RECOMBINANT DNA

James Madison University Institutional Biosafety Committee

(Please fill out a separate form for each project.)

Principal Investigator:
Department:
Phone Number:
Project Number:
Project Title:
Funding agency(ies)

1. Current status (check one)

____ Initiated Date _____

Expected completion date_____

____ Will be initiated Date_____

____ Continuing

____ Will not be initiated or will be discontinued

____ Completed Date_____

2. This project is being conducted as originally submitted, or all amendments to this proposal have been previously approved.

____ Yes ____ No

If amendments are being proposed , please describe on a separate sheet. Upon review, the Principal Investigator may be requested to complete a new proposal. If containment level or class has changed, please submit a new proposal.

_____ _____
(Signature of Principal Investigator) (Date)

Received and approved by the Institutional Biosafety Committee

_____ _____
(Signature of Chairperson of Institutional Biosafety Committee) (Date)

REGISTRATION DOCUMENT FOR RESEARCH INVOLVING INFECTIOUS AGENTS

James Madison University Institutional Biosafety Committee

In addition to overseeing the use of recombinant DNA technology the Institutional Biosafety Committee (IBC) of James Madison University also oversees the use of infectious agents in biological research. To ensure the proper and safe usage of such agents in teaching and research laboratories at the University, all investigators are required to abide by the regulations and procedures described in Biosafety in Microbiological and Biomedical Laboratories published by the U.S. Department of Health and Human Services (May 1993). In order to monitor activities involving infectious agents, this form must be submitted by all instructors and primary investigators employing infectious agents in their research. It should be updated when any changes occur and at the very least be updated annually. Those investigators who have provided all the information regarding infectious agents on the "Registration Document for Research Involving Recombinant DNA" need not complete this form.

General Registration Information

1. Principal Investigator:

2. Department:

3. Phone:

4. Building and room number(s) where research is to be conducted:

5. Project title:

6. Project start date:

7. If part of grant proposal, list agency, grant title: (if pending, list requested funding dates; if funded, list number and funding dates)

8. Does this project contain proprietary information?: If yes, please describe.

Description of Activities Employing Infectious Agents

Describe in detail; (a) the nature and goals of the project, (b) the basic procedures employed, (c) each of the infectious agents used (including full name, source, genotype, pathogenicity, antibiotic resistance pattern), (d) the biosafety level chosen and the rationale for choosing this level.

Agreement Sheet

I agree to abide by the regulations and procedures described in the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories published by the U.S. Department of Health and Human Services (May, 1993).

_____ _____

(Signature of Principal Investigator) (Date)

____ Received and reviewed by the Institutional Biosafety Committee

_____ _____
(Signature of Chairperson of Institutional Biosafety Committee) (Date)

Approval Sheet

I agree to abide by the Guidelines for Research Involving Infectious Agents (NIH Guidelines) as published in the Federal Register 7/5/1994 in conducting all work using infectious agents.

_____ _____
(Signature of Principal Investigator) (Date)

____Received and reviewed by the Institutional Biosafety Committee

____Approved

____Approval not required

_____ _____
(Signature of Chairperson of Institutional Biosafety Committee) (Date)

Approval Sheet

I agree to abide by the Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) as published in the Federal Register 7/5/1994 in conducting all work using recombinant DNA molecules.

_____ _____
(Signature of Principal Investigator) (Date)

____ Received and reviewed by the Institutional Biosafety Committee

____ Approved

____ Approval not required

_____ _____
(Signature of Chairperson of Institutional Biosafety Committee) (Date)

ANNUAL RENEWAL FORM FOR PROJECTS INVOLVING INFECTIOUS AGENTS

James Madison University Institutional Biosafety Committee

(Please fill out a separate form for each project.)

Principal Investigator:

Department:

Phone Number:

Project Number:

Project Title:

Funding agency(ies)

1. Current status (check one)

____ Initiated Date _____

Expected completion date_____

____ Will be initiated Date_____

____ Continuing

____ Will not be initiated or will be discontinued

____ Completed Date_____

2. This project is being conducted as originally submitted, or all amendments to this proposal have been previously approved.

____ Yes ____ No

If amendments are being proposed , please describe on a separate sheet. Upon review, the Principal Investigator may be requested to complete a new proposal. If containment level or class has changed, please submit a new proposal.

_____ _____
(Signature of Principal Investigator) (Date)

Received and approved by the Institutional Biosafety Committee

_____ _____
(Signature of Chairperson of Institutional Biosafety Committee) (Date)

Approve May 1, 1998 by Linwood H. Rose, President