Institutional Bio-safety Policy

In accordance with the Department of Health and Human Services Guidelines for Research Involving Recombinant DNA Molecules, CU has established an Institutional Bio-safety Committee (IBC) whose responsibilities need not be restricted to recombinant DNA and shall meet the requirements as outlined in Section IV-B-2 of the NIH Guidelines for Research Involving Recombinant DNA molecules. All faculty, staff and students or users of the facilities at CU, who are contemplating use of recombinant DNA research must comply with these Guidelines. All protocols, in which Recombinant DNA will be used, regardless of the funding source, must be submitted to the Institutional Bio-safety Committee for review. The Guidelines are also applicable to projects conducted outside the U.S. by persons associated with or sponsored by this institution.

The following documents will be used by the University as a guide for research, teaching and other activities involving the use of or exposure to potentially biohazardous materials.

1. NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496), published July 5, 1994 and all subsequent amendments issued by the Secretary, Department of Health and Human Services (DHHS). This document will hereinafter be referred to as "NIH Guidelines." Current amendments may be obtained on the NIH Office of Recombinant DNA Activities Home Page at http://www.nih.gov/od/orda/.
2. DHHS Guidelines for Bio-safety in Microbiological and Biomedical Laboratories, 4th Edition May 1999, HHHS Publication No. (CDC) 93-8395) and all subsequent regulations and amendments issued by the Secretary, DHHS. This document will hereinafter be referred to as "BMBL Guidelines".
3. OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030; available at OSHA's home page at http://www.osha.gov/.

Institutional Bio-Safety Committee (IBC)

The Institutional Bio-safety Committee of CU shall be comprised of members selected to have collectively, experience and expertise in recombinant DNA technology, and the capability to assess experiments and potential risks to public health or the environment.

IBC Responsibilities

The primary responsibilities of the IBC are to:

- Review all projects involving, the use of recombinant DNA molecules, carcinogens, infectious disease agents, and other potentially dangerous materials which are not exempt from such reviews;

- Report approvals in accordance with Federal and agency requirements;

- Report non-compliance to the Executive Assistant for Government Relations and Research and other appropriate persons;

- Recommend training of investigators/directors and laboratory personnel engaged in such research;

- Review periodically recombinant DNA research being conducted at the institution to ensure that the requirements of the Guidelines are being fulfilled;

- Adopt emergency plans for accidental spills and personnel contamination resulting from such research;

- Report within 30 days to the Executive Assistant for Government Relations and Research any significant problems with or violations of the Guidelines, and any significant research-related accidents or illnesses, unless the IBC determines that the PI has done so

- The IBC may not authorize initiation of experiments not explicitly covered by the Guidelines until NIH (with the advice of the Recombinant DNA Advisory Committee when required) establishes the containment required

- Perform such other functions as may be delegated to the IBC in fulfilling its responsibility for ensuring that research is carried out in full conformity with the provisions of the Guidelines

Principal Investigators/Project Directors Responsibilities

The principal investigator/project director is responsible for full compliance with the NIH guidelines in the conduct of recombinant DNA research. As part of this responsibility, the principal investigator/project director shall:

- Initiate or modify no recombinant DNA research requiring prior approval by the IBC.
- Determine whether experiments are covered by Section III-C of the Guidelines and follow appropriate procedures.
- Report within 30 days to the IBC and NIH Office of Recombinant DNA Activities (ORDA) all significant problems with and violations of the Guidelines and all significant research related accidents and illnesses.
- Report to the IBC and NIH (ORDA) new information bearing on the Guidelines.
- Be adequately trained in good microbiological techniques.
- Adhere to IBC approved emergency plans for dealing with accidental spills and personnel contamination.
- Comply with shipping requirements for recombinant DNA molecules.

Application for Approval or Registration of Research

All research programs at CU involving recombinant DNA molecules, except those categories of research specifically exempted by the NIH Guidelines, require either approval by or registration with the Institutional Bio-safety Committee (IBC). Approval or registration is required regardless of whether the research program is funded by an agency requiring such certification or not. All new, continuation, or renewal applications involving non-exempt recombinant DNA molecules submitted to the Sponsored Programs Office should be accompanied by the approval from the IBC. Approval from or notification of the IBC is also required whenever investigators initiate or significantly change research involving recombinant DNA molecules under existing grants or contracts.

To comply with institutional policies for studies involving recombinant DNA molecules, the Principal Investigator/Project Director must submit to the Bio-safety Committee a Recombinant DNA Registration Document addressing the following points:

- Source(s) of DNA;
- Nature of inserted DNA sequences (including identification by name of the biological source);
- Host(s) and vector(s) to be used;
- Statement whether a deliberate attempt will be made to obtain expression of a foreign gene, and, if so, what protein will be produced;
- Containment conditions as specified by the current NIH Guidelines;
- If applicable, information on medical surveillance; and,
- A signed statement that the Principal Investigator/Project Director is familiar with the current NIH Guidelines and agrees to abide by their provisions, including a statement that the recombinant DNA molecules being used will not be transferred to other investigators/directors or institutions unless their facilities and techniques have been assured to be adequate.

The Principal Investigator/Project Director has the continuing responsibility to consider whether there is any reason that an increase in biocontainment practices or facilities may be appropriate in any ongoing program approved by the IBC. Should he/she perceive the need for any such increase, the investigator has the responsibility to notify the IBC and to institute the appropriate increases in the level of biocontainment. In contrast, the biocontainment practices and facilities approved by the IBC may not be decreased without prior approval by the IBC and by the funding agency and/or NIH/Office of Recombinant DNA Activities (ORDA) provided that such approval is required.

Copies of the NIH Guidelines (as published in the Federal Register, June, 1994) and subsequent revisions are available through the IBC office, 231 Rowell or copies can be obtained directly from the Office of Recombinant DNA Activities (ORDA), National Institutes of Health, Building 31, Room 4B11, Bethesda, Maryland 20892; phone (301) 496-9838. Investigators who have difficulty interpreting the Guidelines are advised to consult with colleagues and/or call the NIH Recombinant Advisory Committee (RAC); phone (301) 496-6051.