1.0 CHAPTER 1 – SCOPE, POLICY and RESPONSIBILITIES

1.1 SCOPE

1.1.1 General Applicability

The *UCSB Biosafety Handbook* applies to all UCSB faculty, staff, hosted visitors, students, participating guests and volunteers, contract laborers, supplemental personnel and employees of firms working at locations where UCSB has management control of specific biohazards.

1.1.2 Purpose

The purpose of the *UCSB Biosafety Handbook* is to specify the practices, procedures and requirements for safe handling and use of biohazardous materials for research and teaching activities at UCSB.

1.1.3 Definition of Biohazardous Materials

Biohazardous materials and organisms include all infectious agents (bacteria, chlamydia, fungi, parasites, prions, rickettsias, viruses, etc.) which can cause disease in humans, or cause significant environmental or agricultural impact. In addition, work with human or primate tissues, fluids, cells or cell culture; recombinant DNA; transgenic plants or animals; human gene therapy; releases of recombinant DNA to the environment; and work with animals known to be reservoirs of zoonotic diseases will be partly or wholly covered by the policies and procedures set forth here.

1.2 POLICY

It is the policy of the university that all research and teaching involving biohazardous materials will be conducted in a safe manner in order to protect the academic community, as well as the greater community at large.
Further, it is university policy that

NO Risk Group 4 Agents may be used or stored at UCSB

1.3 RESPONSIBILITIES

1.3.1 Chancellor

The Chancellor shall:

A. Establish and implement policies that provide for safe conduct of research and teaching involving biohazardous materials.

B. Maintain an active Institutional Biosafety Committee.

C. Appoint a Biosafety Officer.

D. Ensure compliance with the regulations and guidelines by Principal Investigators conducting research at UCSB.

1.3.2 Institutional Biosafety Committee (IBC)

1. Charge of the Committee

The IBC is advisory to the Chancellor on all matters relating to the safe use of biohazardous materials and organisms. It is the committee's responsibility to establish, monitor, and enforce policies and procedures that meet or exceed applicable norms or regulations for biohazardous materials. Any use of biohazardous materials must be reviewed and approved by the committee. The committee has the authority to impose disciplinary measures in cases where there is violation of UCSB's established biosafety practices and procedures. The committee shall maintain diverse membership representing the community and a variety of university interests. Non-committee faculty or staff with special expertise will be asked to advise the committee when the need arises.

2. Committee Membership and Procedures

A. The IBC is comprised of voting members and nonvoting members. Voting members include a representative from the community with no monetary or research ties to UCSB. Also included are faculty representatives from the College of Medicine, the general campus, an infectious disease specialist, a recombinant DNA specialist, the campus veterinarian, and the UCSB Biosafety Officer. IBC members are selected so that they have the collective experience and expertise to fully evaluate the biohazard risks associated with the wide variety of research proposals which come under its scrutiny. Non-committee faculty or staff with a particular expertise will be asked to advise the committee when the need arises.

B. No member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he or she has been or expects to be engaged, or has a direct financial interest.

C. IBC meetings are normally held quarterly. The IBC will meet no less than three times per year.

3. Functions of the IBC

A. Establish, monitor and enforce policy, practices, and procedures for all work involving biohazardous materials at UCSB. The IBC shall ensure adopted policies, practices, and procedures meet applicable regulatory standards and guidelines.

B. Review biohazardous materials work conducted at or sponsored by UCSB for compliance with adopted policies, regulations, and guidelines. This review shall include an independent assessment of the containment required and an assessment of the facilities, training, and expertise of personnel involved in the research. The IBC shall ensure that the Principal Investigator is provided with the results of the review and determination of approval in a timely manner.

C. Set required containment for research projects. The IBC will use biosafety levels (BSL) recommended by the CDC and NIH as the usual standards of containment to be set for work with a given biohazardous material. The IBC may, at its discretion, increase or reduce the BSL depending on the circumstances presented by a specific project.

D. Periodically review the effectiveness of the UCSB biosafety program.

E. Adopt emergency plans to cover accidental biohazardous materials spills and personnel contamination. The IBC will coordinate with institutional officials and will cooperate with state and local public health departments.

F. Investigate any significant violation of policies, practices and procedures. The IBC will also investigate any significant research related accidents or illnesses. The IBC will determine and impose appropriate disciplinary action following a thorough investigation, which reveals significant violations of policy, practices, or procedure. The IBC will report its findings and actions to appropriate UCSB institutional officials and to the granting agencies as required.

G. Determine when employees who work with biohazardous materials should be offered health surveillance. Determine the specific medical surveillance tests which are appropriate for a given biohazardous materials risk. The institution shall establish and maintain a health surveillance program for at-risk personnel.

H. Develop design specifications and criteria for containment facilities.

I. Perform such other functions as may be delegated to the IBC by the Chancellor.

1.3.3 Principal Investigator

The Principal Investigator (PI) is defined as the faculty member in whose assigned space a research activity is conducted.

The Principal Investigator is responsible for full compliance with the policies, practices and procedures set forth in this *Handbook*. This responsibility extends to all aspects of biosafety involving all individuals who enter or work in the PI's laboratory or collaborate in carrying out the PI's research. Although the PI may choose to delegate aspects of the biosafety program in his/her laboratory to other laboratory personnel or faculty, this does not absolve the PI from the ultimate responsibility. The PI remains accountable for all activities occurring in his/her lab. Documentation of training and compliance with appropriate biosafety practices and procedures is essential.

1. General Responsibilities

As part of the general responsibilities, the Principal Investigator shall:

B. Develop and implement written laboratory-specific biosafety procedures (Exposure Control Plan) consistent with the nature of current and planned research activities and available laboratory facilities. The PI shall ensure that all laboratory personnel, including other faculty members, understand and comply with these laboratory-specific biosafety procedures.

C. Delay initiation or modification of biohazardous materials work which requires prior Institutional Biosafety Committee (IBC) approval (e.g., Biosafety Level 2 or greater containment required) until that work, or the proposed modification, has been approved by the IBC and has met all other requirements of this Handbook and any protocol specific requirements.

D. Ensure that any research projects required by the NIH Guidelines or by another agency to have prior agency approval

before initiation be reviewed and approved by the IBC before seeking or obtaining agency approval.

http://www.niehs.nih.gov/odhsb/biosafe/nih/rdna-apr98.pdf

E. Notify the IBC upon initiation of work requiring the use of biohazardous materials categorized as belonging to Biosafety Level 2 or greater.

F. Ensure that all laboratory personnel, maintenance personnel and visitors who may be exposed to any biohazard are informed in advance of their potential risk and of the behavior required to minimize that risk. It is essential that everyone who may have any potential exposure to biohazardous materials enter and/or work in the laboratory under the principle of Informed Consent.

G. Ensure that all maintenance work in, on, or around contaminated equipment is conducted only after that equipment is thoroughly decontaminated by the laboratory staff.

H. Report any significant problems, violations of the policies, practices and procedures set forth in this *Handbook*, or any significant research related accidents and illnesses to the Biosafety Officer within 24 hours at 824-9888 or bruce.hanley@ehs.ucsb.edu.

I. Notify the Biosafety Officer immediately if a laboratory-acquired infection is known or suspected.

J. Be adequately trained in good microbiological techniques.

K. Ensure that all research personnel are appropriately trained in biosafety and receive appropriate medical surveillance when needed.

L. Develop (with the assistance of the Biosafety Officer) emergency plans for handling accidental spills and personnel contamination.

M. Create and foster an environment in the laboratory which encourages open discussion of biosafety issues, problems and violations of procedure. The PI will not discipline or take any adverse action against any person for reporting problems or violations to the Biosafety Officer or IBC.

N. Comply with shipping requirements for biohazardous materials and infectious agents.

2. Submissions of Proposed Work to the Institutional Biosafety Committee (IBC)

The Principal Investigator shall:

A. Make an initial determination of the required levels of physical and biological containment in accordance with the requirements set forth in this *Handbook*.

B. Select appropriate microbiological practices and laboratory techniques to be used for the research.

C. Submit any significant changes to the IBC for review and approval. Examples could include: i) a change in Biosafety Level, i.e. work with mouse cells is changed to work with human or primate cells; ii) work begins with a new cell line that carries a potentially infectious organism; iii) work with a small part of an agent's genome is modified to working with > 2/3 of that genome; iv) addition or change in animal species; v) change in host-vector system; etc.

3. Prior to Initiating Research

The Principal Investigator shall:

A. Make available to all laboratory staff protocols that describe the potential biohazards and the precautions to be taken.

B. Instruct and train all research personnel in: (i) the practices and techniques required to ensure safety and (ii) the procedures for dealing with accidents.

C. Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

D. Ensure that collaborators are made aware in advance of any biohazardous material sent to them and the biosafety precautions to be followed. Principal Investigators are advised to maintain a log of all biological material received and sent out.

4. During the Conduct of the Research

The Principal Investigator shall:

A. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.

B. Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biosafety Officer.

C. Immediately notify the Biosafety Officer of any laboratory spills, accidents, containment failure or violations of biosafety practice

which result in the release of biohazardous material and/or the exposure of laboratory personnel (or the public) to infectious agents.

D. Correct work errors and conditions that may result in the release of biohazardous materials.

E. Ensure the integrity of all containment systems used in the project.

F. Restrict access as required by the laboratory-specific biosafety practices procedures and by the biosafety containment level approved by the IBC.

1.3.4 UCSB Biosafety Officer

The UCSB Biosafety Officer is appointed by the University, is a staff member of Environmental Health and Safety and serves as a member of the Institutional Biosafety Committee. The Biosafety Officer's duties include, but are not limited to:

1. Services to the Laboratories

A. Conduct periodic inspections to ensure that required laboratory practices and procedures are rigorously followed.

B. Provide technical advice to facilitate safe handling, storage, and use of biohazardous materials.

C. In consultation with faculty, staff, and the IBC; develop and implement policies, procedures, and practices to reduce the risks of work with biohazardous materials with consideration given to minimizing interference with the conduct of research and teaching.

D. Assist withf emergency plans for handling accidental spills and personnel contamination. Investigate laboratory accidents involving biohazardous materials research.

E. Review proposed biohazardous materials work. Acting within guidelines established by the IBC, approve low risk activities. Forward all other proposals to the IBC.

2. Training Services

A. Plan, develop, and conduct training on biosafety issues, practices, and procedures.

B. Review and approve laboratory-specific training plans for high-hazard biohazardous materials research laboratories.

3. Institutional Biosafety Committee Support

A. Report to the IBC any significant problems, violations of UCSB biosafety policy, practices or procedures and any significant research related accidents or illnesses of which the Biosafety Officer becomes aware.

B. Implement the decisions of the IBC.

C. Serve as a liaison between the PIs and the IBC.

4. Services on Behalf of the Laboratories

A. Review biosafety facility construction/remodeling plans and specifications. Inspect construction/remodeling and authorize initiation of biohazardous materials work following completion of construction.

B. Provide advice on biosafety facility design, ventilation needs, and other supporting services.

C. Advise on the selection, installation, maintenance, and use of laboratory equipment, which provides or aids in containment of biohazardous materials.

1.3.5 Laboratory Staff

Whoever works in the laboratory in a technical (rather than purely administrative) capacity is defined as a laboratory worker even if the person is a faculty member, student, intern, visiting scholar or volunteer.

The laboratory staff members are the most critical element in maintaining a safe working environment. Each person must look out for their own safety and that of their co-workers. If individuals do not follow the university and laboratory-specific biosafety practices and procedures in the conduct of their laboratory duties, we cannot have a safe working environment. It is the laboratory staff's responsibility to:

A. Conscientiously follow lab-specific biosafety practices and procedures.

B. Report to the Principal Investigator or the lab supervisor all problems, violations in procedure or spills as soon as they occur.

C. Report to the Biosafety Officer any significant violations in biosafety policy, practices or procedures which are not resolved by the Principal Investigator within a reasonable amount of time.

D. Refuse to take any adverse action against any person for reporting real or perceived problems or violations of procedures to supervisors, the Principal Investigator, the Biosafety Officer or the Institutional Biosafety Committee.