



Boston College
**Environmental
Health and
Safety**

Biological Safety Manual
for
Biochemical Laboratories

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I. PURPOSE

The purpose of this manual is to provide a framework of safety guidelines to each affected Boston College operation in order to encourage the exercise of prudent practices and to assist compliance with all government regulations in relation to biological experimentation.

II. SCOPE

This manual applies to any Boston College science laboratory or research operation conducting experimentation involving humans, animals, or plants, or microscopic organisms from humans, animals, or plants where the research activities, regulated or otherwise, involve pathogens or recombinant DNA.

III. RESPONSIBILITIES

A. Institutional Biosafety Committee:

1. Will meet at least twice annually;
2. Will establish campus-wide biosafety policies as needed;
3. Will approve, establish, and periodically update this manual;
4. Will communicate this manual to the principal investigator(s) of each affected operation;
5. Will monitor compliance of all affected operations with this manual and with all applicable government regulations of biological experimentation and research;
6. Will exercise the pertinent laboratory research project safety level permit procedure;
7. Will document the agenda of, and actions taken at, each meeting.
8. Will review for compliance with the NIH Guidelines and the city of Boston/ Newton Use Regulations, all recombinant DNA research conducted at or sponsored by Boston College, and approving those projects that it finds in conformity with the Guidelines and Regulations.
9. Will review protocols involving pathogenic/ infectious agents

are

B. Department Administration:

1. Will provide clerical, financial, organizational and training resources to affected department operations to support compliance with this manual;
2. Will establish and maintain appropriate department practices and procedures common to the affected department operations, directly or through a designee, in order to support compliance with this manual, including:
 - a. area security,
 - b. area labeling and signage.
 - c. storage of chemicals, plants, and viable organisms,
 - d. pest control,
 - e. prudent lab practices,
 - f. waste disposal,
 - g. shipping and receiving,
 - h. training plan, and
 - i. medical surveillance,
 - j. laboratory decommissioning;
3. Will maintain and provide upon request all necessary documentation to show compliance with this manual by all affected department operations.

III. C. Principal Investigator/Professor:

1. Will be familiar with the requirements of this manual;

2. Will be familiar with the departmental practices and procedures supporting compliance with this manual;
3. Will be familiar with all relevant University policies and the provisions of any pertinent sponsored project agreement(s);
4. Will register each affected research project with the IBC through the Biological Safety Officer (BSO) and will provide a periodic update to the IBC as requested;
5. Will instruct researchers, technicians, students and other subordinates participating in the affected operations in proper operational policies, procedures, practices and techniques;
6. Will secure medical clearance for subordinates as necessary;
7. Will report any and all illnesses, injuries and infections suffered by subordinates that may be the result of research activities with biohazardous material to the Biosafety Officer and Health Services.

D. Experimenters/researchers:

1. Will be familiar with the requirements of this manual;
2. Will be familiar with the required departmental practices and procedures;
3. Will receive all required training in proper policies, practices and procedures;
4. Will conduct all experimentation using the proper practices and procedures.

E. Biological Safety Officer

1. Will implement and enforce all programs and policies for Biosafety promulgated by the Biosafety committee.
2. Will report the status of the Biological Safety program, including incidents or exposures, to the Biosafety Committee at each periodic meeting with regards to compliance to federal, state, local and university biological safety requirements and regulations;
3. Can recommend suspension of any operation involving biohazardous materials in violation of approved IBC permits. Operations may resume only after review and approval by the IBC;
4. Will coordinate or supervise periodic safety evaluations of laboratories to use biohazardous materials;
5. Will coordinate or conduct biohazard safety training for authorized users of biohazardous materials and maintain associated records;
6. Will develop emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents;
7. Will provide security and technical advice to Principal Investigators and Biosafety Committee on research safety procedures;
8. Will file an annual report to the City of Boston in accordance with the Board of Health and Hospitals, City of Boston, Recombinant DNA Technology: Use Regulations.

authorized

F. Research Administration

1. The Office of Research Administration will file annual permits with the City of Newton.

IV. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

- A. The IBC was originally instituted at Boston College by a faculty member of the Biology Department under the authority of the university's Office of Research Administration (ORA) in order to comply with regulations of the National Institutes of Health.
- B. Membership of the Committee will consist of at least one representative from:
 1. The Office of Research Administration,

2. The Office of Environmental Health and Safety (OEHS),
 3. Each department with one or more affected research operations, and
 4. the local residential area.
- C. The IBC will be headed by a chair or two co-chairs.
- D. The chair(s) will schedule and convene a meeting at least twice per year.
- E. The IBC will maintain a current list of its membership by name, department, mailing address, and profession (Attachment 1).
- F. The IBC will maintain a list of affected research operations by principal investigator name and department (Attachment 2).
- G. The IBC will report persistent non-compliance by individual operations to the respective department head and to the respective supervising dean or director with a recommendation for appropriate disciplinary action.
- H. The IBC will promptly report any unremediated significant violations of the NIH Guidelines and any significant recombinant DNA-related illnesses or injuries to the appropriate authorities, including the Commissioners of Public Health in Boston or Newton, and the NIH Office of Recombinant DNA Activities.
- V. PROJECT REGISTRATION AND APPROVAL
- A. All affected operations must register with the IBC those research projects falling into one or more of the following categories:
1. Research involving recombinant DNA,
 2. Research involving animal or human body fluids or tissues,
 3. Research involving possible infectious agents, or
 4. Any other work activities defined as BL - 2.
- B. Registration is accomplished by the principal investigator
1. Filling out the appropriate registration form either Attachment 3 "Registration Form for Recombinant DNA Projects" or Attachment 4 "Registration Form for Biohazardous Research Projects (Non-Recombinant DNA)", and
 2. Submitting the appropriate form to the Chair or the Biological Safety Officer for review and submission to the IBC.
 3. Periodic updates will be provided upon request by the BSO or if research activities change significantly
- C. Project permit approval by the IBC is accomplished by one of the following:
- 1a. Review and approval of project permits by a majority of the IBC committee in formal meeting, with signature of the committee chair,
 - 1b. Notification of the principal investigator in writing by the chair; or, where government regulations allow, or
 - 2a. Review and approval by signature of the IBC chair or other member authorized by IBC to approve projects, in consultation with at least one other member of the committee and the OEHS representative,
 - 2b. Notification of the principal investigator in writing by the chair, and
 - 2c. Review and approval by a majority of the IBC committee at its next formal meeting or by letter ballot.
- D. The IBC may impose limits or conditions for safety on a project in order for the project to merit its approval.

- E. Providing all government regulations regarding registration and approval of a research project have been met, research may commence:
 - 1. Upon approval of the IBC.
- F. Approval of a project can be denied by the IBC
 - 1. If necessary operational safeguards are not available,
 - 2. If the project would violate government regulations, or
 - 3. If insufficient information has been provided.
- G. Denial of approval will be issued in writing to the principal investigator by the IBC chair.

VI. AREA SECURITY

- A. All affected operations will be located and performed in secure areas in accordance with NIH guidelines.
- B. Security practices and procedures are to be defined and established by the respective department administration or its designee.
- C. The Principal Investigator is to restrict laboratory access as appropriate during work with biohazards.

VII. LABELING

- A. All affected operations will be covered by a system of signage and labeling indicating the presence of biohazard(s).
- B. The system is to be defined, established and maintained by the respective department administration or its designee under the following conditions:
 - 1. At all entries to a lab or area involving regulated biohazards at BL-1 there will be posted
 - a. a universal biohazard symbol, and
 - b. "BL-1";
 - 2. at all entries to a lab or area involving regulated biohazards at BL-2 or above there will be posted
 - a. Universal biohazard symbol,
 - b. The appropriate containment level symbol (BL-2, etc.),
 - c. The identity of the infectious agent(s),
 - d. The name and telephone number of the person to contact in case of incident, and
 - e. An "AUTHORIZED PERSONNEL ONLY" sign;
 - f. A condensed list of BL1/BL2 prudent "Practices" signs
 - 3. All work areas, storage cabinets, and equipment involved in processing regulated biohazards will be labeled with some form of the universal biohazard symbol;
 - 4. Designated biohazardous waste receptacles will be so labeled;
 - 5. All secondary containers of biohazardous material samples will be labeled with
 - a. The name of the infectious agent(s),
 - b. The universal biohazard symbol, and
 - c. The name of the person responsible.

VIII. PLANT AND ANIMAL HOUSING

- A. Each affected operation will be covered by a program of plant and/or animal housing and care, as applicable.
- B. The Animal Care Manual, implemented by the Committee on Animal Care under the auspices of the Office of Research Administration, provides animal housing and care policies and procedures.
- C. The plant housing and care program is to be defined and implemented by the respective department administration or its designee under the following conditions:
 - 1. The facility for plant storage will be defined and labeled;
 - 2. Procedures for facility cleaning and maintenance will be defined;
 - 3. Procedures for plant storage and cultivation will be defined;
 - 4. Procedures for disposal of soil and dead plants will be defined;
 - 5. Access to these facilities will be limited to authorized personnel.

IX. CHEMICAL AND VIABLE MATERIAL STORAGE

- A. Each affected operation will be covered by a program of chemical storage policies and procedures consistent with the Chemical Hygiene Plan.
- B. This program is to be defined and implemented by the respective department administration or its designee in compliance with the Chemical Hygiene Plan and under the following conditions:
 - 1. Materials requiring refrigeration are refrigerated;
 - 2. Chemical and viable materials are not mingled with food;
 - 3. Incompatible chemicals are segregated;
 - 4. Chemical storage areas are suitable for the stored materials;
 - 5. Chemical storage areas are labeled with the respective hazard;
 - 6. Chemicals and viable materials are stored in sealed containers.

X. PEST CONTROL

- A. All affected operations will be covered by a pest control program.
- B. The program is to be defined and implemented by the respective department administration or its designee under the following conditions:
 - 1. Control is performed by certified pest control agents;
 - 2. Inspections are performed monthly, at a minimum;
 - 3. The least obtrusive control procedures feasible are used;
 - 4. Reports are provided subsequent to each inspection;
 - 5. Reports are kept on file.

XI. SAFETY LEVELS AND PRUDENT PRACTICES

- A. See Attachment 5 for a brief description of the different levels of containment for biohazardous material.
- B. See Attachment 6 for prudent practices at the BL-1 containment level.
- C. See Attachment 7 for prudent practices at the BL-2 containment level.
- D. Currently, operations requiring BL-3 and BL-4 containment levels are not allowed.

XII. WASTE DISPOSAL

- A. All affected operations will be covered by a proper biohazardous waste disposal procedure. All procedures for treatment and disposal must comply with the Massachusetts State Sanitary Code (105 CM R4 80.000).
- B. The procedure is to be defined and established by the respective department administration or its designee under the following conditions:
1. Disinfection procedure options will be described (i.e., autoclaving, incineration, chemical disinfection (sterilization), etc.);
 2. Individual(s) designated and qualified to perform each optional procedure will be defined;
 3. Method(s) of segregation and labeling of biohazardous waste prior to treatment will be defined;
 4. Treatment procedure(s) will be defined;
 5. Records of treatment and disposal, including control data, will be maintained;
 6. No waste shall be discarded in the trash or down a sink drain that has not been fully decontaminated via an approved treatment method.
- C. Physically dangerous waste and sharps waste is defined as discarded items that may cause punctures or cuts to include: hypodermic needles/syringes, Pasteur pipettes, scalpel blades, disposable razors and suture needles. Glass will be disposed of in appropriate glass boxes. Control and disposal of sharps at BC must comply with the following requirements:
1. Sharps must be segregated from other wastes and disposed of in leak proof, rigid, puncture resistant, shatterproof containers. These containers are supplied by your departments.
 2. Place all other biohazardous waste into designated biohazardous waste bags inside labeled biohazardous waste boxes.
 3. The sharps must be rendered non-infectious by autoclaving, chemical disinfection or incineration.
 4. All sharps containers must be labeled with a tag stating the date, principal investigator, lab room number, treatment status and who the treatment was performed by.
 5. Sharps containers will be picked up by an outside consultant on an as needed basis when boxes are full. Please contact the Office of Environmental Health and Safety to have boxes picked up.
 6. DO NOT dispose of physically hazardous waste in the regular trash.
- D. Broken glass must be autoclaved or otherwise sterilized before being discarded in broken glass containers provided by your department

XIII. SHIPPING AND RECEIVING

- A. Each affected operation must observe the regulations of shipping etiologic agents, diagnostic specimens, and biologic products as contained in 42 CFR Part 72 of the federal regulations.
- B. For additional information, contact:

Centers for Disease Control and Prevention
 Biosafety Branch
 Office of Health and Safety
 Mail Stop F-05
 1600 Clifton Rd, N.E.
 Atlanta, GA 30333

404-639-3883

- C. Each affected operation must refuse to accept etiologic agents, diagnostic specimens, and biologic products not shipped in compliance with federal regulations.
- D. In case of leaking or damaged packaging of this material, call the Center for Disease Control at 1(800)232-0124.
- E. It is the responsibility of the respective department or its designee to ensure compliance with shipping and receiving regulations.
- F. Contact the Boston College Office of Environmental Health and Safety for assistance and the most current regulations

XIV. TRAINING

- A. All affected operations will be covered by a biosafety training plan.
- B. It is the responsibility of the respective department administration or its designee to define a biosafety training plan under the following conditions:
 - 1. the curriculum of training will be defined, and will include the applicable practices and procedures as defined in this manual and by the respective department administration;
 - 2. the trainee(s) will be designated;
 - 3. the training upon initial use of biologic materials and equipment,
 - 4. all personnel working in an affected operation will receive training;
 - 5. documentation of the training (date and attendance) will be maintained.
- C. It is the responsibility of the principal investigator to ensure that all researchers in his/her operation are familiar with the department policies and procedures as well as the pertinent prudent practices and safety precautions applicable.
- D. Attachment 8 is the document used to register an individual in an affected operation at BL-1 or higher with the department. The principal investigator will provide operation-specific training to each researcher, document the training on the form, and forward it to the department administrator or designee responsible.
- E. General Biosafety training will be provided by the Office of Environmental Health and Safety in addition to the project specific training described above.

XV. MEDICAL SURVEILLANCE

- A. All affected operations will be covered by a medical surveillance program under the following conditions:
 - 1. All personnel working in an affected operation or laboratory, even if not working directly with affected experimentation, will have access to the Boston College Health Services, and additional medical referral and medication if necessary, at Boston College expense, in the event of possible infection or health problems related to the activities of the operation;
 - 2. Any such individual incidents of possible research-related illness or infection in affected operations will be reported to the respective department administration

and the BSO. The BSO will ensure that legitimate incidents of illness or infection be reported to the pertinent government regulatory agencies.

3. As required by the IBC as indicated on project registration forms (Attachments #4), individuals shall be examined and given medical clearance to participate in affected projects
 - a. Initially, prior to involvement, and
 - b. Subsequently, once per year, at Boston College expense by a doctor in the Health Services Department or his/her designee. The worker's health history will be reviewed and related to the specific research project and possibly infectious agents involved;
4. Health Services will administer immunizations to each individual requiring clearance, as appropriate, with his/her consent;
5. Health Services will have the authority to deny medical clearance to an individual whose risk of suffering adverse health affects is deemed too high or who refuses appropriate immunization; examples of medical conditions which may place a worker at increased risk include gastrointestinal disorders and treatment with steroids, immunosuppressive drugs, or antibiotics. Workers with such disorders or treatment should be evaluated to determine whether they should be engaged in research with potentially hazardous organisms during their treatment or illness.
6. It is the responsibility of the respective department administration and Health Services to maintain documentation of medical clearances and incidents of possible research-related illness or infection and report the findings directly to the IBC and BSO.
7. Any significant problems, violations of NIH Guidelines, or any significant research-related accidents and illnesses shall be reported to NIH/ORDA within thirty days. Reports shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health/MSB 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010.

XVI. AUDITING

- A. Each affected operation will be audited for compliance under the following conditions:
 1. The audit will be performed at least once per year;
 2. The auditor will be selected by the IBC;
 3. The auditor will report findings and recommendations to the IBC and to the respective department administration;
- B. It is the responsibility of the respective department administration or its designee to:
 1. Keep the document on file;
 2. Implement the recommendations of the auditor;
 3. Report on the implementation to the IBC at its subsequent formal meeting.
- C. Project approval can be withdrawn by a majority vote of a quorum of the IBC if the project operation is found to be in violation of government regulations and/or terms of the initial approval and is not remediate.

XVII. LABORATORY DECOMMISSIONING

- A. All affected operations will be covered by a policy of decommissioning when the laboratory area is no longer used for the registered activity.
- B. The policy and procedures will be established by the OEHS and will include:

1. Disinfection and disposal of all viable material,
 2. Disinfection of all permanent surfaces,
 3. Disinfection of all pertinent equipment, and
 4. Removal of obsolete labels and warnings.
- C. It is the responsibility of the respective department administration or its designee to inform the OEHS of a lab decommissioning and to comply with the pertinent policies and procedures.
- D. Projects registered with the IBC that are no longer in progress must be terminated with the IBC. Projects that move to new lab areas must be re-registered with the IBC.

XVIII. DOCUMENT CONTROL

A. Manual

1. This manual will be reviewed and revised as necessary annually.
2. Each edition of this manual will be circulated as follows:
 - a. To all current members of the IBC,
 - b. To the principal investigator in each science lab or research operation affected by this document, and
 - c. To the department administrator and/or chair of each affected department.
3. The control copy of this manual will be held by the IBC chair or his/her designee.

B. Meeting Minutes

1. IBC meeting minutes will be kept by the BSO chair or his/her designee, including description of:
 - a. Policies or procedures adopted,
 - b. Projects submitted for approval,
 - c. Results of all votes on project approvals,
 - d. Report of research operation audit,
 - e. All other matters raised for discussion or debate.
2. Copies of the minutes will be distributed to all IBC members and respective department administrators, as well as the appropriate authorities (City of Boston, City of Newton, NIH)

C. Registrations

1. Submitted project registration documents will be held by the BSO with copies sent to the IBC chair.
2. Copies of an approved registration form will be sent to the respective registrant and the respective department administrator by the chair.

D. Audits

1. Reports on audits of research operations will be held by the BSO with copies sent to the IBC chair and by the respective department administrator or his/her designee.

E. Pest Control

1. Reports on pest control activity will be held by the respective department administrator or his/her designee.

F. Waste Disposal

1. Records of treatment of contaminated waste will be held by the respective department administrator or his/her designee.

G. Training

1. Records of formal training (attendance and/or quizzes and/or signed statements) regulated operation researchers will be held by the Office of Environmental Health and Safety. Copies will be sent to departments.

H. Medical Surveillance

1. Records of medical clearance secured by individuals working at the BL-2 containment level or higher will be held by Health Services with their medical records. (see Attachment 9).

ATTACHMENT 1.
 BOSTON COLLEGE
 INSTITUTIONAL BIOSAFETY COMMITTEE

MEMBERSHIP

NAME	WORK ADDRESS	PROFESSIONAL TITLE
M. Kathy Dunn	Boston College Biology Department Higgins Hall	Assoc. Professor IBC Co-chair
Evan Kantrowitz	Boston College Chemistry Department Merkert Center	Professor IBC Co-chair
Stephen Erickson	Boston College Office of Research Administration McGuinn Hall	Director
Charles Hoffman	Boston College Biology Department Higgins Hall	Assoc. Professor
John Madden	Boston College Chemistry Department Merkert Center	Administrator
J. David Naparstek	City of Newton Health Department 1294 Centre St. Newton, MA 02158	Commissioner of Health
Sunil Gulab	Boston College Office of Environmental Health and Safety St. Clements Hall	Biological Safety Officer

ATTACHMENT 2
BOSTON COLLEGE

RECOMBINANT DNA OR OTHER
REGULATED BIOLOGICAL RESEARCH OPERATIONS

P.I. NAME	DEPARTMENT	PROJECT
Grant Balkema	Biology	Epitope Mapping of Synaptic Ribbon. (BL-1) *
William Brunken	Biology	Functional Role of Indoleamines in the Retina; Role of the ECM in Development. (BL-1) *
Thomas Chiles	Biology	The Regulation and Function of AP-1 in Primary B Lymphocytes. (BL-1) *
Thomas Chiles	Biology	The Regulation of Cdk4 Expression and Activity in B Lymphocytes. (BL-1) *
Michael Clarke	Chemistry	Toxicology of ruthenium ammine complexes in HeLa and Jurkat cells.
Kathy Dunn	Biology	Regulation of Symbiotic Plant Genes. (BL-1)*
Charles Hoffman	Biology	Transcriptional Regulation of the Schizosaccharomyces Pombe fbpl Gene. (BL-1) *
Evan Kantrowitz	Chemistry	The Allosteric Mechanism of Fructose 1,6 biphosphatase from Pig Kidney and E. Coli. (BL-1) (NIH exempt)
Evan Kantrowitz	Chemistry	Studies on the Catalytic Mechanism of E. coli Alkaline Phosphatase. (NIH exempt)
Evan Kantrowitz	Chemistry	The Allosteric Mechanism of Aspartate Transcarbamoylase from E. coli. (NIH exempt)
Daniel Kirschner	Biology	Expression of Mylan Po Glycoprotein. *
Clare O'Connor	Biology	Methylation of Atypical Protein Aspartyl Residues. (BL-1) *
William Petri	Biology	Sequencing Drosophila vitelline membrane genes. (BL1) *
Mary Roberts	Chemistry	Interfacial Activation of Soluble Phospholipases. (BL-1) (NIH exempt)

ATTACHMENT 2 (continued)

BOSTON COLLEGE

RECOMBINANT DNA OR OTHER
REGULATED BIOLOGICAL RESEARCH OPERATIONS

P.I. NAME	DEPARTMENT	PROJECT
Thomas Seyfried	Biology	Analysis of Ganglioside Biosynthetic Gene Expression and Epilepsy Gene Mapping. (BL-1) *
Marc Snapper	Chemistry	Expression of Receptor Gene (SEAP) in T-Lymphocytes using Hela and Jurkat cells.
Chester Stachow	Biology	DNA Replication in the Mitochondria of <i>S. pombe</i> . (BL-1) *
Martha Teeter	Chemistry	Expression of Synthetic Gene for Human Dopamine Receptor *

* Denotes work with rDNA materials.

ATTACHMENT 3.**REGISTRATION FORM FOR RECOMBINANT DNA PROJECTS**

Institutional Biosafety Committee

Boston College

140 Commonwealth Avenue

Chestnut Hill, MA 02467

Principal Investigator: _____

Title: _____

Anticipated Starting Date: _____

Description of Project: (Include source(s) of DNA/RNA, whether there will be expression of a toxic or pathogenic gene product (if so, describe) and whether >2/3 of a viral genome will be in any single clone.)

Host-Vector-Donor System:

Large Scale(≥ 10 liters): Yes ___ No ___ Is an RDNA gene product efficiently expressed:

Yes ___ No ___ Unknown _____

Research Location (s):

Containment levels (date and subsection of applicable NIH Guidelines).

Lab personnel to contact in emergency situations requiring immediate remedial action:

Certification:

1. I am familiar with and agree to abide by the provisions of the local, state, and federal government regulations for recombinant DNA use and technology. The information above is accurate and complete.

Principal Investigator: _____

Date: _____

- 2a I certify that the Institutional Biosafety Committee (IBC) has reviewed on _____ the proposed project for RDNA and has by a majority vote found it in compliance with the provisions of all known local, state, and federal regulations for recombinant DNA use and technology. The IBC will monitor the project throughout its duration to ensure its continued compliance. Medical surveillance required? yes ___ no

Chairperson, Biosafety Committee: _____

Date: _____

OR

- 2b. I certify that I have been authorized by the IBC to administratively review and approve Class III-D and - E experiments. Class III-D experiments include those which require IBC notice simultaneous with initiation such as experiments involving formation of recombinant DNA molecules containing no more than two-thirds of the genome of any Eukaryotic virus or experiments involving whole plants. Class III- E experiments are those that are exempt from the NIH guidelines. The proposed project has been found to be in compliance with all known local, state, and federal regulations for recombinant DNA use and technology. The institution will monitor the project throughout its duration to ensure its continued compliance. Medical surveillance required? ___yes ___no

Chairperson _____ Date: _____

ATTACHMENT 4

**REGISTRATION FORM FOR BIOHAZARDOUS RESEARCH PROJECTS
(NON-RECOMBINANT DNA)**

Institutional Biosafety Committee
Boston College
140 Commonwealth Avenue
Chestnut Hill, MA 02467

Principal Investigator: _____
Title: _____

Anticipated Starting Date:

Description of Project: (Note: if hazard is a blood-borne pathogen, training and approval must be obtained from the OEHS prior to initiation of the project.)

Nature of biohazard:

Containment level (with reference to applicable regulatory guidelines).

Research Location (s):

Lab personnel to contact in emergency situations requiring immediate remedial action:

Certification:

1. I am familiar with and agree to abide by the provisions of the applicable local, state, and federal government regulations . The information above is accurate and complete.

Principal Investigator: _____ Date: _____

2. I certify that the Institutional Biosafety Committee (IBC) has reviewed on _____ this proposed project and has by a majority vote found it in compliance with _____ the provisions of all known applicable local, state, and federal regulations . The IBC will monitor the project throughout its duration to ensure its continued compliance.

Chairperson, IBC: _____ Date: _____

ATTACHMENT 5.
BIOSAFETY CONTAINMENT LEVELS

(condensed from *Biosafety in Microbiological and Biomedical Laboratories*, U.S. Department of Health and Human Services, 1993, 3rd edition)

Biosafety Level 1 practices, safety equipment, and facilities are appropriate for undergraduate and secondary educational training and teaching laboratories, and for other facilities in which work is done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans.

Biosafety Level 1 represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for hand washing.

Biosafety Level 2 practices, equipment, and facilities are applicable to clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. With good microbiological techniques, these agents can be used safely in activities conducted on the open bench, provided the potential for producing splashes or aerosols is low.

Biosafety Level 2 is appropriate when work is done with any human derived blood, body fluids, or tissues where the presence of an infectious agent may be unknown. (Laboratory personnel working with human-derived materials should refer to the Bloodborne Pathogen Standard for specific, required precautions).

Biosafety Level 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs in that :

- (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists,
- (2) access to the laboratory is limited when work is being conducted,
- (3) extreme precautions are taken with contaminated sharp items, and
- (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

BIOSAFETY LEVEL 3 and 4 PROJECTS ARE NOT APPROVED AT BOSTON COLLEGE

ATTACHMENT 6.
Biosafety Level 1

A. Standard Laboratory Practices:

1. Access Restriction: At the discretion of the laboratory director.
2. Work Surfaces: Work surfaces shall be decontaminated daily and following spills of biohazardous materials. A bottle of disinfectant should be kept in every work area for spills on skin or work surfaces. Any spills should be cleaned up immediately.
3. Contaminated Wastes: All liquid or solid wastes are decontaminated before disposal. Contaminated materials that are to be decontaminated away from the laboratory are placed in a durable leak proof container which is closed before being removed from the laboratory. Materials to be decontaminated off-site from the laboratory are packaged in accordance with applicable local, state, and federal regulations, before removal from the facility. Refer to OEHS procedures and policies for more specific information.
 - a. Liquid Wastes: Liquid wastes containing microbial organisms or recombinant DNA materials must be decontaminated before sink disposal by mixing with Wescodyne (1% final concentration) or some other appropriate chemical disinfectant (i.e. bleach). Allow for a contact time of at least 10 minutes. Liquid Decontaminant: It is recommended that personnel use a broad spectrum decontaminant (such as Lysol, Wescodyne, dilute chlorine bleach or equivalent), for all types of surface and liquid decontamination. Disposal of Decontaminated Liquid Waste: Once the waste has been chemically treated, it should be treated as ordinary waste:
 - (1) Simple aqueous solutions may be dumped down the sink as ordinary waste.
 - (2) Radioactive wastes should be processed in accordance with appropriate procedure.
 - b. Solid Wastes: Solid wastes contaminated with recombinant DNA materials or microbial organisms must be decontaminated prior to disposal. All solid wastes must be packaged in a well-sealed terminal biohazards bag before autoclaving and disposal. Materials which have been decontaminated should not be labeled with biohazards signs or symbols. Do not leave bags in corridors.
 - c. Reusable Materials: Decontaminate prior to reuse.
4. Pipetting: Pipetting by mouth is prohibited. Mechanical pipetting devices are to be used.
5. Food, Etc.: Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Food is stored outside of the laboratory area in cabinets or refrigerators designated and used for this purpose only.
6. Handwashing: Personnel must wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.
7. Work Practices: Minimize the generation of aerosols.
8. Insect and Rodent Control: An insect and rodent control program is provided.

B. Special Work Practices:

1. Each area used commonly by more than one operation (i.e. coldrooms, warmrooms, etc.) will have a designee from one of the operations to be responsible for area maintenance and disinfection.

C. Safety Equipment (Primary Barriers):

1. Special containment devices or equipment are generally not required for manipulation of materials assigned to biosafety level one (BL1).
2. Lab Coats: It is recommended that laboratory coats be worn to prevent contamination or soiling of street clothes.
3. Gloves: It is recommended that gloves be worn to prevent skin contamination. Gloves are to be worn if the skin on the hands is broken or if a rash exists.
4. Protective Eyewear: Protective eyewear (safety glasses, goggles, etc.) should be worn for anticipated splashes of microorganisms or other hazardous materials to the face.

D. Laboratory Facilities:

1. The laboratory is designed so that it can be easily cleaned. Rugs in laboratories are not appropriate, and should not be used because proper decontamination following a spill is extremely difficult to achieve.
2. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents and moderate heat.
3. Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment are accessible for cleaning.
4. Each laboratory contains a sink for handwashing.
5. If the laboratory has windows that open, they are fitted with fly screens.

ATTACHMENT 7.
Biosafety Level 2

A. Standard Laboratory Practices:

1. Access Restriction: At the discretion of the laboratory director.
2. Work Surfaces: Work surfaces shall be decontaminated daily and following spills of biohazardous materials. A bottle of disinfectant should be kept in every work area for spills on skin or work surfaces. Any spills should be cleaned up immediately.
3. Contaminated Wastes: All liquid or solid wastes are decontaminated before disposal. Contaminated materials that are to be decontaminated away from the laboratory are placed in a durable leak proof container which is closed before being removed from the laboratory. Materials to be decontaminated off-site from the laboratory are packaged in accordance with applicable local, state, and federal regulations, before removal from the facility. Refer to OEHS waste procedures and policies for more specific information.
 - a. Liquid Wastes: Liquid wastes containing microbial organisms or recombinant DNA materials must be decontaminated before sink disposal by mixing with Wescodyne (1% final concentration) or some other appropriate chemical disinfectant (i.e. bleach). Allow for a contact time of at least 10 minutes.
Liquid Decontaminant: It is recommended that personnel use a broad spectrum decontaminant (such as Lysol, Wescodyne, dilute chlorine bleach or equivalent), for all types of surface and liquid decontamination.
Disposal of Decontaminated Liquid Waste: Once the waste has been chemically treated, it should be treated as ordinary waste:
 - (1) Simple aqueous solutions may be dumped down the sink as ordinary waste.
 - (2) Radioactive wastes should be processed in accordance with appropriate procedure.
 - b. Solid Wastes: Solid wastes contaminated with recombinant DNA materials or microbial organisms must be decontaminated prior to disposal. All solid wastes must be packaged in a well-sealed terminal biohazards bag before autoclaving and disposal. Materials which have been decontaminated should not be labeled with biohazards signs or symbols. Do not leave bags in corridors.
 - c. Reusable Materials: Decontaminate prior to reuse.
4. Pipetting: Pipetting by mouth is prohibited. Mechanical pipetting devices are to be used.
5. Food, Etc.: Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Food is stored outside of the laboratory area in cabinets or refrigerators designated and used for this purpose only.
6. Handwashing: Personnel wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.
7. Work Practices: Minimize the generation of aerosols.
8. Insect and Rodent Control: An insect and rodent control program is provided.

B. Special Work Practices:

1. Laboratory Access: Access is limited by the laboratory supervisor when experiments are being conducted at BL2. In general, persons who are at increased risk of acquiring infection are not allowed in BL2 laboratories. The supervisor has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. The laboratory supervisor establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements (i.e. immunization) enter the laboratory.
2. Procedures: Project specific practices and procedures are prepared by the Principal Investigator.
3. Immunization: If necessary, laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (i.e..Hepatitis B vaccine, TB testing).
4. Sera Storage: When appropriate, considering the agent(s) handled, baseline serum samples for laboratory personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled.
5. Biosafety Manual: A biosafety manual is prepared and revised as necessary.
6. Training: Laboratory personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary. All researchers are trained in the project-specific practices and procedures.
7. Sharps: A high degree of precaution must always be taken with any contaminated sharp item, including needles and syringes, slides, pipettes, capillary tubes, and scalpels Use of sharp should be restricted for use only when there is no alternative, such as parenteral injection, or aspiration of fluids from diaphragm bottles. Plasticware should be substituted for glassware whenever possible.
 - a. Only needle-locking syringes or disposable syringe-needle units are used for injection or aspiration of infectious or recombinant DNA materials. Used needles must not be bent, sheared, broken, recapped, or removed from disposable syringes. They must carefully be placed in inconveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - b. Syringes which re-sheath the needle, needle-less systems, and other safe devices should be used when appropriate.
 - c. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles and broken glass are decontaminated before disposal according to any local, state, and federal regulations.
8. Containment: Cultures, tissues, or specimens of body fluids are placed in a container that prevents leakage during collection, handling, processing, storage, transport or shipping.
9. Decontamination: Laboratory equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis, after work with infectious or recombinant DNA materials, and especially after overt spills, splashes, or other contamination.

Contaminated equipment must be decontaminated before it is sent for repair or maintenance, or packaged for transport before removal from the facility.

10. Accidents: Spills and accidents which result in overt exposures to infectious or recombinant DNA materials must be immediately reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are kept.
11. Animals: Animals not involved in the laboratory experiments are not allowed in the laboratory.
12. Common-Use Areas: Each area used commonly by more than one operation (i.e. coldrooms, warmrooms, etc.) will have a designee from one of the operations to be responsible for area maintenance and disinfection.

C. Safety Equipment (Primary Barriers):

1. Biosafety Cabinets: Properly maintained and certified (yearly) biosafety cabinets are used whenever:
 - a. Procedures with a potential for creating aerosols or splashes are conducted. These may include, but are not limited to, centrifugation, skaking, blending, sonication or opening containers in the presence of a pressure differential, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
 - b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed heads or centrifuge safety cups are used and if they are opened only in a biosafety cabinet.
2. Lab Coats: Laboratory coats are worn to prevent contamination or soiling of street clothes. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas. All coats are either disposed of in the laboratory or laundered by the institution. Coats should never be taken home by personnel.
3. Gloves: Gloves must be worn to prevent skin contamination. Gloves are disposed of when contaminated, removed when work is completed, and are not worn outside of the laboratory. Disposable gloves are not washed or reused.
4. Protective Eyewear: Protective eyewear (safety glasses, goggles, etc.) should be worn for anticipated splashes of microorganisms or other hazardous materials to the face, especially when microorganisms must be manipulated outside of the biosafety cabinet.

D. Laboratory Facilities:

1. The laboratory is designed so that it can be easily cleaned. Rugs in laboratories are not appropriate, and should not be used because proper decontamination following a spill is extremely difficult to achieve.
2. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents and moderate heat.
3. Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment are accessible for cleaning.
4. Each laboratory contains a sink for handwashing.
5. If the laboratory has windows that open, they are fitted with fly screens.

6. A method for decontamination of infectious or regulated laboratory waste is available (i.e. autoclave, chemical disinfection, incinerator, or other approved decontamination system).

ATTACHMENT 8.
BOSTON COLLEGE

REGISTRATION OF RESEARCHER
AT BIOSAFETY CONTAINMENT LEVELS 1 OR 2

Principal Investigator _____

Project Name _____

Project Biosafety Containment Level _____

Project Location:

Department _____

Building _____ Room _____

Researcher Name _____

I certify that the researcher named above has been trained by me in appropriate project-specific practices and procedures appropriate to the containment level indicated.

Signed: _____ Dated: _____
(principal investigator)

submit to designated department administrator for filing

ATTACHMENT 9.
BOSTON COLLEGE

CERTIFICATION OF MEDICAL CLEARANCE
FOR BIOSAFETY WORKERS

Date _____

Principal Investigator _____

Project Name _____

Project Biosafety Containment Level _____

Project Location:

Department _____

Building _____ Room _____

Researcher Name _____

I certify that I have reviewed the risk of infection with the researcher named above and have reviewed his/her medical history and have examined him/her. I recommend one of the following:

The researcher named above has been adequately immunized and there is no medical reason to deny medical clearance. I hereby give him/her medical clearance.

Signed: _____ Dated: _____
(Health Services Physician)

The researcher named above is denied medical clearance because _____

Signed: _____ Dated: _____
(Health Services Physician)

PI fills in requested information and sends with researcher to Health Services;
Physician submits to principal investigator and department administrator for filing.