



Town of Franklin

HEALTH DEPARTMENT
355 East Central Street
Franklin, Massachusetts 02038-1352
p. 508-520-4905 f. 508-520-4989

NEW: Y or N
RENEWAL: Y or N
CALENDAR YEAR: _____
FEE AMOUNT: \$600.00

Biotechnology Recombinant DNA and Infectious Agent Registration

Please Type

Principal Investigator			Alternate Contact (When PI is Away)		
First Name	Last Name	Degree	First Name	Last Name	Degree
Institution /Company			Department		
Office Address (Include Office Room Number)			Mailing Address (If Different)		
Telephone #	Fax #	E-Mail Address	Project #		
			Assigned by Biosafety Office		
Planned Starting Date:					
Project Title					

Memorandum of Understanding and Agreement (MUA)

I am familiar with and agree to abide by the NIH Guidelines, OSHA standards, and other federal, state and local regulations relating to this project.

I accept responsibility for training all personnel involved in the proposed project in matters of potential biohazards, relevant biosafety practices, techniques and emergency procedures.

I will submit reports to the Board of Health dealing with (i) any accident that results in potentially toxic exposure to recombinant DNA materials, or any incident

releasing recombinant DNA materials into the environment; (ii) any problems with physical or biological containment; (iii) exposures to infectious agents and (iv) any novel information bearing on the safety of this work such as new technical data relating to biological hazards of specific recombinant DNA molecules or infectious agent.

I will not carry out the work described in this registration until it has been filed with, and if necessary, approved by, the BOH.

Signatures	
Principal Investigator _____	Date _____
Additional Investigator _____	Date _____
Reviewed and Accepted _____	Date _____
Chair, BOH	
☐ The work described in this application is deemed to be exempt from NIH recombinant DNA guidelines.	
Date _____	
Biological Safety Officer	

Please Type

Location of Work. (Include building and room numbers)

Staff Associated with the Project/Production.

Non-Technical Summary of Proposed Work (for representatives of the general public on the Biosafety Committee)

Human Tissues

Unfixed human tissues or fluids (covered by OSHA Bloodborne Pathogen Standard). e.g. Human or simian blood, CSF, plasma, secretions

Microorganisms

Bacterial (Please note whether an *E.coli* K12 based strain is to be used), **Fungal, Mycotic...**

**Viruses, Viral Vectors ,
Prions**

Eukaryotic Cell Lines

Helper Virus or Packaging System:

Fraction of eukaryotic viral genome in recombinant DNA $< \frac{1}{2}$ _____, $> \frac{1}{2}$ but $< \frac{2}{3}$ _____, $> \frac{2}{3}$ _____

Please Type

Nucleic Acids (Please give name, commercial source, literature reference)		
Plasmids (note those that are pBR322 based)	Oligonucleotides	Inserted DNA (Indicate oncogenes and toxins)
Target Cells		Plants or Animals (Indicate immunocompromised strains)
		Agent Administration (to animals)
		Route, Volume, Concentration
Source of Transgenic Plants or Animals?		
"Select"* Agents: Toxins or Microbiologicals		
Describe the Experiment/Production noting the approximate start date for each phase. Please give references where appropriate		
Describe the Biohazard Potential Are special medical surveillance practices recommended?		

Revised 12/2001

*"Select" Agents are thought to be useful to terrorists. The Centers for Disease Control (CDC) publishes a list of these agents. Some require CDC permits for their use.

REGISTRATION FORM FOR RDNA PRODUCTS

Title: _____

Anticipated Starting Date: _____

Brief Description of Project:

Institution Company: _____

Lab Facility Address(es) _____

Building(s): _____

Room(s): _____

Principal Investigator(s): _____

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

Containment Levels (date and subsection of applicable NIH Guidelines):

Host-Vector-Donor System: _____

Lab Personnel to contact in emergency situations requiring immediate remedial action: _____

Sterilization/Disinfection methods: _____

Infectious waste hauler: _____

Biosafety Manual copies to BOH: _____

Certification:

I, I am familiar with and agree to abide by the provisions of the Town of Franklin Recombinant DNA Technology: Use Regulations. The information above is accurate and complete.

Principal Investigator: _____ Date: _____

Biosafety Officer: _____ Date: _____



Board of Health

Bruce Hunchard, Chairman
Dr. Mario DeBaggis, V. Chairman
Dr. Darrolyn Lindsey MD, Member
John McVeigh, CHO, RS, RBP Agent

Municipal Building
150 Emmons Street
Franklin, MA 02038

Instructions for Completing Biological Materials and Recombinant DNA Application

Biosafety protocols/guides must be submitted to the Board Of Health (BOH) for research or production activities involving:

- microbiological agents infectious to humans and/or animals; provide a copy of any required State and or federal permit.
- exotic plants, animals, and microbes (e.g., non-indigenous plant or insect pathogen, or biological control agent); provide a copy of any required federal permit.
- animals, including their blood, tissues, and cell lines, for which a reasonable potential for transmission of zoonotic agents exists, e.g., wild-trapped animals, sheep, and rhesus macaques.
- carcinogens, mutagens, drugs, and toxins when administered *in vivo* or *in vitro* to induce a biological outcome.
- select agents. CDC regulates these microbes and toxins due to their threat to public health and safety. The list of select agents is available at <http://www.cdc.gov/od/ohs/lrsaf/42cfr72.html#Appendix A> and upon request from BOH.
- recombinant DNA molecules and recombinant DNA-containing organisms or cell cultures which are subject to the NIH *Guidelines for Research Involving Recombinant DNA Molecules*.

Sections IV and V cover the use of recombinant DNA molecules and potentially biohazardous components of your production or research project. Skip sections that do not apply. In Section V, please provide an overview of the project and a detailed description of the practices employed in the management of biohazardous elements; discuss safety aspects of facility, containment equipment, personnel practices, and staff training that will ensure safe conduct.

(Include HEPA ventilation controls, room bio-safety levels, air pressure safeguards and autovlaves.)





