



Biosafety Fact Sheet on



REGISTERING PROJECTS WITH COMS

HIM/NRB Biosafety Regulations

Harvard Institutes of Medicine / New Research Building (HIM/NRB) has adopted regulations from the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and Occupational Safety and Health Administration (OSHA) as institutional policy. The [NIH Guidelines for Research Involving Recombinant DNA Molecules \(NIH Guidelines\)](#) places the responsibility for implementing its guidelines in the hands of an Institutional Biosafety Committee (IBC). In the Longwood Medical Area, the [Harvard Committee on Microbiological Safety \(COMS\)](#) serves as BWH IBC. Details regarding the COMS approval process can be found in the [COMS Policy Manual](#).

All research involving the use of the following must be registered with the COMS:

- *Recombinant DNA materials*
- *Infectious microorganisms, regardless of their pathogenicity*
- *Human or non-human primate blood, cell lines, and unfixed tissues*

COMS applications can be found on the [HIM/NRB Environmental Health and Safety website](#). The Principle Investigator (PI) of the application agrees that they will provide biosafety training, maintain a safe work environment, and notify COMS immediately of accidental exposures or if a staff member develops symptoms related to the agents used in the laboratory. Further requirements of the PI stipulated by the NIH Guidelines are detailed in the NIH Guidelines.

Filling out the COMS Application

In order to expedite the review of your application, provide the most complete information as possible. By following the helpful hints below, your application will be reviewed in as timely a manner as possible.

- In the “*Non-Technical Summary*” section, provide a clear description of the proposed work in language that can be understood by someone that is not an expert in your field.

- In the “*Describe the Experiment in Detail*” section, provide a detailed, but brief description of the experiment. Include information on how all biological agents will be used. Do not cut and paste information from other documents such as animal protocols or grants into this section, as these documents may have information that is not relevant to the biological safety of the project.
- If you include citations, or reference scientific papers in your application, provide a copy of the full publication, if possible.
- List the specific names and sources (i.e. commercial company or research laboratory) of all biological agents and transgenic animals.
- If the project involves the use of animals, provide a copy of the animal protocol (IACUC form) even if the animal application is pending the biosafety approval and fill out the “*Describe Agent Administration*” section.
- In the “*Describe the Biohazard Potential of These Experiments*” section, list procedures where exposures might occur and the biosafety levels of agents in use, if known. Leaving this section blank or stating “none” is not acceptable.

Use of Viral Vectors

If you are using viral vectors to insert or knockout genes address the following issues in the Biosafety Section:

- Identify any oncogenes, tumor suppressor genes, toxin producing genes, or other genes with the potential to cause harm, if expressed.
- Indicate if the viral DNA can integrate into the host genome.
- Discuss the probability of generating replication-competent viruses including methods to reduce this probability such as multiple plasmid systems and self-inactivation.

Also See...

- Biosafety Fact Sheet on Working at Biosafety Level 2
- Biosafety Fact Sheet on Working with Lentiviral Vector Systems
- [HIM/NRB Biosafety Manual](#)