Biosafety Guidance

The JH Biosafety Office is required by federal regulations and/or institutional policy to maintain a registry of any investigator/lab that stores or uses recombinant DNA or synthetic nucleic acid molecules, potentially pathogenic organisms or infectious agents, biological toxins or human-derived tissues or body fluids.

Institutional Biosafety Committee (IBC) review and approval is required for the possession or use of recombinant or synthetic nucleic acid molecules as per the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.* IBC review and approval is required for the use or possession of potentially pathogenic organisms, potentially infectious agents and biological toxins by JHU policy.

All faculty, students or staff storing or using the above materials and/or human-derived tissues or bodily fluids (including human cell lines) for clinical or laboratory research must register with the Biosafety Office by completing any required training and submitting one of the following two forms to the IBC Office:

Registration of Research Involving Human Tissues, Cell Lines, and/or Body Fluids form:
http://www.hopkinsmedicine.org/hse/forms/HumanTissueRegistration.pdf

Registration of Research with Infectious Agents, Pathogens, or Biological Toxins" form:
http://www.hopkinsmedicine.org/hse/forms/PathogenToxinRegistration.pdf

Registration of Research with Recombinant or Synthetic Nucleic Acids Molecules form:
http://www.hopkinsmedicine.org/hse/forms/RDNARegistration.pdf

Registration and training requirements are available at:
http://www.hopkinsmedicine.org/hse/biosafety/index.html
http://www.hopkinsmedicine.org/hse/ibc/index.html

Investigators are responsible for submitting application materials required for IBC review, and for ensuring that investigator and staff training requirements are completed. The IBC will notify investigators when the application is approved, or if changes are required.

Investigators submitting human subjects research applications through the PHIRST system should indicate whether Biosafety review is required. The IRB staff will notify IBC when review is required. IBC and IRB review may proceed concurrently, and the PI must submit any changes required by IBC to the IRB for review.

After approval, PIs should submit changes which affect IBC safety requirements to both the IRB and the IBC. The amendment may not be initiated until both the IRB and the IBC approve it.