

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
	Identification	Page 1 of 2
Title: Biosafety Office and Institutional Biosafety Committee	Date Effective 12/14/04	Supercedes P&P dated

BACKGROUND

The Johns Hopkins *Biosafety Office* is required by Federal and University regulations to maintain a registry of any possession or use of recombinant DNA, pathogenic organisms, infectious agents, biological toxins or human tissues by University or Hospital faculty, students or staff.

Additionally, the Johns Hopkins *Institutional Biosafety Committee* (IBC) is required by the NIH Guidelines for Research Involving Recombinant DNA Molecules and/or University policies to review and approve all research conducted by faculty, students, or staff that involves the above materials.

JHSPH POLICY AND PROCEDURES

Registration

JHSPH faculty, students or staff who will possess or use recombinant DNA, pathogenic organisms, infectious agents, biological toxins, or human tissue or bodily fluids (including human cell lines) must register with the Biosafety Office and complete any required training. Registration requirements and procedures, and training requirements, are provided at www.hopkinsbiosafety.org and www.hopkinsibc.org.

Review of Research Protocols

All human subjects research that involves recombinant DNA, viable pathogenic organisms, infectious agents, or biological toxins, including the use of any of these as potential vaccines, must be reviewed and approved by the IBC in addition to CHR. Guidance on preparing submissions for IBC review is available on the IBC website, www.hopkinsibc.org.

Investigators are responsible for ensuring that application materials required for the IBC review are submitted to the Biosafety Office and that investigator and staff training requirements are met. IBC will notify investigators directly when their proposal is approved or if changes are required.

Reviews by CHR and the IBC may be done concurrently and approval of both Committees is required before the research may be initiated. If CHR approves the research prior to IBC approval, and IBC requests changes to the research, the investigators must submit the

revised protocol (one clean copy of the revised protocol and one copy showing tracked changes) to CHR for review and re-approval *prior* to initiating the research. CHR approval of new proposals, continuing review applications or amendments does not require prior approval by the IBC.

A copy of any proposed *amendments* to a research project approved by CHR and the IBC must be submitted to both IBC *and* CHR for review. The amendment may not be initiated until approved by both Committees.

A copy of the *CHR continuing review application* must also be submitted to the IBC for review.

RESOURCES & REFERENCES

NIH Guidelines for Research Involving Recombinant DNA Molecules
http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlnes_Ink_2002z.pdf

JHU Policies HSE503 and HSE504 www.hopkinsmedicine.org/hse