

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Educational Support for Human Subjects Research	Date Effective 06-30-04	Supercedes P&P dated

Background

Ensuring the protection of human research subjects requires that researchers, CHR members and ORS staff understand, and are able to apply, the highest ethical standards to the review and conduct of human subjects research. They must also have knowledge of, and follow, all relevant Federal, state and local regulations that apply to human subjects research. To help achieve these objectives, the JHSPH HRPP organizes and supports a variety of educational activities on the ethical conduct and regulatory aspects of human subjects research.

JHSPH Policy and Procedures

Educational activities supported by the HRPP include both *required training*, that must be completed by all researchers, CHR members and ORS staff, and a variety of *ongoing activities* that compliment the required training. These activities are intended to help researchers recognize and resolve issues concerning research ethics or regulations that may be encountered in the planning or conduct of their research.

Required Basic Training in Protection of Human Research Subjects

Except as noted below, all investigators, collaborators, consultants, subcontractors, students, staff and other key personnel who will be involved in human subjects research, must complete either the JHSPH or School of Medicine (SOM) computer-based human subjects training program prior to submitting an application to CHR for research that will be conducted or supported by JHSPH. This rule applies regardless of whether the research is funded or unfunded, and irrespective of the funding source or where the research is performed. Those covered by this policy include investigators, collaborators, consultants, contractors, subcontractors, students and other key research personnel. Applicants for fellowship grant support must complete the training

program before their application is submitted, if the use of human subjects is indicated on the face page. All CHR members must also complete the training program.

Research personnel unaffiliated with JHSPH, may satisfy this requirement by providing evidence of training from their local institution before CHR reviews the application. Otherwise, either the JHSPH or the SOM training program must be completed.

Researchers transferring from another institution may, during their first 6 months at JHSPH, provide evidence of human subjects training within 6 months prior to transferring from their former institution or complete the JHSPH or SOM program. Thereafter, they must complete either the JHSPH or the SOM training program.

Staff of the Office for Research Subjects must complete the JHSPH training module within the first 6 months of their employment in the ORS.

Accessing the training module

The JHSPH training module is an internet-based instructional program that can be accessed from the CHR website: <http://www.jhsph.edu/chr/>. The SOM training module can be accessed from the SOM IRB website: <http://irb.jhmi.edu/>. Each module can be completed in about one hour and includes a test of comprehension. Upon successful completion of the JHSPH module, investigators are able to print a certificate as evidence of their training in human subjects research.

Researchers without access to the internet can obtain a hard copy of the JHSPH training program from the Office for Research Subjects in Room E1100, JHSPH. The hard copy of the evaluation (test) must be forwarded to the CHR Office with a short cover memo indicating: (1) the title of the study, (2) the name of the Principal Investigator, (3) the individual's role in the project, and (4) the individual's telephone number and address. The evaluation will be graded and, if successfully completed, a certificate will be mailed to the individual.

Persons who do not pass the test on the first attempt will be allowed to repeat the program. If a second attempt is also unsuccessful, they should contact Pat German in the Office for Research Subjects at 410-614-4088 or pmgerman@jhsph.edu.

Other Ongoing Training Activities

Brown bag sessions

Each month during the academic year the ORS organizes noon-time sessions that focus on ethical issues related to the planning, review and conduct of human subjects research. The sessions are open to all faculty, students, staff and guests.

Local, regional or national meetings and courses

The School provides support for HRPP staff, CHR Co-Chairs and CHR members to attend local and regional meetings and take part in courses or workshops that focus on issues related to the ethical conduct of human subjects research.

Educational materials and guidelines

Members of the CHRs and of the HRPP Executive Committee receive an IRB Members handbook, which describes the principle functions of the IRB and their roles as members, the CHR Reviewer's Guide, and a complete and continuously updated set of HRPP Policies and Procedures to use as resources when reviewing research proposals and reports. They also receive educational pamphlets, and regulatory guidelines and announcements relevant to human subjects research. Copies of Human Research Report and access to the online IRB Forum are available in the ORS.

Lectures and seminars

The HRPP collaborates with the Johns Hopkins Bioethics Institute to develop an annual series of 3-4 lectures or seminars for faculty and students on controversial or cutting edge issues related to the ethical conduct of human subjects research. Federal agencies (e.g. OHRP) and PRIM&R are periodically invited to take part in School-wide seminars or lectures on human subjects research.

Bioethics consulting service

The HRPP, in collaboration with the JHU Program on Research Ethics, is developing a research bioethics consultation service. This will allow researchers to discuss ethical issues related to their research with one of the School's bioethicists. Consultation will be through e-mail and face-to-face. This service is expected to begin in December 2004.

Research Coordinator Training

The Director and Assistant Director of the ORS regularly participate in the School of Nursing's training program for research coordinators from JHSPH, the SOM and the School of Nursing. Training sessions are held on campus and are also available via internet as part of the School's distance education program.

Consultation with ORS Staff

ORS staff are available daily to meet with faculty, students and staff to discuss issues related to the planning and review of their research.

Training of ORS Staff

All ORS staff must complete the JHSPH human subjects training module within the first 6 months of employment and a basic IRB training course within 2 years. Attendance at local and regional meetings, bioethics seminars and Federal advisory committee sessions, and participation in IRB forums is encouraged. New and existing guidelines and regulations governing human subject research are routinely discussed at bi-weekly CHR staff meetings.