

 <b>JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH</b>	<b>Human Research Protection Program Policies &amp; Procedures</b>	
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Title: <b>What Needs Review by CHR</b>	Date Effective April 19, 2005	Supercedes P&P dated October 12, 2004

## BACKGROUND

As a rule, CHR must review and approve all proposed research that meets *any* of the following conditions:

- JHSPH employees or students (either as Principal Investigator, co-investigators or collaborators) will intervene or interact with living individuals for research purposes; or
- JHSPH employees or students (either as Principal Investigator, co-investigators or collaborators) will obtain, release or access identifiable private information about living individuals for research purposes; or
- JHSPH receives a direct Federal award to support research that involves human subjects (even if all of the activities will be carried out by a subcontractor or collaborator).

Exceptions to this rule are:

- the Principal Investigator is on the School of Medicine faculty and an SOM IRB agrees to serve as the IRB of record for the project (see [Reciprocity Agreement with Johns Hopkins School of Medicine](#),
- the Principal Investigator is not a JHSPH or SOM faculty member and CHR formally delegates review responsibility to the IRB for the collaborating institution. This is only possible, however, when the collaborating institution has an FWA (see [IRB of Record](#)). In practice, CHR rarely agrees to delegate review responsibility to an IRB of an international institution, or
- some human subjects research done by JHSPH students at other institutions, supervised by a Principal Investigator from that institution and approved by an IRB at the other institution (see [Student Research](#))

This document further clarifies when CHR review and approval of a project are required. It defines when an activity is human subjects research and provides examples of when JHSPH, its faculty, students or staff, or collaborating institutions, are engaged in human subjects research. The document also provides guidance on how public health research may be distinguished from public health practice and describes specific kinds of research activities that must be submitted to the CHR for review and approval. For additional guidance on, and examples of, what constitutes engagement in human subjects research and requires review and approval by CHR see [Engagement in Research](#).

## JHSPH POLICIES AND PROCEDURES

### Does the proposed activity require review by CHR ?

The following questions must be sequentially answered to determine whether an activity is human subjects research and requires review and approval by CHR.

#### First: Does the proposed activity meet the definition of *research*?

*Research* is a systematic investigation, including research development, testing and evaluation, that is designed to develop or contribute to *generalizable knowledge*. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

If an activity does not meet the definition of research, CHR review and approval are not required.

#### Second: Is the research *human subjects research*?

*Human subjects research* is research that involves a *living individual* about whom an investigator (whether professional or student) conducting the research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information.

*Identifiable private information* is information about (1) a behavior in which an individual can reasonably expect that no observation or recording is taking place, or (2) information disclosed for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g., school or medical records. *Private information* must be individually identifiable, i.e. the information can identify, or be associated, with a specific individual.

Since the regulations define a human subject as a living individual, research involving the deceased is *not* human subjects research and does *not* require review and approval by CHR. (Also see [HIPPA requirements concerning private information on deceased individuals.](#))

*CHR review and approval are required for all research that meets the definition of human subjects research.*

#### Third: Will you or JHSPH be *engaged* in human subjects research?

When JHSPH faculty, students or staff intervene or interact with living individuals, or obtain, release or access identifiable private information about living individuals, for research purposes, they are *engaged* in human subjects research, *even when the research is done at another institution and led by a PI from that institution*. Similarly, when JHSPH receives a direct Federal award to support human subjects research, it is *engaged* in the research, even if all of the activities will be carried out by a subcontractor or collaborator.

*When JHSPH, or its faculty students or staff, are engaged in human subjects research, that research must be reviewed and approved by CHR unless CHR has delegated review to the IRB of a collaborating institution.*

*When a collaborating institution is engaged in federally supported human subjects research, and CHR review is required, the collaborating institution must provide to CHR its FWA number and evidence that the research has been approved by its IRB.*

Useful examples of when researchers or institutions are, or are not, engaged in human subjects are available (see [Engagement in Research](#)).

**The final determination as to whether an activity is human subjects research or practice, and whether an investigator or an institution is engaged in research, lies with the CHR and is made on a case-by-case basis. Investigators are encouraged to contact the Office for Research Subjects for assistance in determining whether a proposed activity is research that requires review and approval by CHR. Such research must be approved by CHR before it is initiated. Human subjects research that is begun without prior approval by CHR cannot be approved retroactively.**

### **Is the activity *public health research* or *public health practice*?**

Some public health activities that involve human subjects are research and others are practice. Determining whether public health activities such as surveillance, emergency responses and program evaluation are research or practice may be difficult. The key to this issue is in the latter part of the definition of research, i.e. is the activity “*designed to contribute to generalizable knowledge?*”. The NIH defines generalizable knowledge as “*knowledge related to health that can be applied to populations outside the population served.*” Participants may or may not benefit directly, but there is an expectation that a larger group (others with the same disease or condition, the local community, or a segment of a larger population) will gain from the knowledge obtained.

*Intent* is also an important consideration. In general, if the primary intent of the activity is to prevent disease, to improve a public health program, or to provide emergency relief, and no research is *intended*, the activity is not research. If, however, the intent changes to generating knowledge that can be generalized, the activity becomes research and is subject to review by the CHR. For example, a survey to gather information that would be used to strengthen an educational program for HIV/AIDS prevention would be research if the investigators believed their results could be applied to other populations and intended to publish them. If, however, the results were intended only to benefit the HIV/AIDS prevention program in the population from which the data were obtained, the activity would not be *generalizable* and would not be considered research.

Some questions to consider when determining whether a public health activity is research or practice are:

- Will participants be subjected to additional risks or burdens beyond usual practice to make the results generalizable?
- Will the information that is generated from the activity be presented at a scientific meeting or contribute to peer-reviewed scientific literature?

If the answer to any of these questions is “yes”, the activity should be considered human subjects research and must be reviewed and approved by CHR.

Whenever there is any question, JHSPH faculty should describe the proposed activity in a memorandum and request a written opinion from CHR as to whether a particular public health activity is research or practice. If it is considered that a project begun as public health practice *might* provide information that would later be considered generalizable, it should be reviewed by CHR *before the project is begun*. In *no instance* can CHR approve research that has already been performed.

## **Review requirements for specific research activities**

Review requirements for specific types of research are described below. JHSPH faculty are encouraged to contact the Office for Research Subjects if they are uncertain whether a planned activity constitutes human subjects research.

### **1. Research That Lacks Definite Plans to Involve Human Subjects**

Certain types of proposals are submitted to funding agencies with the knowledge that human subjects may be involved within the period of support, but without a specific description of the human subjects research that may be undertaken. Such proposals include institutional grants, training grants and proposals that include a planning phase. *CHR approval is not necessary for such proposals at the time of an award*. However, human subjects may not be involved in any project supported by the award until,

- CHR approves the project, and
- the funding agency is provided with certification of CHR approval (Form OMB #0990-0263). This form is available on the CHR website or from the Office of Research Administration.

#### *Training Grant Projects*

CHR does not review core proposals for training grants unless the core proposal involves human subjects research. However, all individual projects involving human subjects that are supported by the training grant must be submitted to CHR for review and approval prior to enrollment of any subjects in the research.

For Institutional National Research Service Awards (training grants) the instructions for completing *Item 4. Human Subjects* on the face page of the [grant application](#) are as follows:

In Item 4a, Sec 9f: provide a list of all human subjects research projects supported by this training grant that have already been reviewed by CHR and their CHR approval dates or exemption designations.

Note: The application requires a list of all human subjects research projects, already reviewed by CHR, that are being conducted by core faculty of the training grant. To assist in preparing this list, the Office for Research Subjects can provide a report of investigators who have active/pending protocols on file with the Office. The report

will contain the name of the faculty member, protocol title, and the latest approval date or certification of exempt status.

### *Projects That Include a Planning Phase*

Some projects that involve human subjects include an initial planning phase in which human subjects will not take part. This phase may, for example, focus on the development of research instruments, performance of animal studies, or purification of chemical compounds. In such cases, investigators may request CHR to review the planning phase of the project so that funds for those activities may be released. This can be done by submitting a memo from the Principal Investigator using the [CHR template](#). The memo should describe the specific activities to be carried out during the planning phase and include a copy of the funding proposal. Approval will be indicated by a memo from ORS containing the assigned CHR project number.

The CHR New Application Form A or N should be submitted, and CHR approval obtained, before the research phase is begun. The application should include the CHR number assigned for the Planning Phase.

## 2. Center Grants and Program Projects

### *Center grants*

Center grant proposals typically include a Principal Investigator and several co-investigators working on several studies that share a common objective. Center grants usually include human subjects research. When this is the case, the center grant must be reviewed as a whole prior to the initiation of the research.

### *Program project grants*

Program project grant proposals typically include a core component and several individual research projects that address a single topic or area of research. The individual projects may or may not involve human subjects. The core component usually involves support for shared facilities or staff and does not include human subjects research activities. The CHR need not review all core proposals unless the core includes human subject research.

Generally, program project grants are not reviewed as a whole by CHR. Rather, each component project that includes human subjects research must be individually reviewed and approved by CHR prior to initiating the research. The core component should not be submitted for review by CHR unless it involves human subjects research. Investigators should follow the instructions for [training grants](#) when completing the face page of the HHS grant application.

## 3. Coordinating Centers and Statistical Centers

Institutions whose employees maintain “Coordinating Centers” for multi-site observational studies or clinical trials or “Statistical Centers” that receive or possess private information for research purposes that is individually identifiable (either directly or through coding systems) are considered to be engaged in research. The IRB of the institution housing the

Coordinating or Statistical Center must review and approve the management and operation of the center prior to enrollment of subjects. This review is in addition to the required reviews by the IRBs at each of the local study sites.

### *Coordinating Centers*

“Coordinating Centers” or “Operations Centers” usually do not interact or intervene directly with research subjects. In such cases, CHR does not review each collaborative protocol. However, the application submitted to CHR must include, and CHR must approve, the following:

- a description of the role of the Center in the conduct of the study, and of data analysis and data safety monitoring systems;
- sample protocols and informed consent documents that will be distributed to each collaborating institution;
- a statement that the privacy and confidentiality of research subjects will be protected and a statement as to how this will be achieved;
- recruitment instruments, including flyers, newspaper ads, television spots, etc. that will be used either nationally or as prototypes for the local study sites;
- the local IRBs’ FWA numbers and assurance by the Center that initial and continuing IRB approval will be obtained from each local study site; the coordinating center is responsible for ensuring that each local site has approval from its IRB prior to enrolling human subjects, and
- a description of how the Center will ensure that informed consent is obtained from each subject in compliance with HHS regulations.

Any substantive modifications by a local study site of the sample consent information that relate to risk or alternative study procedures must be reviewed and approved by the IRB of the Center and the local IRB before the changes are implemented.

### *Statistical centers*

When the work of a Statistical Center involves no interaction with research subjects and the risk associated with the Center’s activity is limited to potential harm resulting from breach in confidentiality, CHR does not review each collaborative protocol. However, the application to CHR for research done by the Center must include:

- a description of mechanisms for ensuring the privacy of subjects and confidentiality of their data,
- a copy of the IRB approval from each local study site with the local IRB’s FWA number; the coordinating center is responsible for ensuring that each local site has approval from its IRB prior to enrolling human subjects, and
- a description of how the Center will ensure that informed consent is obtained from each subject in compliance with HHS regulations.

## 4. Grants and Contracts

CHR is required to review all new and competing grant or contract proposals for research that involves human subjects. For new proposals with an identified funding source, investigators must submit the entire grant or contract proposal, with individual salaries “blocked out”, with the completed CHR new research application. These requirements apply to both exempt and non-exempt research. Changes or additions to the source(s) of funding for all CHR-approved studies must also be forwarded to CHR for review.

CHR primary reviewers will review the grant or contract proposal, and the CHR new research application, and will complete a grant/contract review checklist. When the application is approved, the Office for Research Subjects will forward copies of the first 5 pages of the proposal, the statement of approval, and the grant/contract review checklist to the Office of Research Administration (ORA). ORA will not issue a budget number or release funds until it has verified that both the application and the grant or contract have been approved by CHR. For research projects reviewed by a School of Medicine IRB, ORA will verify with the IRB that it has approved the research application and the grant or contract before a budget number is provided and funds are released.

## 5. Pilot Activities

Pilot activities include small-scale studies to refine a research design, determine the feasibility of a larger study, or pilot test a research instrument. Pilot activities that must be approved by CHR are those in which an investigator (1) systematically collects data through intervention or interaction with a living individual, or (2) obtains identifiable private information about a living individual that is intended to develop or contribute to research.

An example of a pilot activity requiring CHR approval would be: refining a questionnaire through feedback obtained from a small group of individuals in preparation for a larger study. On the other hand, casually asking a colleague to check a research instrument for understanding is not human subjects research and does not need CHR approval.

Investigators who are uncertain as to whether a planned activity requires CHR review are encouraged to consult with the Office for Research Subjects.

## 6. Self-Experimentation

Federal regulations do not distinguish between self-experimentation and research on subjects who are recruited for a specific project. Faculty or students who participate in self-experimentation should consider themselves human subjects involved in research that requires CHR approval.

## 7. Oral History Studies

Oral history interviews are usually obtained from individuals selected because of their unique relationship to a topic. The information obtained provides particular perspectives on the topic, but is not necessarily “generalizable”. For this reason, oral history interviews do not meet the definition of human subjects research, are not subject to the Federal requirements, and do not require review by CHR.

## 8. Student Research

All JHSPH students who plan to do *human subjects research* must have CHR approval before working with human data or samples, or contact with human subjects commences. There are four possible ways that a student project can receive IRB approval:

- If the student will be carrying out a specific part of a project that has already been approved by CHR or a School of Medicine IRB, the Principal Investigator may request that the student be added as a named student investigator. The investigator should submit a memorandum to ORS indicating the name of the project, the name(s) of the student investigator(s), a description of the part of the project that will be the responsibility of the student(s), and evidence of human subjects training for the student(s). Alternatively, the Principal Investigator may choose to submit a separate application for the work to be done by the student naming him or her as a student investigator.
- If a student's project is a separate study, not previously approved by CHR or a School of Medicine IRB, a JHSPH faculty member must submit a new application for CHR review and approval, naming him or herself as Principal Investigator and listing the student as a student investigator. Only JHSPH faculty members can serve as Principal Investigator projects submitted for CHR review.
- If a student is doing his or her dissertation research at another institution, no application need be submitted to CHR provided that the research is supervised by a member of that institution and the project has approval from an IRB at that institution. The JHSPH Office for Graduate Research and Education must, however, be notified of this arrangement by letter and provided a copy of the IRB approval.
- If a student has initiated his or her dissertation research at another institution, as described above, but has returned to JHSPH to complete or analyze the data for research purposes as a student, an application must be submitted to CHR by the JHSPH Principal Investigator with the student named as a student investigator.

For additional information on CHR review of student research see [Student Projects](#).

## 9. Research Projects Transferred to JHSPH

Investigators who are newly appointed to JHSPH and wish to transfer a research project from a non-Johns Hopkins institution should submit to the Office for Research Subjects: a copy of the entire grant or contract, copies of the IRB approved research protocol, consent documents, and all research instruments, a current statement of approval from their previous IRB, and a cover letter that includes the investigator's telephone number and e-mail address.

CHR will review this information and determine if a new CHR application must be submitted or if the approval by the investigator's previous IRB may be substituted for CHR approval. If CHR determines that the protocol may be transferred in its existing state with the previous IRB approval, the investigators must complete the JHSPH human subjects

training module and submit a new CHR application prior to expiration of the current project approval period.

All newly appointed faculty who plan to conduct human subjects research are encouraged to contact the [ORS Research Subjects Specialist](#) assigned to their department to review policies and procedures for submitting new applications.