

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
	Identification	Page 1 of 2
Title: What Needs Review by CHR	Date Effective April 19, 2005	Supercedes P&P dated October 12, 2004

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.