

 <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 10/12/04	Supercedes P&P dated

## 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.