

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: What Needs Review by CHR	Date Effective 10/12/04	Supercedes P&P dated

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.