



M E M O R A N D U M

TO: Research Faculty

FROM: Perry B. Molinoff, MD

DATE: December 22, 2005

SUBJECT: IRB Cooperative Agreement with The Children's Hospital of Philadelphia

The University of Pennsylvania and The Children's Hospital of Philadelphia share a rich history of research collaboration. One of the major challenges for investigators engaged in these collaborations is the requirement to submit human research protocols to both Penn and CHOP for institutional review board approval. Researchers undoubtedly find this dual review process burdensome as well as confusing. To reduce redundant reviews and to lessen unnecessary burden on investigators, Institutional Review Board (IRB) members, and staff, the Penn and CHOP IRBs have entered into a cooperative IRB agreement.

Under this innovative agreement, some research protocols meeting specific criteria may undergo a single IRB review by either an IRB at Penn or CHOP. For qualifying protocols, this agreement eliminates the requirement for dual review for by both institutions.

Be aware that this agreement is limited to research where either Penn or CHOP clearly serves as the lead. Only when protocols meet the criteria outlined below, either Penn or CHOP will serve as the IRB of record and will perform the initial review as well as required continuing reviews and review of amendments.

The Process

The agreement defines a mechanism to determine if the protocol review will be conducted by Penn or by CHOP. An investigator preparing a protocol should refer to the criteria below to determine which IRB will have jurisdiction for the review, approval and on-going oversight of the research.

Penn Oversight

For studies qualifying for Penn IRB oversight, [scenarios 1, 3, and 5 below], the investigator will prepare the protocol submission according to Penn IRB requirements.

The submission requirements and related forms may be found at <http://www.upenn.edu/regulatoryaffairs/human/ApplicationProcedures.html>.

Upon receipt of the approval from Penn's IRB, the investigator will submit the following to the CHOP IRB:

- A cover letter outlining the role of CHOP in the study;
- The CHOP IRB face sheet;
- The investigative team conflicts of interest forms for all CHOP members participating in the study;
- The Penn protocol and consent form (if applicable); and
- Penn's IRB approval letter.

The CHOP IRB will assign a CHOP protocol number for the study and will generate a letter acknowledging reliance on Penn's IRB. The investigator will be responsible for submitting a copy of the Penn continuing review materials including a copy of the Penn IRB approval letter.

CHOP Oversight

For studies qualifying for CHOP IRB review [scenarios 2, 4, and 6 below], CHOP IRB submission requirements will apply. For information, contact the CHOP IRB office at 215.590.2830. Upon receipt of approval from the CHOP IRB, the investigator will submit the following to the Penn IRB:

- A cover letter outlining the role of Penn in the study;
- The Penn IRB Face Sheet;
- The Penn Conflicts of Interest Form.
- A copy of the CHOP protocol, and consent form (if applicable); and
- A copy of the CHOP IRB approval letter.

The Penn IRB will assign a Penn protocol number for the study and will generate a letter acknowledging reliance on CHOP's IRB. The investigator will be responsible for submitting a copy of the Penn continuing review materials including a copy of the Penn IRB approval letter.

Study Scenarios

The six scenarios that fall under the umbrella of the Cooperative Agreement are as follows:

- 1. Where all research is to be conducted at Penn, and the only involvement of CHOP is the performance of a procedure or test that is available outside of the research context or that involves blood or other specimens obtained from research subjects enrolled at Penn but analyzed at CHOP; in this circumstance, Penn will be the IRB of record.**
- 2. Where all research is to be conducted at CHOP, and the only involvement of Penn is the performance of a procedure or test that is available outside of the research context or that involves blood or other specimens obtained from research subjects enrolled at CHOP but analyzed at Penn; in this circumstance, CHOP will be the IRB of record.**
- 3. Where all research is to be conducted at Penn, and the only involvement of CHOP is the participation of a CHOP-based faculty member involved in the research as a sub-investigator; in this circumstance, Penn will be the IRB of record.**
- 4. Where all research is to be conducted at CHOP, and the only involvement of Penn is the participation of a Penn faculty member involved in the research as a sub-investigator; in this circumstance CHOP will be the IRB of record.**
- 5. When recruitment will be conducted at CHOP and research, including obtaining consent, is done at Penn: in this circumstance Penn will be the IRB of record.**
- 6. When recruitment will be conducted at Penn and research, including obtaining consent, is done at CHOP: in this circumstance CHOP will be IRB of record.**

Yvonne Higgins and Lynn Bevan have led the process resulting in this cooperative agreement. Please contact Yvonne at 215-573-1206 or Lynn at 215-590-2830 if you have questions.