Missouri State
UNIVERSITY

Mercy Health Springfield and Missouri State University Cooperative IRB Agreement
February 3, 2014

Missouri State University ("University") and Mercy Health Springfield ("Mercy") in Springfield, Missouri have a growing relationship of collaboration. One of the major challenges for investigators engaged in these collaborations is the requirement to submit human research protocols to their Institutional Review Boards (IRBs) for review and approval. Researchers undoubtedly find this dual review process burdensome as well as confusing. To reduce redundant reviews and to lessen unnecessary burden to investigators, members and staffs of the University and Mercy have entered into a cooperative IRB agreement.

Under this innovative agreement, some research protocols which meet specific criteria as described below may undergo a single IRB review by either IRB at University or Mercy. For qualifying protocols, this agreement eliminates the requirement for dual review by both institutions. Notwithstanding any provision of this agreement, either institution may in case elect to conduct its own IRB review in lieu of relying on the review by the other institution.

Be aware that this agreement is limited to studies where researchers from either University or Mercy serve as the lead. Only when protocols meet the criteria outlined below, will the IRB for either University or Mercy serve as the IRB of record and will perform the initial review as well as required continuing reviews and review of amendments per 45 CFR 46.101-.409.

The Process

The agreement defines a mechanism to determine if the protocol review will be conducted by University or Mercy. 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.

Missouri State University Review and Approval

For studies qualifying for University IRB oversight (Scenarios 1 and 3 below), the investigator will prepare the protocol submission according to the University IRB requirements.

The submission requirements and related forms may be found at www.orc.missouristate.edu.
Upon receipt of the approval from University's IRB, the investigator will submit a copy of the following to the Mercy IRB:

- The University protocol and consent form (if applicable); and
- University IRB approval letter.

The Mercy IRB will assign a Mercy protocol number for the study and will generate a letter acknowledging reliance on University's IRB.

Mercy Review and Approval

For studies qualifying for Mercy review (Scenarios 2 and 4 below), Mercy IRB submission requirements will apply. For information, contact the Mercy Medical Research Institute office at 417-841-0250. Upon receipt of approval from the Mercy IRB, the investigator will submit a copy of the following to the University IRB:

- The Mercy protocol and consent form (if applicable); and
- Mercy IRB approval letter.

The University IRB will assign a University protocol number for the study and will generate a letter acknowledging reliance on Mercy's IRB.

The University or Mercy (whichever serves as the IRB of record) will provide copies of continuing review documentation and/or closure to the other party.

Study Scenarios

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

1. Where all research is to be conducted at University and the only involvement of Mercy 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 University but analyzed at Mercy; in this circumstance University will the IRB of record.

2. Where all research is to be conducted at Mercy and the only involvement of University is the performance of a procedure or test that available outside of the research context or that involves blood or other specimens obtained from research subjects enrolled at Mercy but analyzed at University; in this circumstance Mercy will be the IRB of record.

3. Where all research is to be conducted at University and the only involvement of Mercy is the participation of a Mercy physician or coworker member involved in the research is as a co-investigator; in this circumstance University will be the IRB of record.

4. Where all research is to be conducted at Mercy and the only involvement of University is the participation of a University faculty or staff member involved in the research is as a co-investigator; in this circumstance Mercy will be the IRB of record.

Both parties agree that the rights and welfare of human subjects shall be protected in accordance with applicable policies set forth in 45 CFR 46 and the Health Insurance Portability and Accountability Act (HIPAA) and implementing regulations.

Mercy Authorized Official

Steve Kemp, MBA
Mercy Vice President of Operations

Date 2/14/14

Missouri State University Authorized Official

Frank Einhellig, Ph.D.
Provost and Institutional Official

Date 2/6/14

Mercy IRB Approval

Russ Conroy, RRT, MBA
Chair, Institutional Review Board

Date 2-14-14

Missouri State University IRB Approval

Joseph Hulgus, Ph.D.
Chair, Institutional Review Board

Date 2/5/14