

Collaborative and Biomedical Research Review

Summary/Purpose: IRB review authority and procedures for collaborative and biomedical research.

Introduction

This policy covers two situations, which often overlap. First, it sets policy for research collaborations, broadly defined as UM investigators conducting research at other research institutions, including subcontracting such work. Second, it covers IRB review of certain biomedical research, such as trials of FDA approved drugs and devices presenting more than minimal risk or drugs and devices not FDA approved. Because UM's IRB is constituted to expertly review social/behavioral research and not biomedical research, biomedical research may require review by an alternative IRB that has that expertise.

Policy

- Research done by UM investigators who collaborate with investigators at other research institutions can be reviewed either by UM's IRB or by the IRB at the collaborating institution. In the second case, an Authorization Agreement must be executed with both UM and the collaborating institution official's signatures.
- The review of biomedical research 1) that is conducted by UM researchers at UM, 2) that is conducted by UM researchers at a collaborating research institution, or 3) that is subcontracted from UM will either be reviewed by University of Mississippi Medical Center's (UMMC) IRB or deferred to the collaborating or subcontracted institution's biomedical IRB.

Where there is an Authorization Agreement, the external institution's IRB will:

- Provide copies to UM's IRB on any
 1. reports of 1) adverse events or 2) unanticipated problems involving risks to participants or others
 2. progress/renewal reports
 3. other correspondence related to the approved research.

UM's IRB reserves the right to conduct a site visit of the research (after obtaining approval from the collaborating institution's IRB and any other authority required).

[See policy on Research in Schools and Organizations Having No IRB for institutions with no IRB.]