Collaborative and Biomedical Research Review Policy

Summary/Purpose: IRB review authority & procedures for collaborative & 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 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 requires review by an IRB having that expertise.

POLICY

- Social/behavioral research conducted by UM faculty/staff/students at another institution will be subject to review by UM’s IRB. These investigators must ask the local institution's IRB if it wishes to review the research and must provide written evidence to the UM IRB of either local IRB approval or that the local IRB declined review.

- 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. The latter will require an authorization agreement between the chief research officers of both institutions and modification to UM’s Federalwide Assurance with the Department of Health and Human Services Office of Human Research Protections.

Investigators in biomedical research conducted under the authority of either UMMC’s IRB or a collaborating institution’s IRB will be given the following information:

- Researchers 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 made to the collaborating institution’s IRB
  3. other correspondence with the collaborating institution’s IRB

- 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)

Approved by IRB November 1, 2006