



POLICIES

Effective Date: January 1, 2010

Retired:

Revised:

Approved by: Wayne J. Riley, M.D., M.P.H., MBA, CEO and President

Subject: Co-ordination of Research Activities at Meharry by the Vice President for Research

PURPOSE: Biomedical research is a complex enterprise that involves numerous components of the college. The purpose of this policy is to further enhance development of a “seamless”, but compliant, process for the conduct of research at Meharry.

POLICY STATEMENT: In order to co-ordinate and facilitate research activity at Meharry, to make sure all necessary and appropriate stakeholders are aware of the research, and to ensure that all research compliance matters have been fully executed, all new studies that utilize the IRB or IACUC will require administrative approval by the Vice President for Research as a final step in the review process.

Accordingly, all of the administrative materials related to the conduct of the study (e.g., copy of proposal, IRB or IACUC approval, consent form, contract with necessary signatures, signed MOU, signed COI disclosure, budget and Meharry Banner account number, etc., as appropriate for each study) that have been reviewed and approved by appropriate Meharry Committees or Offices, must be sent in aggregate to the Vice President for Research for final approval before the study is implemented. Approval by the Vice President for Research must be obtained before letters of approval from the IRB or IACUC are sent to the principal investigator.

Failure to comply with this policy could result in filing a report of non-compliance with the Federal Government (e.g., NIH, FDA, OHRP, OLAW, IBC, etc.).

DEFINITIONS: IRB, Institutional Review Board; IACUC, Institutional Animal Care and Use Committee; MOU, memorandum of understanding; COI, conflicts of interest; NIH, National Institutes of Health; FDA, Food and Drug Administration; OHRP, Office for Human Research Protections; OLAW, Office of Laboratory Animal Welfare; Institutional Biosafety Committee



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PROCEDURE: The Administrators/Directors of the IRB or IACUC offices will provide the Vice President for Research with all of the materials related to each new study for approval. Formal authorization by the Vice President for Research will be required before the approval letters from the IRB or IACUC will be sent to the principal investigator.

EXHIBITS: