

## **Research Involving Human Subjects: AA 110.7**

### **Purpose**

To set forth certain human subjects' rights and protections, and to establish a review process intended to ensure compliance with federal regulations that govern public funding to educational institutions for research involving human subjects, including those issued by the Department of Health and Human Services Public Health Service, the National Science Foundation, and the National Institutes of Health. Morehouse College seeks to ensure that activities related to human subject research, regardless of funding source, will be guided by ethical principles.

### **Applicability**

All employees intending to work with human subjects in research projects regardless of the source of funding, the purpose, extent, or context of the study.

### **Source**

The Internal Review Board and the Office of Sponsored Programs.

### **Policy**

#### I. Use of Human Subjects:

In accordance with federal government regulations, the College has established an Institutional Review Board (IRB) to ensure the protection of human subjects in research projects. All researchers intending to work with human subjects must submit an application to the IRB prior to the start of research activities. Human subject research includes any study involving human subjects, including survey questionnaires. All human subject studies are subject to IRB review regardless of the purpose, extent, context, or source of funding for the study. Class projects and studies that do not receive any external funding also require IRB review. Research initially undertaken without the intent of using human subjects, which later propose to do so, must comply with these procedures.

I. Exempt Research:

Some research activities with human subjects is exempted from full IRB Review, but that determination can only be made by the IRB chairperson in accordance with federal regulations (45CFR46, part 46.101).

II. Federal-wide Assurance for the Protection of Human Subjects (FWA):

The Morehouse College IRB has been granted a Federal-wide Assurance for the Protection of Human Subjects by the U.S. Department of Health and Human Services (DHHS). The Morehouse College IRB is authorized to approve human subject research supported with funds from federal agencies. Researchers whose IRB application is for a federally funded proposal must indicate the federal agency from which funds are sought on the Proposal Cover Page.

Principal Investigators are responsible for ensuring that IRB instructions are followed, that problems with human subject research are promptly reported to the IRB, and that refinements, changes, or any modification to research protocols are reported to the IRB prior to their use in research. Institutions at which human subject research is not conducted in compliance with federal regulations are subject to the loss of all federal funding.

III. Researchers from Other Institutions:

Researchers from other institutions wishing to conduct studies on students, faculty or staff at Morehouse College must submit an application to the Morehouse College IRB even if an IRB review was completed at their home institution (in accordance with Protection of Human Subjects, 45 CFR 46, part 46.114). In addition, human subject researchers who are not Morehouse College students, faculty or staff, must obtain a Morehouse College research sponsor (faculty or staff) who will assume responsibility for the proposed research activity, and the researcher must submit an Unaffiliated Investigator Agreement Form with their application for IRB review. All research, including that conducted by students and professors in the classroom, is subject to IRB review. Types of research that require IRB review include:

- Questionnaires/inventories administered in class by the professor or another researcher.

- Observational research of behavior in a laboratory or field setting
- Experimental research that requires manipulation of subjects

Researchers who plan to conduct human subject research that they believe is exempt from IRB review must submit a full application to the IRB prior to conducting research activities. Federal regulations state that only the IRB may determine whether a research activity is exempt from full review (see "Exempt Research " above).

For information about the federal law concerning human subject research, click this link to the Office for Human Research Protections (OHRP) at the U.S. Department of Health and Human Services: <http://www.hhs.gov/ohrp/> .

## Procedure

### I. Faculty and Staff Research:

For faculty and staff research, ten (10) full copies of the research protocol, questionnaires to be administered, and proposed informed consent forms must be submitted at least four (4) weeks prior to the initial decision date desired. A copy of the Proposal Cover Page (available at the Morehouse College IRB website) must accompany the proposal. Faculty and staff researchers must obtain the signature of their immediate supervisor (department chair) on the Proposal Cover Page. Electronic submission of an IRB application will be accepted, but it must conform to the requirements stated on the OSP website. The IRB will complete initial reviews of faculty research projects within four weeks of their submission.

### II. Student Research and Classroom Projects:

Two (2) copies of proposals for student research projects and classroom projects must be submitted two (2) weeks prior to the initial decision date desired. This proposal should include a brief description of the research protocol, questionnaires, and the proposed informed consent forms. Proposals for student research projects and classroom projects must be submitted by the faculty advisor. The signature of the advisor is required on the Proposal Cover Page. Approval of the department

chair is also required prior to the submission of a student research proposal. The department chair must indicate approval on the Proposal Cover Page. The IRB will attempt to complete initial reviews of student research proposals within two weeks of the time of their submission.

III. Expedited Review:

The Morehouse College Institutional Review Board does not have authority to conduct expedited reviews. All proposals will be subject to a full review by the IRB.

IV. Notification of Approval:

Following review by the IRB for initial or continuing approval, written notification will be sent to the principal investigator and to the College's human subjects administrator. Written notification will clearly indicate either approval or non-approval. When a proposal is not approved, the IRB will provide a statement of the reasons for its decision, provide the principal investigator with an opportunity to respond either in person or in writing, and typically will provide instructions to principal investigators on proposal modifications that would increase the likelihood of approval upon resubmission. However, the IRB is not obliged to approve any research proposals that may present risks to human subjects, regardless of the proposed benefits foreseen by the principal investigator.

V. Criteria for IRB Approval:

In order to approve research, the IRB must determine, within its sole discretion, that the following requirements are satisfied: (1) there are no unnecessary risks to subjects; (2) the risks to subjects are reasonable; (3) the selection of subjects will be equitable; (4) informed consent will be sought and appropriately documented; (5) adequate provision has been made for monitoring data collection to ensure safety of subjects; (6) adequate provision has been made to protect the privacy of subjects; and (7) when subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included.

VI. Conditions of IRB Approval:

IRB approval of a proposed study is limited to the specific study described in the proposal reviewed by the IRB. Approval is limited to 12 months. An extension of IRB approval for an additional 12-month period requires that the principal investigator notify the IRB of the following information: (1) number of subjects seen, (2) location and number of consent forms obtained, (3) adverse reactions encountered and corrective measures taken, and (4) any changes in the research protocol. Proposals for extensions for an additional 12-month period may be submitted no later than two months prior to the start of the second 12-month period. Researchers must report to the IRB any changes made to protocols, questionnaires, or informed consent forms during a study prior to the initiation of such changes. Changes in protocols, questionnaires, or informed consent forms must be approved by the IRB prior to use with human subjects, except when such change is necessary to eliminate apparent immediate hazard to the subjects. If any such immediate changes are made, the IRB must be immediately notified and approval of the change must be sought. Any incident in which a human subject is injured must be reported immediately to the IRB. In all cases, researchers must report to the IRB on the status of their project at the end of each 12-month approval period or at shorter intervals as specified by the IRB.

Projects that pose a high level of risk to human subjects or that have had problems complying with IRB requirements in the past may be subject to continuing reviews at intervals more frequent than 12 months and/or verification of research activities by individuals other than the principal investigator.

VII. Full Review:

Full reviews will be conducted in accordance with the guidelines provided by the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (Protection of Human Subjects, 45 CFR 46, part 46.109). Copies of the proposal will be sent to each IRB member for full review. A review meeting of the IRB will be held approximately one week after a proposal is sent to IRB members. The principal reviewer (PR) will lead the discussion of the proposal at meetings of the IRB.

The PR will complete a full review form that reports the decision of the IRB and advises the principal investigator of required changes to the protocol or consent forms. The same PR will lead annual and ongoing

reviews of revised proposals and consent forms. The IRB chairperson and PR will sign the Notification of Approval and submit the same to the principal investigator.

VIII. Termination of Approval:

The IRB has the authority to suspend or terminate approval of any research that is not being conducted in accordance with these guidelines or that is associated with unexpected serious harm to the subjects. When approval is either suspended or terminated, the IRB will provide the principal investigator with a statement of the reasons for its decision.

## **Revision History**

Last revision completed on 1.1.2008