Notification of Approval

Following review by the IRB for initial or continuing approval, written notification will be sent to the principal investigator by the Morehouse College Human Subjects Administrator (Doreen Stevens). 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 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.**

IRB approvals only are made in writing and have a duration no greater than 12 months. Federal government agency grants typically require IRB approval documentation communicated directly to the granting agency by the Human Subjects Administrator. It is the responsibility of the principal investigator to provide the IRB with the contact information for their granting agency Program Director, in writing, when such documentation is needed.

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.

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 to 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.

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.