1. POLICY

As a result of its review, the IRB may decide to approve or disapprove the proposed research activity, or specify modifications required to secure IRB approval of the research activity. When the research is reviewed by the convened IRB, these actions will be taken by a vote from a majority of voting members. The members must be present physically or via an approved channel of mediated communication per FO 303 – Meeting Administration, except those members recused in accordance with the IRB's conflict of interest policies. When reviewing research by expedited procedures, the IRB Chair (or Designee) can take any of the following actions except to disapprove a study.

Specific Policies

1.1 Actions

The IRB may take one of the following actions as a result of its review of research submitted for initial review or for continuing review. The investigator will be notified of such actions in writing.

A. *Approval*: The IRB has identified no revisions or questions about the research and the application is approved as submitted. The study has been found to meet the requisite criteria for approval and the research may be carried out as described.

B. *Conditional Approval*: The IRB has identified specific minor revisions or clarifications and has determined that research will meet the requisite criteria for approval once these revisions and/or clarifications are addressed. This means that the study is approved in principle; however, no research activities may take place until an appropriately qualified group or individual appointed by the IRB has determined that the investigator has satisfied the conditions for approval. (Note: The individual appointed by the IRB may be an IRB member, an OPHS staff member, or a consultant.)

   The following revisions or clarifications may be required as conditions of approval:

   (1) Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);

   (2) Submission of additional documentation (e.g., certificate of ethics training);

   (3) Precise language changes to the protocol or informed consent documents; or

   (4) Substantive changes to the protocol or informed consent documents which conform to clearly stated parameters.

C. *Deferral*: The IRB has identified substantive clarifications and/or modifications such that the research study does not qualify for Approval or Conditional Approval (see RR 401 – Initial Review and RR 402 – Continuing Review). The study will be eligible for reconsideration by the convened IRB once the investigator has addressed the clarifications and/or modifications.

D. *Disapproval*: The IRB disapproves the study in principle and the research may not take place. This is decided when the research raises significant scientific or ethical concerns and/or fails to meet one or more of the requisite approval criteria. This action must be taken at a convened meeting.

1.2 Risk Level

For each new application the IRB will determine whether the research presents minimal risk or *greater* than minimal risk of harm to subjects. For amendments and continuing research, the IRB will determine whether the risk level has increased, decreased, or remains unchanged.

1.3 Approval Period and Additional Monitoring

The IRB will determine the interval for continuing review. The norm is to grant approval for 365 days. Unless otherwise indicated, the approval period for research reviewed by the convened IRB will end 365 days from the date of the meeting at which the research was approved, or conditionally approved. In the case of research reviewed by expedited procedures the approval period will end 365 days from the date of review and approval by the IRB Chair/Designee.

The IRB may approve the research for a shorter period and will consider, at least, the following criteria to assess whether a period of less than one year is appropriate: (i) degree of risk to the subjects; (ii) history of non-compliance with this study, the investigator or collaborators; and (iii) fluctuating standard of care or other conditions bearing on the study design and assessment of risks and benefits of the research.

The IRB will also determine whether additional monitoring of the research is necessary per RR 405 – Monitoring Ongoing Research. Methods of monitoring ongoing research may include, but are not be limited to, site visits, third party verification, observation of the research and/or consent process as well as data and safety monitoring.

1.4 Investigator Appeal of IRB Action

1.4.1 ***Internal Appeal.*** Investigators may appeal an IRB decision regarding the revisions required by the IRB to the protocol and/or informed consent form and/or other components of the IRB Application or the disapproval of a study. Appeals must be submitted in writing within 30 days of IRB notification of actions and should provide ***new*** information that would aid in evaluating the request for re-consideration. In addition, the IRB, IRB Chair or Designee may invite the investigator to appear before the IRB to supply information or answer questions. The appeal will be reviewed at a regularly scheduled convened meeting, usually within 30 days of receipt.

1.4.2 ***External Appeal.*** If the investigator has exhausted internal appeal, s/he may appeal to the Vice Chancellor for Research, who may then convene an ad hoc committee to provide non-binding recommendation(s) to the IRB to resolve the issue. If the IRB does not accept the recommendation(s), the appeal is denied and the IRB's decision is final. IRB decisions to not approve specific aspects or an entire research protocol cannot be overturned by any other agent of the University.

2. SCOPE

These policies and procedures apply to all non-exempt research submitted to the IRB.

3. RESPONSIBILITY

The IRB Chair/Designee is responsible for providing IRB members with ongoing guidance and leadership.

The IRB Chair/Designee and OPHS Director are responsible for ensuring that all IRB decisions and actions are based on institutional and regulatory requirements.

The IRB Administrator is responsible for keeping IRB Reviewers apprised of regulatory requirements.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109

21 CFR 56.109

45 CFR 46.111

21 CFR 56.111

45 CFR 46.113

21 CFR 56.113

OHRP Guidance on IRB Approval of Research with Conditions