Howard University Office of Regulatory Research Compliance

Addendum/Revision to: Human Research Subject Protection and Institutional Review Boards (IRB) Standard Operating Policies and Procedures (SOPP)

18.0 CONDUCTING EXPEDITED INITIAL REVIEW

18.4 PROCEDURES

18.4.6 Review Outcomes

Review outcomes may include the following categories:

- Approved/accepted as submitted
- Approved/accepted with administrative review
- Revision requested/ or additional information required
- Disapprove/Reject as submitted
- Tabled
- Suspend protocol
- Terminate protocol

20.0 INITIAL FULL REVIEW by THE INSTITUTIONAL REVIEW BOARD (IRB)

20.4.4 Review Outcome(s)

- APPROVED/ ACCEPTED as SUBMITTED
- REVISIONS and/or ADDITIONAL INFORMATION or ADMINISTRATIVE REVIEW REQUESTED: A vote of Revision and/or Additional Information Required may indicate one of the following:
  - Accept with Administrative Review - That the IRB has approved the protocol pending submission of minor revisions: In this case, the IRB has given the individual chairing the IRB meeting the authority to approve the minor revisions which do not involve substantive concerns. The PI responds to the IRB's suggested revisions in writing and sends the response to the ORRC, and to the IRB chair or member who chaired the meeting for further review. The Chair or designee may forward the responses to the entire IRB for additional review, request additional information, or approve.
  - Revision Requested - The IRB requests a revision and resubmission of the protocol before approval: In this case, neither the IRB chair nor a designated IRB member has the authority to approve the protocol upon resubmission. Instead, the PI responds to the IRB's suggested revisions in writing and sends the response to the ORRC who then place the protocol on the agenda for full board review, at a duly convene and constituted IRB board meeting. Approval of the revised protocol is not guaranteed, especially, if the revision is inadequate or raise new concerns. However, if the committee is satisfied with the revision the protocol is approved.
- In either of these two scenarios, the ORRC staff sends the investigator a notification letter, according to the guidelines in the ORRC Customer Service Standards.
- DISAPPROVED/REJECT as SUBMITTED: In this case the application is not approvable with minor revision. However, it can be resubmitted with major revisions.
- TABLED: Means critical information needed to review the application is missing, and therefore, could not be reviewed.
- SUSPENSION: Additional alternative actions may include suspension of a protocol (See section 10.5.2 of the HU Policy and Procedures.
- TERMINATION: Additional alternative actions may include termination of a protocol (See section 10.5.2 of the HU Policy and Procedures.

As it is the case in the original document dated May 26, 2014, the relevant elements of 21 CFR 50.25; 21 CFR 56.111; 21 CFR 312; 21 CFR 812; 45 CFR 46.108; 45 CFR 46.111; 45 CFR 46.116; 45 CFR 46.117; 45 CFR 46 Subparts B; 45 CFR 46 Subparts C; 45 CFR 46 Subparts D & 21 CFR 50 Subpart D shall apply.