HOWARD UNIVERSITY
OFFICE of REGULATORY RESEARCH COMPLIANCE (ORRC)
INSTITUTIONAL REVIEW BOARD (IRB) – SUPPLEMENT-1

A.) TRACKING IRB MEMBERSHIP AND MAINTAINING THE INTEGRITY OF THE IRB ROSTER AND QUORUM AT DULY CONVENED IRB MEETINGS

This document is not intended to replace any Federal Regulation or the Office of Regulatory Research Compliance (ORRC) Operating Policy and Procedures for Human Subject Protection. Instead, it emanated from our internal quality assessment, and the ongoing (July 2016) Food and Drug Administration (FDA) routine site visit. It is therefore, intended to strengthen our internal and administrative tracking, managing, and reporting process.

Identifying and Communicating Need for New IRB Members: To more efficient track IRB membership, and therefore, quorum, all anticipated changes to the IRB membership roster will occur on *quarterly basis*. To initiate a change, the Chair of the IRB, Director of the ORRC/Senior Compliance Administrator (D-ORRC/SCA-ORRC) or an IRB compliance staff will report the need to the Associate Vice President for Regulatory Research Compliance (AVP-ORRC). The AVP-ORRC will identify potential member(s) with the appropriate area of expertise. Upon confirming willingness of the new member to serve on the board, the AVP-ORRC will recommend such member to the Howard University President for appointment in accordance with the Howard University ORRC/IRB policy and procedures. In case of unanticipated needs, communication and appointment will follow this same protocol except that it may be immediate rather than the beginning of a new quarter. Even then, the AVP-ORRC may encourage changes that become effective at the beginning of a new quarter whenever possible.

Assignment of Appointed Members: In compliance with the ORRC IRB Operating Policies and Procedures for Human Subject Protection, and depending on need, new members will be assigned by the AVP-ORRC as a Regular Voting Member, an Alternate, or Ad Hoc.

Alternate Members: In compliance with Federal Regulation and the ORRC IRB Operating Policies and Procedures for Human Subject Protection, an alternate member will be matched with designated regular voting member(s) according to skills (e.g., clinician serve as an alternate to a clinician). When an alternate member represents more than one voting member or vice versa, the relevant voting member will be identified prior to the meeting, and in the meeting agenda. This allows the alternate member to receive and review the necessary application materials prior to the meeting. Please, note that while the regular member and applicable alternate may be present at the same meeting on the same day and time, the alternate will not count towards quorum or vote on that day and time. However, when that the regular member leaves the room or departs from the meeting, then the alternate may vote and count towards quorum.

Tracking of Changes on the IRB Roster: Whereas each IRB member is appointed to serve for a period of 3 years before reappointment/change, the D-ORRC/SCA-ORRC will review, update, file, communicate and distribute the IRB roster whenever changes occur. The ORRC Executive Assistant will support the D-ORRC/SCA-ORRC in coordinating this effort and maintain a file of the revised rosters to be reviewed at the ORRC staff meetings and the IRB meetings. The ORRC technology support staff will have the responsibility of updating the rosters on the appropriate ORRC device.

Reconciling Attendance/Quorum with the Roster at Duly Convened IRB Meetings: Before each IRB meeting, the compliance officer, together with the IRB chair and the D-ORRC/SCA-ORRC, will confirm that the roster is current and use same to determine quorum before the meeting starts. The same roster shall be used to ascertain quorum, members' conflict of interest and recusals for each protocol reviewed. The IRB minute shall reflect and record quorum, members' conflict, recusal as well as ***record the time of such actions***, in compliance with applicable Federal Regulation and the ORRC policy and procedures. Upon completing the meeting and before members' departure, the compliance staff will confirm with the chair that all votes have been properly recorded for each protocol reviewed. The D-ORRC/SCA-ORRC, and an additional staff shall make every effort to be present at all IRB meetings.

Presence of an Ad Hoc Member and the Effect on Quorum: Ad Hoc members are not considered when determining quorum at an IRB meeting.

Post Meeting Follow-up: Within 24hrs, but no later than 72 hours (3 working days) following the meeting, the compliance staff will complete the minutes of the meeting,

check over attendance and quorum for each protocol reviewed. He/she will forward the following to the D-ORRC/SCA-ORRC for review/correction:

a. A copy of the minutes of the IRB meeting
b. Documentation/records of attendance
c. Documentation of voting for each protocol reviewed demonstrating quorum, member conflict (when present), and or recused.
d. When meetings occur remotely, only telephone quorum would be available

The Director of the ORRC will review the above documents and provide immediate feedback to the staff who will revise and submit the final version back to the D-ORRC/SCA-ORRC for approval before communicating same to the IRB chairs. Upon approval of the minutes by the IRB Chair(s) and the IRB members at subsequent meeting, the D-ORRC/SCA-ORRC shall:

a. Forward the final documents to the AVP-ORRC and underscore any concerns about potential reportable events.
b. Ensure that the following are properly filed/achieved (properly labelled folder including the meeting date):
    i. A copy of the final minutes of the IRB meeting – Follow-up/continuous quality control
    ii. Copies of the meeting attendance signature sheet
    iii. Copies of the signature sheet for each protocol reviewed demonstrating quorum, member conflict (when present), and recuses
    iv. For virtual meetings, attendance and quorum will be properly recorded by the relevant compliance officer
    v. Continuous quality improvement by the SCA and other designated staff will validate minutes

B.) REVIEW of PROTOCOLS and RECORDS of THE REVIEWERS' COMMENTS

a. Henceforth, the ORRC staff will work with reviewers to ensure that their comments properly documented in the ORRC review forms as applicable, except when dictated by special circumstances. When the reviewer worksheet is unavoidably not available and the reviewer participates in the board meeting and discussion, the reviewer's comments during relevant specific protocol-related discussions at the board meeting may substitute for the reviewer worksheet. This approach will remain in effect until such a time that the ORRC migrates its records to an applicable electronic compliance platform.
b. Technical support staff shall download and save reviewer's comments onto the ORRC University share drive at the end of each week. Already, it is the ORRC practice that a copy of all protocol documentations is maintained for at least five years after completion of the research at Howard University, in compliance with [21 CFR 56.115(b)] (see the ORRC/IRB policies and Procedure manual). Additionally, we emphasize that the reviewers' comments

shall be properly organized by submission date, IRB numbers and investigators, and shall remain available for at least 5 years after the protocol is closed.

Reporting to Federal Agency:
The ORRC shall follow the Federal Regulation for reporting changes in the IRB composition to the Office of Human Research Protection (OHRP) (45 CFR 46) as enumerated in the ORRC/IRB policy and procedures.

C.) FOLLOW-UP on IRB REVIEW or EMERGING HUMAN SUBJECT-RELATED/COMPLIANCE CONCERNS

It is currently the practice of the ORRC/IRB that protocols undergoing initial or continuing review are not approved until such a time that they satisfy all IRB questions, observations and concerns, albeit some investigators may not response in a timely manner. In order to optimize this process and further streamline human subject concerns emerging during the period of time when a protocol is approved (protocol deviation, amendments, non-compliance, new risks etc.), the IRB shall request a response from the investigators within the following time frame:

a. **New Protocols**: Requests a response within ***8 weeks*** from the notification date.
b. **Continuing Review/ During Protocol Approval Period:** Requests a response within ***4 weeks*** from the notification date (shorter response time may apply depending on the concern). This request for information will set a new review date to 4 weeks. During the protocol approval period, time to respond could be less (e.g., 2 weeks depending on the context).

Staff will use appropriate tools to track the above timelines. Failure to comply with these recommendations shall motivate the IRB to take additional measures (e.g., stop or limit enrollment, administrative hold, protocol suspension or closure etc.). Written communication from the investigator acknowledging the concerns of the IRB and describing progress on response documents shall constitute the investigator's intention to respond and work in progress. For tracking purposes, these deadlines, and evidence of investigators' response shall be documented in the IRB minutes (please see section "B" of the "IRB Minutes Template").

D.) TRACKING OF EXPEDITED, EXEMPT, and ADMINISTRATIVELY REVIEWED APPLICATIONS

During each IRB meeting, the ORRC staff shall document for IRB information the list of protocols that were reviewed and approved through Expedited, Exempt and Administrative reviews during the intervening period (since the last meeting). During and

after transition to the Electronic Compliance Platform, the IRB Chair will have access to protocols reviewed through Expedited and Exempt Process in iMedRIS. Similarly, the Compliance Officer will call the Committee's attention to those protocols during the Full-Board Meetings. The Chair and or Co-Chairs, and the reviewers shall affirm awareness and concordance with the list. Else, they may raise objections. On rare occasions when an objection is raised and sustained by the board, that an application was reviewed in error through one the above mechanisms, the board shall request that the application be reviewed by the full board (see section "F" of the minute template for tracking).