1.0 OVERVIEW

1.1 HUMAN RESEARCH SUBJECT PROTECTION AND INSTITUTIONAL REVIEW BOARDS

Howard University is committed to the highest ethical standards in the conduct of research and specifically to its obligation to ensure the rights and welfare of human research subjects. Human research protection is a shared responsibility involving the University, the Institutional Review Boards (IRBs), investigators, and research staff.

Any undertaking, regardless of funding source, in which a University faculty member, staff member, or student conducts research involving human subjects or a clinical investigation requires IRB review and approval prior to initiation. The University applies the applicable federal definitions for “research”, “human subjects”, and “clinical investigation” in determining which activities require prior IRB review and approval.

This Standard Operation Policies and Procedures are guided by the Ethical Principles of the Belmont Report, and in accordance with the Common Rule set forth by 45CFR46 Subpart A through D.

1.2 AUTHORITY

- As authorized by the President, the Associate Vice President (AVP) for Regulatory Research Compliance (RRC) is the designated human research protection official for the University, and is responsible for the University’s Federal-Wide Assurance of Compliance with Department of Health and Human Services’ (DHHS)s regulations for protection of human research subjects. Whereas, the AVP for RRC reports directly to the Provost, with dotted line to the President; the Director of ORRC, Chair of the IRBs, and others listed in the ORRC organizational chart (see the ORRC Organizational chart) report to the AVP for RRC.

- The AVP for RRC is authorized to act for the institution, specifically committing the University to compliance with all applicable state and federal regulations governing human research activity or clinical investigation.

- The AVP for RRC is responsible for ensuring that the institution establishes and maintains an appropriate number of IRBs sufficient to meet institutional research needs.

1.3 INSTITUTIONAL REVIEW BOARDS

- The Medical IRB has institutional responsibility for reviewing human subject research in the medical sciences.

- The Nonmedical IRB is responsible for reviewing human subject research in the social and behavioral sciences.

- Depending on the nature of the research activity and the expertise of the membership, a research protocol may be transferred between Medical and Non-medical IRBs if necessary to ensure the reviewing IRB has the appropriate expertise to conduct the review.

- The University grants the IRB the authority to act independently in conducting reviews of research. No University official, committee, or body may approve research involving human subjects or clinical investigation that has been disapproved by the appropriate IRB.

- The IRB performs its duties as described in Howard University's IRB policies and procedures maintained by the Office of Regulatory Research Compliance (ORRC).

1.4 INSTITUTIONAL REVIEW BOARD MEMBERSHIP

- After consultation with appropriate University Departments and review of scholarly, scientific, and other credentials, IRB chairs, vice chairs; IRB members are appointed by the Howard University President at the recommendation of the AVP for RRC.

- Membership shall be consistent with applicable federal regulations to ensure appropriate and diverse representation from multiple scientific and non-scientific professions, various ethnic backgrounds, and both genders, as well as sufficient expertise to meet institutional research needs.

- One member, a “community member,” shall not be affiliated with the University.

- IRB members, other than those with ex-officio status, serve staggered four-year appointments.

1.5 ORRC RESPONSIBILITIES

The ORRC under the leadership of the AVP for RRC is responsible for managing protocol review; assisting the University in responding to federal initiatives affecting the ethical conduct of research, policy development, agency liaison, education, quality improvement, federal record keeping and reporting; and handling allegations of noncompliance.

1.6 INSTITUTIONAL REVIEW BOARD RESPONSIBILITIES

Within the guidelines set forth by the applicable federal granting and regulatory agencies and University IRB policy, specific responsibilities and authority of the IRB are as follows:

- Review, approve, require modifications to secure approval, or disapprove all University human research activity or clinical investigation;

- Review proposed changes in previously approved research or clinical investigation and approve, require modifications to secure approval, or disapprove proposed changes;

- Conduct continuing review of previously approved research or clinical investigation at intervals appropriate to the degree of risk, but not less than once per year;

- Monitor, when appropriate, the informed consent process and the conduct of the research or clinical investigation;

- Suspend or terminate approval of research or clinical investigation that is not conducted in accordance with IRB requirements or that has resulted in unexpected serious harm to subjects;

- Handle reports of unanticipated problems and allegations of noncompliance with human subjects' regulations, and in cases where corrective action is needed, issue appropriate sanctions, including but not limited to requesting minor changes to the protocols, re-consenting volunteers, inform journal editors of the lack of appropriate consent for data collection, disapproving the use of the collected data, disqualify the investigators from conducting research involving human subjects or clinical investigation at the University, and recommending further administrative action to University administration.

1.7 RESPONSIBILITIES OF INVESTIGATORS AND RESEARCH PERSONNEL

- The investigator and research personnel engaged in human research activity or clinical investigations are directly responsible for ethical conduct of research involving human subjects and protection of human subjects.

- The investigator is responsible for obtaining IRB approval prior to initiating research activity; implementing research as approved by the IRB and in compliance with all IRB decisions, conditions and requirements; implementing research within sound study designs according to the standards of the discipline; and complying with all applicable federal, state and *tribal regulations and laws* and all University requirements for the conduct of human research.

1.8 COOPERATIVE PROJECT

When University human research or clinical investigation involves a cooperative project with another entity, the AVP for RRC has the authority to enter into a joint review arrangement with another entity, rely upon the review of another qualified IRB, or make similar arrangements in accord with guidelines set forth by the applicable federal granting and regulatory agency and University IRB policy.

1.9 TRACKING IRB MEMBERSHIP, IRB ROSTER, and QUORUM at DULY CONVENED IRB MEETINGS

1.9.1 Identifying and Communicating Need for New IRB Members:

In order 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 in writing, 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.

1.9.2 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.

1.9.3 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. 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 a regular member leaves the room or departs from the meeting, then the alternate may vote and count towards quorum.

1.9.4 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. Only the signed (***bares signatures of the AVP-ORRC, the* D-ORRC/SCA-ORRC, *IRB Chair and Co-Chairs, and the IRB compliance officer***) can be used as attendance sheet during a duly convened IRB meeting, and posted on the ORRC website. 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 ***signed roster*** on the ORRC website quarterly. A newly signed copy of the roster indicating review and concordance will be posted on the ORRC website.

1.9.5 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 signatures have been obtained for each protocol reviewed. The D-ORRC/SCA-ORRC, and an additional staff shall make every effort to be present at all IRB meetings.

1.9.6 Presence of Consultant and Quorum:

Please note that consultants are not considered when determining quorum at an IRB meeting. Therefore, the presence of an Ad Hoc member at a duly convened IRB meeting, will not change the total the number required to achieve quorum.

1.9.7 Post Meeting Follow-up:

Within 24hrs, but no later than 48 hours (2 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. Scanned copies of the meeting attendance signature sheet
c. Scanned copies of the signature sheet for each protocol reviewed demonstrating quorum, member conflict (when present), and or recused.

The Senior Compliance Administrator of the ORRC or designee when unavailable, 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 scanned and filed/achieved (properly labelled folder including the meeting date):
    i. A copy of the ***approved*** (by the board) minutes of the IRB meeting
    ii. Scanned copies of the meeting attendance signature sheet
    iii. Scanned copies of the signature sheet for each protocol reviewed demonstrating quorum, member conflict (when present), and recuses.

1.10 REVIEW of PROTOCOLS and RECORDS of THE REVIEWERS' COMMENTS

1.10.1 Review Forms:

The ORRC staff will not accept reviewers' comments that are not properly documented in the ORRC "*review forms*" when applicable, except when dictated by special circumstances. This approach will remain in effect until such a time that the ORRC migrates its records to an applicable electronic compliance platform.

1.10.2: Reviewer's comments:

To prevent loss of data, the technical support staff shall download and safe all submitted "*reviewer's comments*" from our google submission site 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 to be maintained for at least five years after completion of the research at Howard University, in compliance with [21 CFR 56.115(b)]. 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.

1.10.3 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.

1.11 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. 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.

Staff will use outlook 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").

1.12 TRACKING of EXPEDITED, EXEMPT, and ADMINISTRATIVELY REVIEWED APPLICATIONS

During each IRB meeting, the ORRC staff shall document in the minutes template "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). 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).

1.13 REFERENCES AND RELATED MATERIALS

Code of Federal Regulations: 46, 50, 56, 16