11.0 RECORD KEEPING

11.1 OBJECTIVE

To describe policies and procedures for Howard University (HU) Institutional Review Board (IRB)/Office of Regulatory Research Compliance (ORRC) record keeping.

11.2 GENERAL DESCRIPTION

The ORRC maintains IRB records in accord with applicable regulatory and institutional requirements.

11.3 RESPONSIBILITY

Execution of the SOPP: ORRC Staff, IRB Members, IRB Chair, ORRC Research Compliance Officer (RCO), ORRC Director, Principal Investigator (PI)/Study Personnel.

11.4 PROCEDURES

11.4.1 Storage of and Access to Records

- ORRC staff secures all active IRB records in the ORRC and limit access to the IRB Chair, IRB members, ORRC Director, ORRC staff, Associate Vice President (AVP) for Regulatory Research Compliance (RRC), and officials of federal and state regulatory agencies, the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and accrediting bodies. ORRC staff may grant HU employees with administrative appointments access to the records on an as-needed basis for official HU business. Investigators or their authorized study personnel have reasonable access to files related to their research activities. ORRC staff limit all other access to IRB records to those who have legitimate need for them, as determined by the ORRC Director, RCO, and/or HU Legal Counsel when submitted through state open records statutes.

- Administrative requests for access (e.g., Dean, Associate Dean, Department Chair, and Sponsors' Compliance Officer) must be in writing and contain the following information:
  - The name of the person requesting the information;
  - The information requested;
  - The reason for the request;
  - Assurance of confidentiality.

- When the ORRC receives a request for IRB records, ORRC staff checks to see whether the request is from a PI or his/her authorized personnel. If the

person requesting the record is listed as study personnel on the record requested, the ORRC staff may copy pertinent parts of the record for that person to pick up or may fax, mail, or e-mail the record.

- If the individual requests a substantial amount of material, ORRC staff allow access to the record and a copy machine in the ORRC for use by the person requesting the material.

- If the person requesting the record is not listed as study personnel on the record requested, the ORRC Director or the RCO makes a determination before releasing any records as to whether the request is from appropriate accreditation bodies, University officials, administrators, or regulatory agencies that should have access. Unless the individual states an acceptable reason for not informing the PI of the request for a record, ORRC staff informs the PI that ORRC has received a request for access to the applicable protocol.

- The ORRC maintains protocol records for a minimum of five years (as determined by the ORRC Director or RCO) after a study is closed. This storage requirement applies even if the study has not enrolled a single subject. ORRC staff destroys protocol records for studies that have been closed for five years unless the ORRC Director or RCO waives the requirement for a specific study.

- In addition to protocol files, the ORRC maintains the following information and records. ORRC staff organize and store records in files or binders or in electronic documents as appropriate which include, but are not limited to, the following categories:
  - Standard operating policies and procedures;
  - IRB membership rosters;
  - Meeting minutes, which include documentation of convened IRB meetings;
  - Federal-Wide Assurance;
  - protocol database tracking system;
  - Other IRB correspondence;
  - Agendas for IRB meetings, which include all items to be reviewed and documentation of expedited and exempt reviews;
  - Alleged noncompliance case records;
  - Mandated reports;
  - Resumes of currently active IRB members;
  - Electronic records documenting completion of mandatory IRB training for study personnel, IRB members, and ORRC staff.

- ORRC staff maintains records indefinitely that are not part of specific protocol files, such as meeting minutes, agendas, standard operating policies and procedures, membership rosters, or periodically destroy them, as determined by the ORRC Director or RCO.

- The ORRC also maintains communications to and from the IRB in the ORRC office and keeps any relevant communication related to a specific research protocol in the protocol record.

11.4.2 Protocol Records

ORRC staff maintains a separate record for every research application. The IRB protocol record includes, but is not limited to:

- Full Review Protocol:
  - Initial IRB application;
  - Scientific evaluations of the proposed research if any;
  - For drugs, the investigator's brochure;
  - For devices, a report of prior investigations;
  - Data Safety and Monitoring Board reports, if any;
  - Signed Signature Assurance Sheet;
  - IRB approved informed consent document and assent document, if applicable, with the approval date stamp;
  - Documentation of all IRB review and approval actions, modifications and all relevant correspondence to and from the investigator, including initial and, if applicable, IRB continuation review (CR) and modification, deviation, exception review;
  - Documentation of type of review;
  - Documentation of study close-out;
  - Specific findings (federal and institutional requirements);
  - Continuation/final review materials;
  - Significant new findings provided to human subjects, if any;
  - Reports of unanticipated problems/adverse events involving risks to subjects or others;
  - Reports of protocol violations;
  - All relevant correspondence to and from the investigator and any other correspondence related to the protocol either hard copy or e-mail;
  - IRB Authorization Agreements;
  - Any existing contractual agreements for off-site research;
  - Applications for funding/sponsorship, if applicable;
  - Advertising or recruiting materials, if applicable;
  - Protocol amendments or modifications;
  - Instrument to be used for data collection, if applicable;
  - Department of Health and Human Services (DHHS)/National Institutes of Health (NIH) approved sample informed consent form and protocol, if applicable;
  - Copy of the package insert, drug monograph, or FDA approved label for drug or device studies using the FDA approved medication/device for approved medical indication;
  - Sponsor's grant, contract, or device proposal if the protocol does not involve the administration of drugs, if applicable;

- Human subject protection training for principal investigators and study personnel;
- Health Insurance Portability and Accountability Act (HIPAA) forms, if applicable;
- Institutional Biosafety Committee correspondence and approval letters, if applicable;
- Other committee approvals/correspondence, if applicable;
- Mandated reports, if applicable;
- Criteria for IRB Approval: Reviewer Checklist; If applicable, IRB Continuation Review: Primary Reviewer Checklist(s);
- If applicable, reviewer signature page(s) (e.g., Prisoner Advocate Reviewer Signature Page, Consultant Signature Page).

- Expedited Review of Protocols:
  - Initial expedited review determination is performed by ORRC compliance officer in consultation with the relevant IRB Chair;
  - All of the items listed above under full protocol review, as applicable to individual studies may apply to exempt review;
  - Documentation and determinations required by the regulations and protocol-specific findings justifying those determinations, including that the study is eligible for expedited review and the applicable expedited review category;
  - Description of action taken by the expedited reviewer.

- Exempt Review of Protocols:
  - Initial exempt review determination is performed by ORRC compliance officer in consultation with the relevant IRB Chair;
  - Initial application for exempt review;
  - Signed Signature Assurance Sheet;
  - All items listed under full review protocol, if applicable to individual studies;
  - Documentation and determinations required by the regulations and protocol specific findings justifying the determinations, including documentation of exempt eligibility and specifying appropriate exemption category;
  - Description of action taken by exempt reviewer.

11.4.3 ORRC Access to and Use of Physical Files

- ORRC staff initials and dates the file storage check in/out sheet whenever a staff member accesses a physical file or returns a file to storage. The initial of the individual who is working on the file must be on the checkout sheet.

- Prior to obtaining IRB approval of a protocol, ORRC staff may maintain pending initial review physical files in the ORRC staff offices, provided that: a) the location of the pending files is clearly labeled; b) each file is labeled; and c) the file is accessible to the other ORRC staff. Once the IRB has

conducted initial review and approved a protocol, ORRC staff files the physical record in storage.

- ORRC staff returns protocol records for active or inactive studies to file storage within 21 calendar days after checking out the file.

- ORRC staff modifies the file storage sign in/out sheet when transferring files from one staff person to another. The staff member transferring the file adds the initials of the staff person to whom the file is transferred to the sign in/out sheet.

- ORRC staff may not take files home to work on minutes or reviews without specific approval from the ORRC Director or RCO.

11.4.4 ORRC Database

- Computerized tracking system maintained by the ORRC include:
  - IRB number which identifies the protocol as full, expedited, or exempt; IRB providing review, and ORRC staff managing review;
  - Current status (active/inactive);
  - Protocol type (medical/nonmedical);
  - Title of the research project (protocol);
  - Protocol process type (full, expedited, exempt);
  - Approval stage (pre-approved, approved, suspended, terminated);
  - IRB to which the protocol is assigned;
  - Risk category;
  - Dates of research period (initial approval date and anticipated ending date);
  - Approval period;
  - Names of the PI, co-investigators, study coordinators, and other study personnel as appropriate;
  - Number and age level of subjects;
  - Subject demographics;
  - Enrollment status (open or closed to accrual);
  - Categories of research (e.g., cancer, genetic research);
  - Other committee approvals (e.g., Institutional Biosafety Committee);
  - Funding source type;
  - Research sites (if other than HU campus);
  - Date of initial approval;
  - Date of most recent approval;
  - Date of most recent continuation approval;
  - If applicable, prior notice of end of current approval period;
  - Submission and review dates for each protocol event (initial review, continuation review, final review, modification review, extension review, unanticipated problem review);
  - Other information, such as meeting dates;
  - Comment section.

- The ORRC compliance data manager maintains the ORRC computerized tracking system and performs a backup of this system on a regular basis. Only ORRC staff members have passwords for the ORRC system.

11.4.5 Examples of Materials Maintained in IRB Protocol File

- IRB Application/Forms;
- Requested Revisions from IRB;
- PI's Response to Requested Revisions;
- Initial Review Approval Letter;
- Criteria for IRB Approval: Reviewer Checklist;
- Revised and Highlighted Consent Form (Clean Consent Form is IRB Stamped/Dated once approved);
- Internal Unanticipated Problem/ Adverse Event (AE) and Approval Letter Copy;
- External Unanticipated Problem/AE and Approval Letter Copy;
- Data Safety and Monitoring summary reports;
- Modification Approval Letter Copy, Modification Request/Materials (may include deviation/exception);
- Protocol Violation Review Letter and Attachments;
- Continuation Review (CR) Notification Letter;
- CR Review Request for Protocol;
- CR Response from PI;
- CR Approval Letter;
- General Correspondence between Investigator and Sponsor;
- Subsequent Revised Versions of Investigator Brochures and other; amendments and/or Adverse Event Reports
- Complaints, if applicable;
- CR/FR Lapse of Approval Letters;

- HIPPA Authorization (forms/information/revisions);
- HIPPA Waiver of Authorization;

11.5 REFERENCES

45 CFR 46.115
21 CFR 56.115