8.0 COORDINATION AMONG the OFFICE of REGULATORY RESEARCH COMPLIANCE, IRB, and INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE (IBC)

8.1 OBJECTIVE:

To describe procedures for coordination between the Institutional Review Board (IRB)/Office of Regulatory Research Compliance (ORRC) and the Institutional Biosafety Committee (IBC) on protocols involving recombinant DNA, infectious agents, and/or human gene transfer/therapy products, selected vaccine trials involving Investigational New Drugs (IND), and immunotherapies.

8.2 GENERAL DESCRIPTION:

Both the IBC and the IRB are committed to ensuring the protection of human subjects involved in research. They have enacted a number of coordination activities in significant areas including: joint committee membership; protocol review; training for IBC/IRB personnel; complaints and alleged noncompliance; quality assurance/improvement findings; and joint policy/procedures.

8.3 RESPONSIBILITY:

Execution of SOPP: Institutional Biosafety Committee (IBC) Staff, IBC Biological Safety Officer (BSO) or designee, IRB Members, ORRC and Research Compliance Officer (RCO), Principal Investigators (PI)/Study Personnel.

8.4 PROCEDURES:

The BSO serves as an ex-officio non-voting member of the Medical IRB. The BSO also serves as an ex-officio voting member of the IBC. The BSO is the primary liaison for ensuring coordination between the IBC and the IRB with respect to protocol review.

The ORRC Director serves as an ex-officio non-voting member of the Medical and non-Medical IRBs and is an ex-officio member of the Committee on Safety and Environmental Health, of which the IBC is a subcommittee. The ORRC Director serves as primary liaison in the development of joint IBC/IRB policies and procedures. The ORRC staff, with input from the BSO, selects IRB members based upon appropriate expertise to serve as IRB primary reviewers for recombinant DNA, infectious agents, and/or human gene transfer protocols and select vaccine initial review IRB

applications. The BSO is responsible for training the designated IRB member(s) on biosafety issues to consider in relation to human research protections, including training on risk assessment.

8.5 PROTOCOL REVIEW

- When a PI proposes research which falls under the purview of the IBC, the PI must submit his/her protocol to the BSO. If ORRC staff receives an IRB application, which in their judgment may require IBC approval, ORRC staff contacts the BSO for assistance in determining whether IBC review is required.

- The BSO screens the protocol to determine if prior IBC approval is required or if the study may be submitted directly to the IRB. The BSO notifies the PI and the ORRC in writing of the outcome of his/her review.

- If the BSO determines that the protocol does not need prior IBC approval, the investigator submits an IRB application to ORRC following IRB standard operating policies and procedures. IRB conducts the review using IRB/ORRC standard operating policies and procedures.

- If the BSO determines that the protocol requires prior IBC approval, the investigator must obtain provisional IBC approval before submitting the IRB initial review application. The IRB will not review new protocols falling under IBC purview unless the PI has obtained IBC review and provisional approval first and has included the required IBC documentation in the IRB application.

- Upon receipt of an appropriately completed protocol submission that falls under the IBC's purview, ORRC staff assigns an IRB number to the protocol.

- ORRC staff is responsible for providing the BSO, the IRB's primary IBC reviewer, and the IRB members with electronic copies of agendas and IRB protocol review documents, following standard operating policies and procedures for disseminating information prior to the IRB meeting.

- The BSO or his/her designee provides the IRB with safety expertise, especially with respect to risk assessment. The BSO or his/her designee may attend the convened IRB meeting or send comments in writing. The designated primary reviewer is responsible for conducting primary review following procedures outlined in the Initial Full Review SOPP.

8.5.1 Complaints and Alleged Noncompliance

- If the IBC receives a complaint from a subject, subject family member, staff, or researcher concerning alleged noncompliance or subject rights

and welfare, the BSO immediately (i.e., within 2 days) notifies the ORRC Research Compliance Officer. The BSO may confer with the ORRC RCO to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, IBC, or both committees.

- If the ORRC RCO receives a complaint or alleged noncompliance involving an IBC protocol, the ORRC RCO immediately (i.e., within 2 days) notifies the BSO. The ORRC RCO may confer with the BSO to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, IBC, or both committees.

- If the complaint/alleged noncompliance falls under IRB purview, the ORRC initiates an inquiry following standard ORRC/IRB operating procedures. The IRB is also responsible for determining whether the incident meets requirements for reporting to the federal regulatory agencies. In making the determination, the IRB follows standard ORRC/IRB operating procedures for reporting (See the Mandated Reporting to External Agencies SOPP).

- After the IRB has completed its review of the complaint/alleged noncompliance, the ORRC RCO is responsible for providing the BSO with a copy of the final deliberations. If the IRB determines that the incident is reportable to a federal regulatory agency, the RCO is responsible for sending a copy of the federal report to the BSO.

- If the complaint/alleged noncompliance falls under IBC purview, the BSO initiates an inquiry following standard IBC operating procedures. After the IBC has completed its review of the complaint/alleged noncompliance, the BSO is responsible for providing the ORRC with a copy of the final deliberations. If the IBC determines the incident is reportable to a federal regulatory agency, the BSO is responsible for sending a copy of the federal report to ORRC.

8.5.2 Joint Policy/Procedures

- The ORRC Director, when appropriate, is responsible for initiating efforts to establish joint IRB/IBC policy, procedures, and submission forms.

- The IBC, ORRC staff, the IRB, or Howard University researchers or administrators may submit suggestions or recommendations for the joint policy/procedure/form initiatives to the ORRC Director.

- The ORRC Director and the BSO must approve any revision to existing joint policies or forms.