12.0 INSPECTIONS by EXTERNAL REGULATORY AGENCIES

12.1 OBJECTIVE

To describe the policies and procedures for the Office of Research Regulatory Compliance (ORRC)/Institutional Review Board (IRB) with respect to inspections by external regulatory agencies

12.2 GENERAL DESCRIPTION

IRB and ORRC records are subject to regulation and inspection by governmental agencies [e.g., Food and Drug Administration (FDA) or the Office for Human Research Protections (OHRP)]

12.3 RESPONSIBILITY

Execution of SOPP: Office of Research Regulatory Compliance (ORRC) Staff, IRB Chair, Associate Vice President (AVP) for Regulatory Research Compliance (RRC), ORRC Director

12.4 PROCEDURES

12.4.1 Upon Notice of Inspection

- ORRC staff/IRB Chair(s) asks all inspectors to identify themselves by name and title and show appropriate identification. Inspectors must inform ORRC staff/IRB Chair(s) what agency they represent and state the reason for the inspection. If an inspector is unable to provide identification, IRB Chair(s)/ORRC staff will request that he/she return with the appropriate identification. Inspectors with the FDA must present a Form 482 upon arrival.

- After the inspector has identified her/himself, ORRC personnel notify the ORRC Director of the inspection. In instances when the ORRC Director is not available, ORRC staff offer to assist but inform the inspector that the supervisor is not present in the office. ORRC staff then suggests that, while they will do their best to help him/her, rescheduling the inspection for a time when the ORRC Director is available, as the ORRC Director might be better equipped to answer questions. If the ORRC Director is not present and the federal inspector decides to stay and conduct the inspection, ORRC staff must contact the IRB Chair(s) and the Associate Vice President (AVP) for Regulatory Research Compliance (RRC) immediately.

12.4.2 During Inspection

- The ORRC Director or designee and a designated ORRC staff member are available to the inspector throughout the inspection.

- The ORRC Director or designee, the designated ORRC staff member, the Chair of the appropriate IRB (Medical or Nonmedical), if available, and the AVP for RRC, if available, may meet with the inspector at the beginning of the inspection.

- ORRC staff and the IRB Chair answer all inspector questions or concerns accurately, honestly, and succinctly and answer only the questions asked.

- The federal inspector has the right to visually observe and inspect all facilities and records of the IRB.

- If the inspector requests duplicate copies of IRB records, ORRC staff complies with the requests and keep a list of the records the inspector has received for duplication. The inspector may ask to duplicate these records at the ORRC facility or ask office personnel to duplicate the records. ORRC staff members are available to duplicate these records. If the inspector decides to use duplicating equipment outside the ORRC offices, an ORRC employee must travel with the inspector to the duplication office to verify the documents copied.

- At the conclusion of the inspection, the ORRC Director or designee, designated ORRC staff member, the appropriate IRB Chair, if available, and the AVP for RRC, if available, may attend the exit interview. If an inspector identifies deficiencies, he/she may leave a copy of the findings with ORRC staff, documenting the results of the inspection. If the inspector does not identify any problems during the inspection, the ORRC Director/IRB Chair receives a letter following the inspection from agency headquarters confirming the outcome.

12.4.3 Following the Inspection

- The ORRC Research Compliance Officer (RCO) or designee maintains a record of everything reviewed by the inspector following the inspection, along with copies of any correspondence provided at the conclusion of the inspection or received after the inspection.

- The RCO or designee forwards copies of correspondence received from the inspector to the ORRC Director, IRB, and the AVP for RRC. The AVP for RRC, IRB, and ORRC staff discuss any corrective action and prepare and implement a response plan as appropriate.

- The IRB/ORRC submits a written response regarding the inspection to the appropriate authority, if required. The ORRC Director and, if appropriate, the

AVP for RRC and/or IRB Chair approve any written response. ORRC staff sends copies to the IRB Chair and the AVP for RRC.