1. POLICY

The IRB Chair or IRB designee is authorized to sign any and all documents in connection with the approval of human research projects that involve the use of humans as participants that have been reviewed and approved pursuant to the University policies and procedures.

Specific Policies

1.1 Authorization for Signatory Authority

Requests from the HRPP and IRB staff for authorization to sign documents not described in this policy shall be made in writing to the HRPP Director for each campus.

1.2 Results of Reviews, Actions, and Decisions

The results of reviews and actions taken by the convened IRB and described in a letter that grants or may appear to grant investigators with initial or continuing approval of research, training, or educational projects involving human research participants shall be signed by IRB Chairs or IRB designees only.

The results of reviews for expedited items that require changes from the investigator will be sent via the IRB’s electronic information system.

1.3 Routine Internal Correspondence

Any routine internal letters, memos, or other communication/correspondence between the IRB and/or members of the faculty or staff of the University that provide information concerning the review of human research protocols by the IRB or staff that do not imply or appear to imply approval of the activity shall be signed only by designated IRB staff members.

1.4 Correspondence with External Agencies

Any letters, memos, or other communication/correspondence regarding IRB actions sent to agencies of the federal government, funding agencies (whether private or public), or their agents shall be signed only by the HRPP Director, HRPP Assistant Director or designee.

1.5 Decisions Made by IRB Chair

The IRB Chair or IRB designee shall sign letters, memos or other communication/correspondence representing the decision or opinions of the IRB Chair or IRB designee as long as such correspondence does not imply review and approval of human research projects.

2. SCOPE

This SOP applies to all IRB staff, HRPP staff, and IRB Chairs.

3. RESPONSIBILITY

3.1 The HRPP Director is responsible for establishing the overall procedure for delegating signatory authority.

3.2 The HRPP Director is responsible for implementing and controlling signatory authority delegations.

3.3 The IRB Chair, HRPP staff, and IRB staff are responsible for adhering to applicable institutional signatory authority policies.
4. APPLICABLE REGULATIONS AND GUIDELINES
   45 CFR 46.109
   21 CFR 56.109

5. REFERENCES TO OTHER APPLICABLE SOPS
   None

6. ATTACHMENTS
   None

7. PROCESS OVERVIEW
   The circumstances under which signatory authority may be delegated and to whom such delegation may be granted are described below.

   7.1 All requests from HRPP and IRB staff to obtain authorization to sign documents are submitted to the HRPP Director. The NC HRPP Director consults with the Director of Compliance and the HSC HRPP Director consults with the HSC VPR as well as the IRB Chairs, as appropriate, when considering such requests.

   7.2 All correspondence on IRB submissions must be signed by the IRB Chair or IRB designee and communicated to the investigator via the IRB’s electronic information system.

   7.3 The HRPP Director makes the designations of signatory authority as follows:
   Any letters, memos, or other communication/correspondence between the IRB and the Investigator or the research staff that provide information concerning the review of human research protocols by the IRB or staff that do not imply or appear to imply approval of the activity shall be signed only by designated IRB staff members. Examples include Continuing Review reminder notices, Exempt status letters, Pending letters, Pre-review letters, and Administrative Withdrawal due to lack of education requirements.

   7.4 The HRPP Director or the HRPP Assistant Director signs all correspondence to agencies of the federal government (OHRP, FDA, VA) and funding agencies.

   7.5 Any correspondences representing the decisions or opinions of the IRB Chair are signed only by the IRB Chair or IRB designee. This includes advice on how to write a protocol, how to conduct recruitment, and research practices. The IRB Chair or IRB designee drafts all disapproval and deferral letters.

   7.6 When authorized by the IRB Chair or IRB designee, the IRB staff may use the signature stamp of the IRB Chair or IRB designee for correspondence generated within the IRB’s electronic information system.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020