

SOP: 105
Signatory Authority

1. POLICY

The IRB Chair or designee is authorized to sign any and all documents in connection with the review and approval of 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 participants shall be signed by IRB Chairs or designees only.

The results of reviews for expedited items that require changes from the Investigator will be sent via email from the IRB staff.

1.3 Routine Internal Correspondence

Any routine internal letters, memos, or emails between the IRB and/or members of the faculty or staff of the University that provide information concerning the review of 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 emails sent to agencies of the federal government, funding agencies (whether private or public), or their agents shall be signed only by the HRPP Director or HRPP Assistant Director.

1.5 Decisions Made by IRB Chair

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

2. SCOPE

These policies and procedures apply to all IRB staff, HRPP staff, and all IRB Chairs.

3. RESPONSIBILITY

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

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

The IRB Chair, HRPP staff, and IRB staff are responsible for adhering to 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 HRPP Director consults with the Director of Compliance and IRB Chairs as appropriate when considering such requests.
- 7.2 All letters indicating Convened Board actions such as Approval, Contingent Approval, Deferral, and Disapproval must be signed by the IRB Chair or his/her designee. All correspondence indicating requested changes for expedited items shall be communicated to the investigator by email.
- 7.3 The HRPP Director makes the designations of signatory authority as described below:
 - 7.3.1 Any letters, memos, or emails between the IRB and the Investigator or the research staff that provide information concerning the review of 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) and funding agencies.
- 7.5 Any correspondence representing the decision or opinions of the IRB Chair are signed only by the IRB Chair or designee. This includes advice on how to write a protocol, how to conduct recruitment, and on research practices. The IRB Chair drafts all disapproval and deferral letters.

- 7.6 The IRB Administrative staff or designee may use the HRPP Director or designee's signature stamp for Continuing Review reminder letters.
- 7.7 When authorized by the IRB Chair or designee, the IRB staff may use the signature stamp of the IRB Chair or designee for correspondence. This authorization is documented in the IRB file.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: May 2012