
STANDARD OPERATING PROCEDURE

Signatory Authority

1.0 POLICY

The IRB Chair and his/her designee(s) are authorized to sign any and all documents on behalf of the IRB in connection with the review and approval (or a determination of exemption) of research projects involving the use of humans as research subjects which have been reviewed and approved pursuant to The Christ Hospital IRB policies and procedures. The Chair and his/her designee(s) must sign their own names and no other, indicate their titles under their signatures, and date their signatures. Signatures may be either handwritten executed on paper or electronic. Electronic signatures shall be [21 CFR Part 11](#) compliant.

An IRB designee is an experienced IRB member who is considered experienced in the review of research proposals including scientific, ethical, legal, and non-scientific aspects, and knowledgeable about the perspectives of research subjects including those of vulnerable populations. The designee must have a minimum of three years IRB experience serving as an IRB member.

1.1 Authorization for Signatory Authority

Authorization to sign documents not described in this policy may be designated to the Institutional Official and approved by the IRB Chair. Written documentation of the authority to sign specific documents will be kept on file in the IRB Office.

1.2 Results of Reviews, Actions, and Decisions

1.2.1 Expedited Review

The IRB Chair or designee(s) are authorized and required to sign results of expedited reviews. IRB staff are authorized to affix the signature of the IRB member who approved the research on the official Approval Letter notifying the investigator of the date of protocol initial or continued approval and the date on which the protocol approval will expire.

1.2.2 Full Committee Review

Decisions made by the Full Committee (i.e., the Full Board) including, but not limited to, deferrals, conditional approvals, and approvals, are communicated to investigators in correspondence issued under the IRB

Chair's signature. IRB staff are authorized to affix the Chair's signature on behalf of the Full Committee in communications with the investigator.

1.2.3 Exemption or Not Human Subjects Research

The IRB Chair or his/her designee are authorized and required to sign results of reviews and actions taken that notify investigators of a determination of exemption or a finding that the investigator's project proposal is found to be Not Human Subjects research. IRB staff are authorized to affix the Chair's signature to correspondence affirming a determination of exemption or a finding of Not Human Subjects research.

1.3 Routine Internal Correspondence

Designated IRB staff members are authorized to sign letters, memos, or emails on behalf of the IRB which provide information concerning the review of human research protocols by the IRB that do not imply, nor appear to imply, approval of the activity.

1.4 Correspondence with External Agencies

Any letters, memos, or other communication/correspondence sent to federal government agencies, funding agencies (whether private or public), or their representatives shall be signed only by the IRB Chair or Institutional Official.

1.5 Decisions of the IRB Chair

The IRB Chair or his/her designee shall sign letters, memos or other communication/correspondence representing decisions or opinions of the IRB Chair or IRB designee provided that such correspondence does not imply review and approval of human subjects research projects.

2.0 SCOPE

These policies and procedures apply to the IRB Chair, IRB Office staff, and IRB members.

3.0 RESPONSIBILITY

The IRB Chair, in consultation with the Institutional Official, is responsible for establishing the overall procedure for delegating signatory authority. The IRB Chair, IRB Staff, and IRB members are responsible for adhering to institutional signatory authority policies.

4.0 PROCESS OVERVIEW

The IRB Chair, in consultation with the Institutional Official, will establish signature authority delegation based on the nature of documents being signed and may designate signature authority in his/her absence. The IRB Chair determines the signatory authority (if any) of IRB Office Staff on his/her behalf.

5.0 REFERENCES

[21 CFR Part 11](#)