

The Christ Hospital IRB
Submitted By: Erica Jones
Reviewed By: Steve Roberts, MD
Approved By: Steve Roberts, MD
(I.1.B)

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STANDARD OPERATING PROCEDURE

SIGNATORY AUTHORITY

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 subjects, which have been reviewed and approved pursuant to The Christ Hospital IRB policies and procedures. Individuals must sign their own name and no other, indicate their title under their signature, and date their signature. Electronic signatures shall be executed through the closed and secure TCHHN network utilizing each individual's unique user ID and password.

An IRB designee is an IRB member who is considered experienced. The member has three years of IRB experience (serving as an IRB member and/or working in the IRB office) and is considered to be knowledgeable by the IRB chair.

Specific Policies

1.1 Authorization for Signatory Authority

Authorization to sign documents not described in this policy may be made to the Institutional Official and approved by the Chairman. 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

The IRB Chair(s) or designee(s) are authorized and required to sign results of expedited reviews. IRB Committee decisions (e.g. deferrals, conditional approvals, approvals) are communicated to investigators in correspondence that comes out under the IRB Chair's signature.

IRB staff are authorized to sign the signature of the above IRB member who approved the research on the official approval letter notifying the investigator of the approval date and the date on which the protocol approval will expire. Likewise, IRB staff are authorized to affix the Chair's signature on behalf of the Committee in communications with the investigator.

The IRB Chairman (or his/her designee) is authorized and required to sign results of reviews and actions taken that notify investigators of a determination of exemption or a finding that the project the investigator proposed is found to be not human subjects research. IRB staff are

authorized to add 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 any actions, letters, memos, or emails between and on behalf of the IRB at The Christ Hospital which provide information concerning the review of human research protocols by the IRB 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 sent to agencies of the federal government, funding agencies (whether private or public), or their agents shall be signed only by the Institutional Official or IRB Chairman.

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

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

3. RESPONSIBILITY

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

4. PROCESS OVERVIEW

The IRB Chairman, 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 Chairman decides (if any) signatory authority the IRB Office Staff will be designated to undertake on his/her behalf.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.115

REVISION HISTORY:

Date Revised	Reason For Change	Revised By
04/21/21	Include procedure for electronic signature; update individual staff titles to IRB Office Staff	Erica