
STANDARD OPERATING PROCEDURE

Periodic Review and Assessment of IRB Members, Chair, and Staff

1.0 PURPOSE

The purpose of this policy is to establish procedures for the periodic review and assessment of the members, chair, and staff of The Christ Hospital Institutional Review Board (IRB).

2.0 POLICY

The President/CEO will appoint IRB members, including the chair, in accordance with federal regulations for a non-specific term. IRB members will serve without compensation, except for the IRB chair who will receive compensation due to the extended duties and time requirements. The Christ Hospital IRB is directed by a chairperson and is comprised of at least five members with multidisciplinary expertise and backgrounds, including a non-affiliated member and a non-scientific member, as required by the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA). In addition, the IRB office staff includes an Administrator to oversee and manage day-to-day operations, and a Regulatory Coordinator who assures the IRB meets federal regulations, as well as institutional policies and procedures.

3.0 PROCEDURE

3.1 IRB Chair

The performance of the IRB Chair will be reviewed on an as-is basis, but no less than every two years by the President/CEO in consultation with the Institutional Official. Should the determination be made that the IRB Chair (1) failed to act in accordance with the IRB's mission, (2) failed to follow the policies and procedures set forth herein and in the federal rules and regulations, (3) has an undue number of absences, and/or (4) failed to fulfill the designated responsibilities of the IRB Chair, he/she will be removed by the President/CEO. Feedback is given during a one-on-one performance evaluation meeting with the President/CEO or Institutional Official.

3.2 IRB Office Staff

The IRB Administrator and Regulatory Coordinator are appraised annually based on The Christ Hospital's core values and job-related performance factors (specific duties and responsibilities) for the position held by the employee. These are

specified in the job description for each position. Feedback is given during a one-on-one performance evaluation meeting with the employee's manager.

3.3 **IRB Members**

The membership roster is reviewed at least annually by the IRB Administrator (or designee) and the IRB Chair to assure appropriate membership and diversity as outlined in [45 CFR 46.107](#) and [21 CFR 56.107](#). The performance of each IRB member will be reviewed on a biennial basis by the IRB Chair. Performance is assessed according to the IRB mission and policies and procedures. To fulfill his or her duties, IRB members are expected to be knowledgeable of the regulations governing human subject protection, biomedical and behavioral research ethics, and the policies of The Christ Hospital relevant to human subject protection. Members will be assessed on their level of participation during and outside of convened IRB meetings, thoroughness of reviews, maintenance of confidentiality, and understanding of the regulations. When necessary, the IRB Chair and/or Institutional Official will meet privately with a member to discuss concerns about his/her performance. Attendance is recorded, and if a member misses a majority of meetings without substantive cause/explanation, the IRB Chair will discuss the advisability of resignation with the board member and report on the discussion to the Institutional Official. Feedback on the biennial performance review will be provided to each IRB member by letter, e-mail, phone call, or in person.

4.0 **REFERENCES**

4.1 Code of Federal Regulations

4.1.1 U.S. Department of Health and Human Services (HHS): [45 CFR 46.107](#)

4.1.2 U.S. Food and Drug Administration (FDA): [21 CFR 56.107](#)

4.2 AAHRPP Domains and Elements: [II.1.B.](#)