

The Christ Hospital IRB
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(II.1.B)

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STANDARD OPERATING PROCEDURE

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

POLICY:

The President/CEO will appoint IRB members, including the Chair, in accordance with federal regulations for a non-specific term. They will serve without compensation, although the chairperson receives 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, backgrounds, a non-affiliated member and a non-scientific member, as required by federal policy and FDA regulations. In addition, the IRB Office staff includes a Administrator to oversee and manage day-to-day operations, and a Regulatory Specialist who assures the IRB meets federal regulations, as well as institutional policies and procedures.

PROCEDURE

IRB CHAIR

The performance of 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.

IRB OFFICE STAFF

The IRB Administrator and Regulatory Specialist 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 that position. Feedback is given during a one on one performance evaluation meeting with the employees' manager.

IRB MEMBERS

The membership roster is reviewed at least annually by the IRB Administrator (or designee) and the Chair to assure appropriate membership and diversity as outlined in 21 CFR 50 and 45 CFR 46. IRB Members' performance will be reviewed on an biennial basis by the IRB Chair. Performance is assessed according to the IRB mission and policies and procedures. In order 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 germane to human subject protection. Member's will be assessed on

level of participation during and outside of meetings, thoroughness of reviews, maintenance of confidentiality and understanding of the regulations. When necessary, the Chair and/or Institutional Official will meet privately with a member to discuss concerns about their performance. Attendance is recorded and if a member misses a majority of meetings without substantive cause/explanation, the Chair will discuss the advisability of resignation with the board member and report to the Institutional Official. Feedback will be given to each member either by letter, e-mail, phone call, or in person.