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## **STANDARD OPERATING PROCEDURE**

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### **New IRB Members**

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#### **1.0 PURPOSE**

This procedure establishes the process of appointing members to The Christ Hospital Institutional Review Board (IRB), and defines the composition and characteristics of the IRB membership.

#### **2.0 POLICY**

The President/CEO of The Christ Hospital shall appoint IRB members, including the IRB chair, in accordance with federal regulations, each for a non-specific term. With the exception of the IRB chairperson, all IRB members shall serve without compensation. The chairperson shall receive compensation due to the extended duties and time requirement. The board shall be multi-disciplined and comprised of at least five voting members including the chairperson. The voting members shall be representative of the active medical staff, a pharmacist, at least one scientific and one non-scientific discipline, and at least one unaffiliated member. Ethnic and gender diversity shall characterize the member composition. In addition, several persons shall be appointed to serve in an ex officio capacity without vote. Consultants may be asked to serve without vote where their particular competence would assist the consideration by the board; for example, an attorney, clergy, social worker, or medical specialist. Meeting attendance is recorded and if a member misses a majority of meetings without substantive cause/explanation, the chairperson will discuss the advisability of resignation with the board member and report on the matter to the President/CEO of The Christ Hospital.

#### **3.0 PROCEDURE & RESPONSIBILITY**

- 3.1 Curriculum Vitae - When a new member is appointed to the IRB, he/she must submit a Curriculum Vitae (CV) to the IRB Office for IRB records. The member must provide an updated CV annually, or as requested by the IRB.
- 3.2 CITI Training - The new IRB member must complete CITI training in Human Subjects Research protection as outlined in SOP 3.12 - Education of IRB Staff/Board Members/Investigators/Research Staff. This course must be completed every 3 years. (Section 3.2, page 1)
- 3.3 Guidance Documents - The IRB Staff will provide the new member with the following documents for review and reference:
  - 3.3.1 IRB Member Handbook
  - 3.3.2 IRB Reviewer Checklist
  - 3.3.3 SOP 2.01 - Guidelines for New Protocol Submission
  - 3.3.4 SOP 3.01 - Scientific/Scholarly Review of Protocols - Minimizing Risk to Subjects
  - 3.3.5 SOP 3.12 - Education of IRB Staff/Board Members/Investigators

- 3.4 The new member must complete a Conflict of Interest form: Conflict of Interest Statement for Institutional Review Board (IRB) Members. This form must be recompleted annually.
- 3.5 The new IRB member must attend one IRB meeting as an “observer” prior to being appointed as a “voting” member.
- 3.6 The new member is strongly urged to attend a local research seminar, which takes place each year in the fall. While such conferences are considered to be valuable educational tools, attendance is not mandatory.

#### **4.0 REFERENCES**

- 4.1 IRB Standard Operating Procedure: SOP 2.01 Guidelines for New Protocol Submission
- 4.2 IRB Standard Operating Procedure: SOP 3.01 Scientific/Scholarly Review of Protocols - Minimizing Risk to Subjects
- 4.3 IRB Standard Operating Procedure: SOP 3.12 Education of IRB Staff/Board Members/Investigators