

**The Christ Hospital IRB**  
**Submitted By:** Erica Jones, CIP  
**Reviewed By:** Elizabeth Arend, JD  
**Approved By:** Steve Roberts, MD

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## **STANDARD OPERATING PROCEDURE**

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### **State and Local Laws in Human Subjects Research**

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#### **1.0 POLICY**

The Christ Hospital IRB is committed to assuring that research approved by the IRB is conducted in accordance with state and local law, in addition to federal law. There are many sources of state and local law that may impact human subjects research, and these laws are subject to change. The IRB and its members should have ready access to legal counsel in order to obtain guidance on issues arising under state and local law. It is also vital that the IRB be kept aware of relevant changes in state and local law to ensure that human subjects receive the full protection of all laws enacted on their benefit. Such changes in state and local laws must be reported to the IRB timely and easily digestible manner in order to achieve this goal.

#### **2.0 PROCEDURE**

The Deputy General Counsel serves as counsel to the IRB. This individual must be accessible to any IRB member for questions regarding legal issues as they pertain to human subjects research. Counsel for the IRB will stay abreast of the relevant literature and report on developments in state and local law relating to human research subject protection. Developments requiring the immediate attention of the IRB will be reported to the IRB chair and presented at the next convened IRB meeting by the Deputy General Counsel.

Outside legal counsel may be sought by Deputy General Counsel if the need arises. In the event that Deputy General Counsel is not available or unable to provide the requested information and such outside counsel is sought, the IRB chair will be provided with the contact information (name, phone number, and email address) of the outside attorney available to answer questions. The advising attorney will research the legal issues involved and provide guidance as soon as is practicable, preferably by the date of the next scheduled meeting of the IRB.

#### **3.0 REFERENCES**

- 3.1 Code of Federal Regulations: [21 CFR 56.103\(c\)](#)
- 3.2 AAHRPP Domains and Elements: [I.1.G](#)