

The Christ Hospital IRB

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(I.I.G)

Number: 1.15

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STANDARD OPERATING PROCEDURE

State and Local Laws in Human Subjects Research

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 for their benefit. Such changes in state and local laws must be timely reported to the IRB in an easily digestible manner in order to achieve this goal.

REFERENCE:

45 CFR 46.101(e), 21 CFR 56.103(c)

PROCEDURE

The Chief Risk Officer serves as counsel for the IRB. This individual must be accessible to any IRB member who may have questions regarding legal issues as they pertain to human subjects research. Counsel for the IRB will stay abreast of the relevant literature, reporting 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 IRB meeting by the Director of Risk Management.

Outside legal counsel may be sought by the Chief Risk Management Officer if the need arises. If such counsel is sought, the IRB Chair will be provided with the name, telephone number, and email address of the attorney who will be available to answer questions in the event that the Director of Risk Management is not available or is not able to provide the requested information. The attorney whose advice is requested 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.

REVISION HISTORY:

Date Revised	Reason For Change	Revised By