The Christ Hospital IRB
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(I.2)

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STANDARD OPERATING PROCEDURE

Determining that Necessary Resources are Available for Care and Safety of Human Research Participants

POLICY:

The Christ Hospital requires that necessary resources are available for the care and safety of human subjects enrolled in research activities at the Hospital. Investigators will assume paramount responsibility for the safety and welfare of human subjects under their care. Department Chairs will review research to ensure availability of necessary resources for the care and safety of research subjects. TCH IRB will consider, as appropriate, whether the research plan includes adequate safety monitoring procedures and, when necessary, will require supplementary care/services to be available to protect research subjects.

PROCEDURE

Investigator Responsibilities:

An investigator identifies necessary resources to protect participants in research studies including:

- Research staff of sufficient number and experience level;
- Availability of medical, social, or psychological services that may be required as the result of participation in research;
- Ancillary services or special equipment to protect participants;
- Special needs for communication with participants (e.g., sign language, translation services).

Institutional Responsibilities:

The Departmental Chair or designee

- Ensures research studies have available necessary resources to protect the safety of research participants.

IRB Responsibilities:

The IRB reviews research to ensure the research plan:

- Makes provisions for adequate collection and review of data to protect the safety of participants; and
- Identifies necessary resources for participant safety, as appropriate.