Investigator Self Experimentation

Purpose

This policy provides guidance for staff members who wish to act as participants in their own research protocols.

Policy

Boston Children's Hospital is committed to the protection of rights and welfare of individuals participating in research activities that involve self-experimentation (including investigator's collecting samples from themselves). When self-experimentation meets the definition of human subject research, review and approval by the IRB is required.

The regulations do not regard research on oneself as different than research on others. Faculty and staff members who wish to act as participants in their own research protocols should consider themselves human subjects.

Boston Children's Hospital requires submission of a protocol or submission of an amendment to the IRB prior to self-enrollment in a project or initiation of the experimentation on oneself. The IRB is authorized to review and approve requests for self-experimentation.

Procedure

Protocol Review

Prior to commencing any research activity that involves self-experimentation (i.e. blood draws, sample collection), the investigator must obtain IRB approval. This may be in the form of an individual research protocol. This applies to either, if the investigator is the only potential subject or as part of a protocol that involves multiple subjects.

The IRB will review each protocol or amendment to add self-experimentation and determine the appropriateness of the research. As part of their review, the IRB will consider the level of self-experimentation and the potential risks and benefits to the investigator as a research subject.

A main concern for the IRB when reviewing a protocol that involves self-experimentation is that the ideation of a novel concept may outweigh the investigator's concern for their own welfare. For this reason, the IRB may institute additional safeguards for the research project.

Consent

The informed consent regulations are also important to consider when an investigator proposes to participate as a research subject in their own protocol. A standard consent form must be developed and include all of the required elements. In addition, the following statements must be added to the consent or as an addendum to the consent for the investigator to sign before participating.

I am an investigator or key personnel on the above-referenced research study and intend to conduct the procedures as described in the approved protocol and consent form on myself: I am aware that the procedures are considered to constitute research on human subjects. I am performing these procedures on myself voluntarily.

Investigator Signature and Date

Related Content

None Identified

Document Attributes

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