The Christ Hospital IRB
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IRB REFERENCE MANUAL
SECTION 11
CRITERIA FOR APPROVAL OF RESEARCH PROJECT BY IRB

11.0 CRITERIA FOR APPROVAL OF RESEARCH PROJECT BY IRB

The Christ Hospital Institutional Review Board (TCH IRB) shall determine that appropriate requirements are satisfied prior to approval of a research project. Research which meets exempt or expedited criteria may be reviewed by the IRB chairman or designee. Research involving greater than minimal risk must be reviewed by the convened "full" board. For these studies, TCH IRB strongly recommends that the Principal Investigator (PI) or designee attend the IRB meeting at which his/her research proposal is under review to present on the proposal and discuss potential issues with IRB members.

11.1 Review Criteria

In order to approve research covered by federal regulations the IRB shall determine that all of the following requirements are satisfied (ref: 21 CFR 56.111):

a. Risks to subjects are minimized:
   i. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   ii. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes

b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

   For the purpose of IRB consideration:
   i. "Risk" is defined as the probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a research study. In evaluating risk, the IRB is to consider the conditions that make this situation dangerous, per se

(i.e., as opposed to those chances that specific individuals are willing to undertake for some desired goals).

ii. "Benefit" is defined as a valued or desired outcome; an advantage.

c. Selection of subjects is equitable. In making this assessment, the TCH IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons. (For additional information, see RM 06 Vulnerable Populations.)

d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by federal regulations, IRB policies and state law, unless a recognized exception or waiver applies.

e. Informed consent will be appropriately documented, unless a waiver of documentation applies, in accordance with and to the extent required by federal regulations (21 CFR 50.27) and IRB guidelines.

f. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. This plan should include a provision for reporting to the IRB any findings of a serious or adverse nature which impact human subjects.

g. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

11.2 Additional Safeguards

When some or all the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects. (Note: TCH IRB does not participate in research concerning prisoners.)

11.3 Research Involving Children

In order to approve research in which some or all of the subjects are children, the IRB must determine that all research is in compliance with 21 CFR 50, Subpart D.

11.4 Modifications/Amendments

TCH IRB may suggest modification or amendments to proposals based on consideration of human subject protection and adequate informed consent.