The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Guideline on Federal and Christ Hospital Requirements for the Protection of Human Research Participants: Ethical and Legal Framework for Human Research Protections at The Christ Hospital

POLICY:

Proper attention to the protection of human research subjects is of vital importance to The Christ Hospital's clinical research activities. Ethical considerations form the foundation for protecting subjects, and regulatory law embodies the ethical review procedures for the vast majority of medical and behavioral research in the United States. This summary is intended to provide investigators with a synoptic overview of the ethical and legal approach to human research subject protections at The Christ Hospital. Since federal regulation dominates the research landscape in this area, much of the material has general applicability.

PROCEDURE:

The following are explanations and guidelines for investigators to refer to with regard to the general principles and ethics of research:

I. **Nuremberg Code**: A significant advance in the application of ethics to human research was the development of specific codes of ethics for research. The first and most widely known of these codes is the Nuremberg Code, which was published in 1947 following the trial of Nazi physicians for human research-related atrocities. Subsequently, other ethical codes for human research protections were developed such as the Declaration of Helsinki, the Belmont Report, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects.

II. **Belmont Report**: For its human research activities, The Christ Hospital applies the ethical principles published in the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," authored by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report provides the ethical basis for the United States' federal regulations pertaining to the protection of human research participants. The Declaration of Helsinki published by the World Health Organization has been adopted by many nations outside of the United States, and investigators doing international research at The Christ Hospital should inquire about what ethical principles apply in the country where their studies are taking place.

The Belmont Report contains three basic principles:

- Respect for Persons
- Beneficence
- Justice

Respect for humans refers to a competent individual's prerogative to make a knowing and voluntary decision to participate in human research without the threat of undue influence or coercion. Frequently termed the principle of autonomy, this principle demands that participants give informed consent.

Beneficence refers to the concept of overall benefit to the participant. Whether or not beneficence is attained is determined by weighing both the potential absolute benefits and harms to the participants. Potential harm to research participants should always be minimized and, secondarily, benefits maximized. Generally, individual rights may not be sacrificed to achieve an overall societal good.

Justice refers to fairness. In the context of human research participation, this is frequently determined by whether the benefits to be gained from the research justify the burdens placed on the individuals studied. A recent example involving the principle of justice centered about the unfairness created by testing of AIDS drugs in African countries in which there was no possibility for the population to benefit from treatment with the drugs after experimentation was completed.

III. **Regulations**: Federal agencies have addressed human protections for research under their jurisdiction by promulgating regulations using federal administrative law. A federal regulation has the force and effect of law and, when valid, may preempt state laws. The major federal regulations pertaining to human research protections are:

a. FDA: Food & Drug Administration --
21 CFR 50 Protection of Human Subjects
21 CFR 56 Institutional Review Boards

b. DHHS: Department of Health and Human Services
45 CFR 46 --
Subpart A: Policy for Protection of Human Research Subjects;
Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research;
Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects; and
Subpart D: Additional Protections for Children Involved as Subjects in Research.

HIPAA: Health Insurance Portability and Accountability Act (Privacy Rule) - The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996. Covered research activities will be conducted in accordance with the HIPAA privacy regulations at 45 CFR Parts 160, 164.

In most instances, more than one set of these regulations apply to a research protocol; when this is the case, each set of regulations must be satisfied independently of each other.

IV. **Guideline for Good Clinical Practice** (E6 Good Clinical Practice: Consolidated Guidance): This guidance, developed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve participation of human subjects. It provides a unified standard for the European Union, Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. It was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries, and the World Health Organization (WHO).

IV. **Federalwide Assurance (FWA)**: To receive research funding from the DHHS, each institution must hold an assurance with DHHS to abide by its regulations for human research protections. The same requirement for agency assurance holds for research sponsored by other federal agencies that have adopted the Common Rule. The Christ Hospital holds a Federalwide Assurance which is valid for federally funded research sponsored by any of the 17 agencies requiring an assurance. The Christ Hospital's Federalwide Assurance is the institution's written, binding commitment filed with the federal government that promises to comply with applicable regulations governing human subjects research and states the procedures which must be utilized to achieve compliance. Through its Federalwide Assurance, The Christ Hospital applies the DHHS regulations for human research protections (45 CFR 46 Subparts A, B, C, D) to all applicable human research activities regardless of the manner of funding for a study. In addition, The Christ Hospital must satisfy the applicable FDA regulations on human subject protections and HIPAA regulations.

V. **State Law**: State law controls the legal age for consent. In Ohio, the age of majority is 18 years of age. Additionally, individuals under 18 may consent to medical treatment in the following circumstances:

a. Diagnosis and treatment for HIV – ORC §3701.242
b. Diagnosis and treatment for STD – ORC §3709.241
c. Diagnosis and treatment for substance abuse/chemical dependency – ORC §3719.012 and J122.04
d. Treatment for victims of certain crimes – ORC §2907.29

Individuals under 18 who are "emancipated minors" may consent to medical care and treatment. "Emancipated" includes, but is not limited to, the following factors: marriage, member of armed services, employed and self-subsisting independent from care/control of parents.

In the area of medical use of radioactive materials, Ohio law has specific requirements to protect human research subjects (OAC §3701 1-58-04). This administrative regulation references federal law and is similar in scope.

Ohio law compels reporting of specific diseases such as tuberculosis, HIV, and other communicable diseases to the Ohio Department of Health (OAC §3701-3.02). Healthcare providers are also obligated to report: abuse (ORC §5123.61), crimes, including domestic violence (ORC §2921.22), and child abuse/neglect (ORC §2151.421). (Also see SOP 1.13 Mandatory Reporting in Human Subjects Research). Ohio laws can be found at http://codes.ohio.gov/orc

Public and federal emphasis on human research protections will likely intensify in the future, as evidenced by increased federal oversight and current enthusiasm for accreditation for human research protection programs. Having a good understanding of the overall framework for human subjects protection will assist stakeholders in the clinical research enterprise to meet their responsibilities in this area.