



Research & Human Subject Definition

Policy

- Children's Hospital policy defines human subject research as any activity that either represents **research** that involves **human subjects** as those terms are defined by Department of Health and Human Services regulations or any activity that represents **research/clinical investigation** that involves **human subjects** as those terms are defined by Food and Drug Administration regulations.
- For drugs the FDA regulations also apply when there is any use of a drug in research except the use of a marketed drug in the course of medical practice.
- For devices FDA regulations apply to studies where the purpose is to determine the safety or effectiveness of a device or data will be submitted to or held for inspection by the FDA as part of a marketing permit. The FDA definition of a human subject includes an individual on whose specimen a medical device will be used if the previously mentioned criteria were met.
- Human subject research that is conducted by the staff of Children's Hospital (CH) on its premises or under its sponsorship, whether or not supported by outside funds, is to be reviewed and approved by the Committee on Clinical Investigation (CCI). Activities that meet either of the definitions of research, below, are subject to review by the Committee on Clinical Investigation. In addition the Committee on Clinical Investigation has included in its jurisdiction review of all uses of human tissue/specimens (including autopsy material) obtained from Children's Hospital patients and the review of all Children's Hospital patient records for research purposes for a determination as to what constitutes human subject research. Some of these activities may not constitute the HHS and FDA definition of human subjects but are included in the Children's Hospital Human Subject Protection Program.

Purpose

The purpose of this policy is to define those activities that constitute human subject research and clinical investigations, and fall under the jurisdiction of the Committee on Clinical Investigation.

Procedure

The CIC uses the following definitions to determine what constitutes human subject research:

Health and Human Services Common Rule Definitions:

Research	45 CFR 46.102(d) defines research as a systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge.
Human Subject	45 CFR 102(f) defines a human subject as an individual about whom an investigator conducting research obtains data through intervention or interaction with individual or identifiable private information. Intervention or Interaction includes physical procedures performed on an individual, manipulation, communication or interpersonal contact with an individual or manipulation of an individual's environment. Private information includes information that an individual can reasonably expect will not be made public, and information about behavior that an individual can reasonably expect will not be observed or recorded. Identifiable means that the identity of the individual is or may be readily ascertained by the investigator or associated with the information.
Systematic Investigation	A study following a methodical plan to establish factual information concerning the truth of a specific hypothesis or theory".
Generalizable	Knowledge that may be justifiably transferred or extrapolated to a broader population or situation than that in which it has been derived."

Food and Drug Administration (FDA) Definitions:

Research:	21 CFR 50.3(c) defines research as an experiment that involves a test article and one or more human subjects.
Human Subject:	21 CFR 50.3(e) defines human subject as: <ol style="list-style-type: none">1. An individual who is or becomes a participant in research, either as a recipient of a test article or as a control. Or <ol style="list-style-type: none">2. Individuals on whose specimen a device was used.
Test Article:	21 CFR 50.3(j) defines test article as any drug (including a biological product for human use ,medical device for human use, human food additive, color, adaptive, electronic product, or any other article subject to regulation under the jurisdiction of the FDA.

Other Activities that Require Review by the Committee On Clinical Investigation

- The use of all tissue/specimens (including autopsy material) obtained from Children's Hospital patients and the review of all Children's Hospital patient

records for research purposes. Some of these activities may not constitute the HHS and FDA definition of human subjects but are included in the Children's Hospital Human Subject Protection Program.

Process for Determining Whether an Activity Constitutes Human Subject Research

Investigators are responsible for determining what constitutes research with human subjects in accordance with the above definitions, institutional policies, and guidance documents. When there is a question, the CCI administrative office is to be contacted for consultation. Investigators who wish to obtain a determination about whether an activity is human subject research may contact the IRB by phone or email, or may submit an application for review. The CCI Chair and the IRB administrative staff are authorized to provide a determination. The determination will be based on whether the activity either represents **research** that involves **human subjects** as those terms are defined by Department of Health and Human Services regulations or represents **research** that involves **human subjects** as those terms are defined by Food and Drug Administration regulations. Determinations will be communicated to investigators in writing, and a copy of the determination will be retained for IRB records.

Process for Determining Whether an Activity is Exempt from the Regulatory Requirement for Review by the Committee on Clinical Investigation

Investigations conducting human research, or research involving discarded/stored biological specimens or chart /database reviews must complete the forms used to request discarded/stored biological specimens and chart /database reviews, exemptions and submit them to the IRB. The staff will determine whether the appropriate form was completed and initiate the required review process. The CCI Chair, the Director of Research Compliance and the IRB Manager are authorized to provide a exemption determination or a review of discarded/stored biological specimens and chart /database reviews research. The form for exemptions is signed by the Director or Clinical Research Compliance or Manager and a copy sent back to the investigator. A review of the discarded /excess human biological materials and review of records and databases by the Director or Clinical Research Compliance, includes a check off section that indicates whether the research involves human subjects, is exempt or expedited and is signed and returned to the investigator.

Related Content

Clinical Investigation Policy and Procedure

- What Quality Improvement and Education/Competency Evaluation Activities are Considered Research and Subject to Committee on Clinical Investigation review?
- Guidelines, Concepts, and Procedures for Differentiating Between Research and Innovative Therapy.

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Approved	_____ Susan Kornetsky Director of Clinical Research Compliance Carleen Brunelli, MBA, PhD Vice President for Research Administration		