



Research & Human Subject Definition

Policy

- Boston 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 Boston Children's Hospital (BCH) on its premises or under its sponsorship, whether or not supported by outside funds, is to be reviewed and approved by the Institutional Review Board (IRB). Activities that meet either of the definitions of research, below, are subject to review by the Institutional Review Board.

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 Institutional Review Board.

Procedure

The IRB 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 a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

Intervention or Interaction includes physical procedures performed on an individual, manipulation, communication or interpersonal contact

Document: irbm_021_001_rsrch_human_subj_definition.docx

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:

1. An individual who is or becomes a participant in research, either as a recipient of a test article or as a control.

Or

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.

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 IRB 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. The IRB 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.

Related Content

Institutional Review Board Policy and Procedure

- What Quality Improvement and Education/Competency Evaluation Activities are Considered Research and Subject to Institutional Review Board review?
- Guidelines, Concepts, and Procedures for Differentiating Between Research and Innovative Therapy.

Document Attributes

Title	Research & Human Subject Definition		
Author	Susan Kornetsky	Dates Reviewed/ Revised	04/01/05 5/4/2007 07/19/07 01/23/08 03/12/2010 10/29/10
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Boston Children's Hospital, 2015	Last Modified	5/1/15
Approved	Susan Kornetsky, MPH Director of Clinical Research Compliance <hr/> August Cervini, MBA Vice President for Research Administration		