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**Boston  
Children's  
Hospital**

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Owner Susan Kornetsky:  
Manager  
Department Research  
Applicability Boston Children's  
Hospital- Policies  
& Procedures

## Research and Human Subject Definition Policy/Procedure

### Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

### Scope

This policy defines those activities that constitute human subject research and clinical investigations and fall under the jurisdiction of the Institutional Review Board.

### Definitions

Department of Health & Human Services Common Rule

**Research:** A **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge** [45 CFR 46.102(l)].

- **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.

**Human Subject:** A living individual about whom an investigator conducting research, which (1) obtains information or biospecimens through **intervention** or **interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates **identifiable private information** or **identifiable biospecimens**.

- **Intervention:** Includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment

that are performed for research purposes.

- **Interaction:** Includes communication or interpersonal contact between investigator and subject.
- **Private Information:** Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

**\*Identifiable private information:** Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**\*Identifiable biospecimen:** A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Food and Drug Administration (FDA)

**Clinical Investigation:** Involves use of a **test article** (i.e., drug, device, food substance, or biologic), one or more human subjects, meets requirements for prior submission to the FDA (involves drugs or medical devices other than the use of FDA approved drugs or medical devices in the course of medical practice), or results are intended to be part of an application for research or a marketing permit.

**Human Subject:** As defined by 21 CFR 50.3(e): (1) An individual who is or becomes a participant in research either as a recipient of a test article or as a control or as an individual on whose specimen a device is used, or (2) a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease. This definition includes the use of tissue specimens even if they are unidentified.

**Test Article:** As defined by 21 CFR 50.3(j): 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.

Boston Children's Hospital

**Work Force** is defined as medical staff that have appointments as "active staff, research staff or employees" of Boston Children's Hospital or one of the Boston Children's Foundations.

## Policy Statements

Boston Children's Hospital 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 (HHS) regulations or any activity that represents research/clinical investigation that involves **human subjects** as those terms are defined by Food and Drug Administration (FDA) regulations.

1. 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.
2. 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 **work force** of Boston Children's Hospital on its premises or under its sponsorship, whether supported by outside funds or not, is to be reviewed and approved by the Institutional Review Board (IRB).

Activities that meet either of the definitions of research above, are subject to review by the Institutional Review Board

## Procedures

Implementing Department of Health & Human Services 46.102 (7)

Per the Federal departments or agencies implementing this policy shall:

- i. Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of "identifiable private information," as defined in paragraph (e)(5) of this section, and "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.
- ii. Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate "identifiable private information," as defined in paragraph (e)(5) of this section, or an "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the FEDERAL REGISTER after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site

Process for Determining Whether an Activity Constitutes Human Subject Research

**Principal Investigator (PI) Responsibilities:** It is the responsibility of each investigator to seek IRB review and approval prior to initiation of any research involving human subjects or before conducting any clinical investigation. The PI is responsible for making a preliminary decision regarding whether their activities meet either:

1. The U.S. Department of Health and Human Services (HHS) definitions of both "**research**" and "**human subjects**" and/or
2. The FDA definitions of both "clinical investigation" and "human subjects."
  - a. The investigator may contact IRB staff or the IRB Chair/Vice Chairs, for advice on the applicability of the federal regulations.
  - b. In cases where it is not clear whether the study requires IRB review, the IRB staff or

the IRB may ask the investigator to send a memorandum to the detailing the proposed research.

- i. The Senior Director, IRB Chair, or their designees make the final determination whether the activities meet the federal definitions.
- ii. In addition, investigators may be referred to other policies and departmental processes to assist in this determination.

### Examples of Activities That Do Not meet the Definition of Regulated Research

For the purpose of evaluating whether an activity meets the definition of research, the following activities have been excluded:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions

## Related Content

- Department of Health & Human Services: Office of Human Research Protections: §46.102
- U.S. Food and Drug Administration: Code of Federal Regulations Title 21
- IRB Policy: IRB Jurisdiction (For additional information on Boston Children's Hospital Work Force)

## Approval Signatures

**Step Description**

**Approver**

**Date**