

Status **Active** PolicyStat ID **13321170**



**Boston
Children's
Hospital**

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Effective 1/1/2023
Next Review 1/1/2026

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Applicability Boston Children's
Hospital- Policies
& Procedures

Waivers and Alterations of Informed Consent: Parental Permission/Child Assent Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy outlines the federal regulations in concern of waivers and alterations of informed consent, and requirements for waiving parental permission/assent for children.

Policy Statements

Boston Children's Hospital observes that the federal regulations allow the IRB to waive or alter the consent and/or requirement of consent documentation when specific criteria are met.

Procedures

Waiver of Documentation of Informed Consent

HHS (45 CFR 46.117(c)) and FDA (21 CFR 56.109(c)(1)) allow the IRB to waive written informed consent for research that meets specific regulatory criteria.

1. **For HHS funded research** (45 CFR 46.117(c)), the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
 - a. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach

- of confidentiality.
- b. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
 - i. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; **or**
 - ii. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
2. **For FDA regulated research** (21 CFR 56.109(c)(1)), the IRB may only waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:
 - a. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
 3. The investigator is required to justify in the protocol how the conditions for waiver of documentation are to be met.
 4. The procedure for waiving the requirement for documentation is not intended to circumvent the requirement for informed consent but rather to protect patient privacy. All required information must still be presented and discussed to ensure a voluntary informed consent process.
 5. In cases in which the documentation requirement is waived (referred to as "obtained through a method other than a written document" in Boston Children's Hospital IRB application and approval materials), the IRB will often require the investigator to provide subjects with written information about the research.

Waiver of Some or All Elements of Informed Consent

For any research that is subject to HHS or FDA regulations the IRB may approve a consent procedure that does not include or that alters some or all of the elements of informed consent, or that waives the requirements to obtain informed consent HHS allows this under (45 CFR 46. 116(f)).

1. HHS requirements

- a. The research or demonstration project is to be conducted by, or is subject to, the approval of state or local government officials, and is designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; **or** possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration; **or**
- b. The research:

- i. involves no more than minimal risk to the subjects;
- ii. could not practicably be carried out without the requested waiver or alteration;
- iii. involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

2. FDA requirements

- a. In light of the Cures Act amendment to the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA intends to revise its informed consent regulations to add this waiver or alteration under appropriate human subject protection safeguards to the two existing exceptions from informed consent (i.e. in life-threatening situations and for emergency research).
- b. Until FDA promulgates these regulations, they have provided final guidance which indicates they **do not** intend to object to an IRB approving a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 21 CFR 50.25, or waiving the requirements to obtain informed consent when the IRB finds and documents that:
 - i. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
 - ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - iii. clinical investigation could not practicably be carried out without the waiver or alteration; **and**
 - iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of Parental Permission

HHS regulations: In accordance with HHS regulations, the waiver of parental permission with reliance solely on the child/adolescent's assent is permitted in two situations.

1. The first situation is when research meets the criteria listed:
 - a. the research involves no more than minimal risk to the subjects;
 - b. the research could not practicably be carried out without the requested waiver;
 - c. if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
 - d. the waiver or alteration will not adversely affect the rights and welfare of the

subjects

- e. the subjects will be provided with additional pertinent information after participation.
2. A second criteria which is **not** limited to minimal risk research is when it is unreasonable to obtain the parent's permission (e.g., the research involves health care issues subject to confidentiality specific to an adolescent subject).
3. This situation is common in areas of adolescent research that involve sexually transmitted diseases, birth control, high-risk behaviors and AIDS prevention.
4. Parental permission is to be obtained whenever reasonable. However, in situations in which the investigator considers it unreasonable, the IRB is to carefully consider the investigator's request and determine whether the waiver falls within the guidelines established by the Society of Adolescent Medicine and federal regulations.
5. Additional waiver questions are included in the protocol application should a waiver of parental permission be requested for this purpose.
6. If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement for protecting the subjects (i.e. neglected or abused children), it may waive the parental permission requirements, provided an appropriate mechanism is substituted to protect the children who will participate as subjects in the research, and provided that the waiver is not inconsistent with federal, state, or local law.

The Food and Drug Administration (FDA) has **not** adopted the section of the federal regulations (45 CFR 46.4089C) that allow for waiver of parental permission. Therefore, protocols that involve children that are subject to FDA regulations may not waive the requirement for obtaining parental permission under these criteria.

IRB Review of Waivers of Informed Consent

1. If an investigator seeks a waiver of informed consent, the section of the protocol application that requires a justification of the means by which the waiver criteria are met for that study must be completed.
2. If a protocol is eligible for expedited review, the expedited reviewer is responsible for determining that the criteria are met prior to accepting a waiver. If the protocol is not eligible for expedited, the IRB reviewer is responsible for determining that the criteria are met prior to accepting a waiver.
3. If the IRB or expedited reviewer agrees with the determinations and findings provided by the investigator in the application form, the agreement will be documented in the IRB minutes or if through the expedited review in the protocol record.
4. In making a determination as to whether the research could not be practicably carried out without the waiver or alteration, the IRB or expedited reviewer will consider the following criteria:
 - a. The size of the population being researched
 - b. The proportion of individuals likely to have relocated or died since the time the personal information was originally collected or the patient was seen for clinical

care.

- c. The risk of introducing potential bias into the research, thereby affecting the generalizability and validity of the results.
- d. The risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek their consent.
- e. The risk of inflicting psychological, social or other harm by contacting individuals or families with particular conditions or in certain circumstances.
- f. The difficulty and loss of privacy inherent in contacting individuals directly when there is no existing relationship between the organization and the individuals.
- g. The difficulty of contacting individuals indirectly through public means, such as advertisements and notices.
- h. Whether, in any of the above circumstances, the requirement for additional financial, material, human, organizational and other resources needed to obtain such consent will make the conduct of the research impracticable because it is an undue hardship.
- i. If the IRB or Expedited Reviewer agrees, the minutes and/or determination letter must document concurrence or the IRB's determination.

Screening, Recruiting, or Determining Eligibility

1. HHS regulations also specify that an IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
 - a. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
 - b. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
2. However, in accordance with HIPPA a waiver of authorization may still be required.
3. There is a section of the protocol application requiring justification of the waiver of authorization for querying medical records when screening for recruitment must be completed.

Related Content

- Department of Health and Human Services Regulations
 - 45 CFR 46.117c: Documentation of informed consent
 - 45CFR 46.116f: General waiver or alteration of consent
- U.S. Food & Drug Administration CFR – Code of Federal Regulations
 - 22 CFR56.109c1: Waiver of documentation of informed consent

- 21 CFR50.25: Elements of informed consent
- 21CFR50.3: Definition of minimal risk
- 21CFR56.102i: Definition of minimal risk
- IRB Policies
 - Exception from Informed Consent Requirements for Emergency Research (For additional information on emergency care and other limited circumstances)

Approval Signatures

Step Description

Approver

Date

Applicability

Boston Children's Hospital- Policies & Procedures

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