

Institutional Review Board (IRB) Policies & Procedures Manual



Document: irbm-004-004-exemptions - nov2020.docx

Exemptions

Purpose

This policy outlines the process for determining that an activity is exempt from human subject review and to list the specific federal regulation categories that Boston Children's Hospital accepts as exempt.

Policy

In accordance with federal regulations 45 CFR 46 and 21 CFR 50 and 56, Boston Children's Hospital allows specific categories of research to be exempt from human subject review. Any research that falls within these categories must not be subject to any state laws that would prohibit an exemption.

- Any IRB member may determine that a human subject activity is exempt from IRB review.
- Limited review in any of the exempt categories will be conducted by an IRB member.
- Prisoners: The exemptions in this policy do not apply to research subject to prisoners. The only exception is for research aimed at a broader subject population that only incidentally includes prisoners.
- Children: For federally funded studies that involve children, exemption 2 only applies to educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Exemption 3 for benign behavioral intervention does not apply.
- For non-federally funded research, the expanded categories below are allowed in adults, children and prisoners.

Definitions

Exempt: Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories specified in the HHS and FDA regulations.

Expanded Exempt Review Categories: The procedures and categories of research not listed in 45 CFR 46.104(d) but that have been determined by the BCH IRB to be exempt from the regulations due to their low risk level. This exemption provision does not apply to research that is funded by the federal government or to clinical investigations of FDA-regulated products.

Limited IRB Review: IRB review limited to the determinations required to assure provisions of privacy and confidentiality of the regulations. IRB members conducting limited IRB review may not disapprove research.

Procedure

Exemption Categories

Boston Children's Hospital will exempt from human research review only those research activities that involve human subjects that fall within one or more of the specified exempt categories. Categories considered exempt from IRB review are as follows:

Category 1

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

Category 3

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

- (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review regarding privacy and confidentiality.

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research

Category 4

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- (i) The identifiable private information or identifiable biospecimens are publicly available.
- (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA regulations the purposes of "health care operations" or "research" or
- (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Category 5

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to

conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects

Category 6

Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Boston Children's Hospital does not recognize exemption categories 7 and 8

Expanded Exempt Categories:

Research that involves interviews or questionnaires with adults will qualify as exempt even when the subject of the research is a child. This expanded category is only applicable if the research is not federally funded or regulated by FDA. Example: Adult parents are asked questions regarding their children who the research subjects are.

Exemption Review Process

1. If an investigator believes that a study meets the criteria for exemption, the Principal Investigator (PI) is asked to submit an IRB protocol using the CHeRP SmartForm: **Request for Exemption**.
 - a. Investigators who are requesting an exemption for **Category 4** secondary use of specimens or data are asked to instead submit an IRB protocol using the CHeRP SmartForm: **New Research Activity Limited to Secondary Use of Human Biological Material and/or Review of Health Information**.
 - b. These applications are to be submitted for confirmation of their exempt status by an IRB member.
 - c. As applicable, some exemption categories are also subject to a **limited review** of privacy and confidentiality protections by an IRB member.
2. The SmartForm asks for:

- a. A brief summary of the research.
 - b. That the investigator indicates which exemption category their research qualifies.
 - c. Further justifications for meeting the exempt status and **limited review** may be applicable.
3. The **Request for Exemption** Form is reviewed by an IRB member to determine:
- a. Risks to subjects are minimized.
 - b. Whether some form of informed consent should still be obtained.
 - c. If necessary, subjects and/or the research will be appropriately monitored.
 - d. Whether any ethical concerns exist.
 - e. Whether the request meets the exemption criteria.
4. Research falling into one of the following exempt status review categories must undergo limited IRB review. The limited IRB review will ensure that there are adequate provisions to protect the privacy of subjects and the confidentiality of data, as per 45 CFR 46.111(a)(7). All such research is deemed to be minimal risk.
- a. Exemption 2 c: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) and the information is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained.
 - b. Exemption 3 c: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection, and the information is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained.
5. If the reviewer finds that research is greater than minimal risk, the reviewer must document the rationale for this determination and the rationale for review by the convened IRB.
6. If the reviewer determines that the activity is exempt from review, the investigator will be notified, and a tracking number will be assigned.
7. Once a research study has been certified as exempt, annual reviews are not required; however, investigators are asked on an annual basis to report whether the research is still ongoing and whether all activities still remain exempt.
8. Modifications that fall outside of the exempt categories will require review by the IRB through expedited or full review as applicable.
9. Exempting an activity from review does not absolve the investigator from ensuring that the welfare of the subjects who participate in the research is protected and that the methods used, and the information provided to gain subject consent are appropriate to the activity. The IRB reviewer may require that a form of consent be obtained, or other safeguards put in place to protect the human subject.

10. It is the investigator's responsibility to notify the IRB of any changes or modifications that are made to the study's design and/or procedures, that do not fall within one of the categories exempted from the regulations.

Related Content

IRB Forms

Request for Exemption

New Research Activity Limited to Secondary Use of Human Biological Material and/or

Review of Health Information

Document Attributes

| Title | Exemptions | | |
|-----------------------------|---|----------------------|--|
| Author | Susan Kornetsky | | Dates Reviewed/ Revised |
| Reviewed/ Revised by | Susan Kornetsky | | 4/1/2005 6/20/2005 5/04/2007 3/10/2010 5/1/2015 1/24/2020 |
| Copyright | ©Boston Children's Hospital, 2020 | Last Modified | 11/24/2020 |
| Approved | <div data-bbox="427 972 1450 1058"> <p>Susan Kornetsky, MPH Director of Clinical Research Compliance</p> </div> <div data-bbox="427 1064 1450 1119"> <p>August Cervini, MBA Vice President for Research Administration</p> </div> | | |