Waivers and Exceptions

Overview

The Human Research Protection Program (HRPP) and the Institutional Review Board (IRB) are tasked to protect the rights and welfare of human subjects recruited to participate in research conducted under the auspices of Brown University. This is accomplished through careful review of research protocols to ensure compliance with federal and state regulations and Brown policies regarding the ethical conduct of biomedical or social/behavioral research. In some situations, allowances can be made to alter or omit elements of these requirements provided certain criteria have been met and processes are in place for participant protection.

Waivers

A **waiver** refers to an express or written statement of relinquishment of certain requirements under **federal or state-mandated regulations**. Investigators can request a waiver during an initial study or modification review. Requests must be expressly documented through the appropriate section of the Human Subjects Research Application. While certain requests can be reviewed using Expedited procedures, any request for a waiver may be assigned to a convened meeting for Full Board review. Determinations will be provided within the approval memo for the associated submission and documented within the study record.

Waiver approvals do not eliminate requirements for participant tracking. Investigators must keep accurate records of study enrollment.

Waiver or Alteration of Consent (§ 46.116)

An IRB may waive or alter the requirement to obtain informed consent provided the following criteria are met in each applicable circumstance.
Review HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process and ensure the criteria is met and accurately described in your study protocol.

Public Service or Benefit (§ 46.116 (e))

1. The research involving public benefit and service programs conducted by or subject to the approval of state or local officials
2. The research could not practicably be carried out without the waiver or alteration.

Requests for a waiver of consent for public service or benefit is not equivalent to Public Health Surveillance, which does not meet the definition of human subjects research.

Ex: This waiver is most often seen at Brown for research collaborating with government entities investigating public health emergencies and epidemics.

General (§ 46.116 (f))

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. 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;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Ex: General waivers of consent are most often seen at Brown for the use of identifiable secondary data. Alterations of consent are most commonly seen at Brown in the case of deception, where the inclusion of all elements of consent may reasonably affect the research aims.

Screening, recruiting, or determining eligibility (§ 46.116 (g))

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Ex: Waivers of consent for screening purposes are most often seen at Brown for chart review of electronic health records.

Waiver of Documentation of Consent (§ 46.117)

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following.
Review HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent and ensure the criteria is met and accurately described in your study protocol.

1. 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.
2. 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
3. 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.

Ex: Waivers of documentation of consent are most often granted at Brown for research involving online, unaccompanied consent or with international research in remote locations where signing forms is not normative behavior. Participants must be offered a copy of the written document meeting the required elements of informed consent.

Electronic Documentation of Informed Consent

Electronic formats of informed consent that collect an authenticated electronic signature (i.e. encryption, user verification) are acceptable as documented signed consent. Both REDCap and Qualtrics offer options for the collection of authorized electronic signatures, as well as certain software (i.e. Adobe) and several subscription services (i.e. DocuSign). Investigators that utilize an acceptable format for electronic consent and conduct a full consent procedure with participants (provide ample time for consideration, allow participants the opportunity to ask questions and confirm that participants are fully aware and understand the research activities and expectations) do not need to request a waiver of documentation of consent.

Waiver of Parental Permission (§ 46.408(c))

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 to protect the subjects, it may waive the consent requirements for obtaining parental permissions, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.
Review HRP-416 - CHECKLIST - Children (Q6) and ensure the criteria is met and accurately described in your study protocol.

Waiver of HIPAA Authorization (§164.512(i)(2)(ii))

The IRB may grant a full or partial waiver of authorization for the use or disclose PHI for a particular research project provided the following criteria are met.
Review HRP-441 - CHECKLIST - HIPAA Waiver of Authorization and ensure the criteria is met and accurately described in your study protocol.

- The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of
    - an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure;
    - an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law;
    - an adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
- The research could not practicably be conducted without the requested waiver or alteration.

- The research could not practicably be conducted without access to and use of the PHI.

It is important to note that Brown University is not a HIPAA-covered entity. This means that any data Brown Investigators obtain directly is not considered PHI. However, receipt of secondary data either from an electronic health record or data repository may be considered PHI and require an authorization or a waiver to access the data. Additionally, while Brown University may issue approval for the procedures, authorization documents or grant waivers of authorization, it is ultimately at the discretion of the data holder to accept these determinations and release the data.

Electronic Signatures for HIPAA Authorizations

Since e-signatures are not mentioned in HIPAA Rules, and the HHS has not prohibited their use, they are acceptable provided they are compliant with the Federal Electronic Signatures in Global and National Commerce (ESIGN) Act and the Uniform Electronic Transactions Act (UETA). Importantly, it is ultimately at the discretion of the data holder/covered entity to determine acceptability of the HIPAA Authorization form and the documentation of signature.

Exceptions

An **exception** refers to an express or written statement of relinquishment of certain requirements under a Brown University institutional policy. IRB policies are created to document the requirements and expectations necessary to acquire IRB approval. IRB policies undergo rigorous review for participant protection, procedural competency and realistic applicability involving the review and approval of multiple departments and stakeholders throughout Brown. The content and language of the policies comply with federal and state law, and broader Brown institutional policies. This provides an accessible reference for our research community in developing sound study procedures and ensures consistent and equitable handling of protocol review under each relevant topic area.

Investigators can request an exception to an approved policy during an initial study or modification review. Submissions that include a policy exception request will be reviewed at a convened meeting by the Full Board in entirety **regardless of the study's overall risk determination**. Repeated requests by a PI that are substantively similar in circumstances and justification may be reviewed and granted by the Chair and/or Vice Chair.

Making a Request

To request a policy exception, PI's must submit a stand-alone document within their submission (amendment or initial submission) that includes:

- Detailed description of the request.
- Justification for the need for the exception.
- Discussion of the IRB policy and the applicable section(s) under consideration for exception.

- Description of any potential risks that may need to be mitigated by allowing the exception.
- Inclusion of any applicable materials associated with the request.

Determinations will be provided within the approval memo for the associated submission and documented in the study record. **Each exception is specific to the study and request for which it was granted. It is not transferrable to any other study or portion of the study not included in the request.** There is no guarantee that an exception request will be granted by the IRB and there is no grievance process if an exception request is denied.