Human Research Protection Program Departmental Policy and Procedure

3.3 Informed Consent Waivers and Alterations

Responsible Office: Human Research Protection Program Department (HRPPD)

Effective Date: August 31, 2026

I. Policy Statement

a. Alterations and Waivers of Informed Consent

i. Obtaining legally effective informed consent of individuals before involving them in research is one of the central protections provided in the regulations governing

ii. research. Informed consent in research is founded on the Belmont Principle “respect for persons”

iii. The IRBs have the authority to approve a consent procedure that does not include or which alters some or all of the federally mandated elements of informed consent provided the approved procedure meets applicable federal regulations. The FDA and DHHS requirements for waivers differ. Consequently, the investigators and IRB must comply with the applicable regulations, which differ depending upon study sponsor or regulatory status of the proposed research.

iv. The IRB may approve an investigator’s request to waive or alter the requirement to obtain informed consent if the investigator demonstrates with specificity that the criteria under 45 CFR 46.116(e) or 46.116(f) are met.

v. An IRB may not approve a request to alter or omit any of the general requirements for informed consent [45 CFR §46.116(a)]

vi. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, an IRB

cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

vii. If a broad consent procedure is used, an IRB may not alter or omit any of the elements described in 45 CFR §46.116(d)

viii. FDA guidance does allow an IRB to waive or alter the informed consent process; in addition, the FDA regulations allow for exceptions to the informed consent requirements for clearly defined circumstances of emergency use of a test article, and waivers granted for planned emergency research (See 2.5 EXCEPTION FROM INFORMED CONSENT FOR PLANNED EMERGENCY RESEARCH).

b. Waiver of Documentation of Informed Consent

i. As allowed by OHRP (45 CFR 46.117 (c)) and FDA regulations (21 CFR 56.109(c)), the IRB may waive the requirement to obtain written documentation of informed consent. This provision can be used only for the waiver of documentation of consent, not for waiver or alteration of the consent process itself. A waiver of documentation of consent does not mean that requirements of the consent process are removed.

ii. To approve a waiver of documentation, the IRB must find that the protocol-specific justification for waiving documentation satisfies regulatory criteria:

1. FDA regulated studies: IRB may waive documentation for some or all of the subjects if the conditions listed in 21 CFR 56.109(c) are met.

2. Non-FDA regulated studies: the IRB may waive the requirement to obtain a signed consent form for some or all of the subjects if requirements in 45 CFR 46.117(c) are met.

iii. Even if a waiver of the participants' signatures is granted by the IRB, the

investigator still must provide the participants with all of the information described in 3.1. INFORMED CONSENT REQUIREMENTS to constitute a complete and appropriate consent process. The IRB may require submission of one of the following:

1. an information sheet, or
2. an oral script in a language understandable to the participants.

iv. In all cases in which the requirement for documentation of consent is waived, the IRB may require the Researcher to provide participants with the written consent document with an option to sign the consent document, or with a written statement regarding the research.

v. When a waiver of documentation is approved by the IRB, the investigator must document the consent process and determination of the subject in the research records.

II. Scope

a. This policy and procedure applies to all human subjects' research requesting a waiver or alteration of the consent process under either OHRP and/or FDA regulated research.

III. Procedures For Policy Implementation

a. Waiver or Alteration of Informed Consent:

i. The PI may request a waiver or alteration of informed consent by submitting a justification for the request in the IRB application. Alternatively, the IRB may determine that a waiver or alteration is appropriate without a request from the PI.

ii. To waive or alter informed consent requirements, the IRB must find and document that the requirements in 45 CFR 46.116(f) and FDA regulation are met. To approve such a request under 46.116(f), the IRB must find and document the following:

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

iii. If the IRB reviews the protocol at a convened meeting, HRPPD staff document the waiver of informed consent approval in the IRB meeting minutes following 8.1 IRB MINUTES.

iv. If the protocol is eligible for expedited review, the expedited reviewer documents on the expedited review documentation in ETHOS whether each of the criterion has been met.

v. Above Criteria III.A.2.d relating to identifiable private information or identifiable biospecimens is required only per 45 CFR 46.116(f) but will be required for all studies where the UTSW IRBs waive or alter informed consent

b. Waiver or Alteration of Informed Consent for FDA Regulated Studies

i. For FDA-regulated clinical investigations, the IRB may approve a waiver or alteration of the informed consent process when permitted under applicable FDA regulations. To approve a waiver or alteration of the consent process, the IRB must determine and document that:

1. The clinical investigation involves no more than minimal risk to the

participants;

2. The research cannot practicably be carried out without the waiver or alteration;
3. The waiver or alteration will not adversely affect the rights and welfare of the participants; and
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

c. Waiver or Alteration of Informed Consent for Non-FDA Regulated Studies determined to be public benefit or service programs

i. The IRB may also waive the requirement to obtain informed consent or alter some of the elements if the IRB finds and documents (under 45 CFR 46.116(e)) that the research or demonstration project is to be conducted by or is subject to approval of state or local government officials and is designed to study, evaluate or examine:

1. public benefit or service programs; or
2. procedures for obtaining benefits or services under those programs; or
3. possible changes in or alternatives to those programs or procedures; or
4. possible changes in methods or levels of payment for benefits or services under those programs; AND
5. The research could not practicably be carried out without the waiver or alteration.

ii. If the IRB reviews the protocol at a convened meeting, HRPPD staff document the waiver of informed consent approval in the IRB meeting minutes following 8.1 IRB MINUTES.

iii. If the protocol is eligible for expedited review, the expedited reviewer

documents on the expedited review approval documentation in ETHOS whether each of the criterion has been met.

d. Waiver of Informed consent for Non-FDA regulated Planned Emergency Research

   i. The PI submits an IRB application for review by the convened IRB. The HRPPD staff screen the application using procedures outlined in 2.1. Initial Review Of Research. The guidance document entitled Harmonized Rule on Waiver of Consent For Emergency Research is used by the PI, HRPPD staff and IRB members ensure the regulatory requirements are met. The PI must address any additional issues not included in the standard IRB application, such as plans for public disclosure in communities prior to initiation.

   ii. At a convened meeting, the IRB must find and document that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings [Federal Register: Oct 2, 1996 (Vol. 61, Issue 192)]. Note: this waiver is not applicable to research involving prisoners (subpart C of 45 CFR Part 46). See 2.5 Exception From Informed Consent For Planned Emergency Research for review and approval requirements.

   iii. The individual chairing the meeting goes through each regulatory requirement. The IRB discusses whether the research meets each requirement and raises any applicable controverted issues. HRPPD staff record the discussion in the minutes, following the procedures in 8.1 IRB Minutes.

e. Research Involving Children.

   i. A waiver of parental or guardian permission in non-FDA regulated studies may be granted:

1. In public benefit or service programs under 45 CFR 46.116(e), as described above.
2. In general research under 45 CFR 46.116(f), as described above.
3. When the IRB finds the research meets the requirements for HHS Secretarial waiver, under 45 CFR 46.101(i), that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings as described above (Planned Emergency Research).
4. When consent of parents or guardians is not a reasonable requirement because it poses additional risk to the potential subject or the parents' interest may not adequately reflect the child's interest (e.g., neglected or abuse children), in accord with 45 CFR 46.408(c) and 46.116(f).
5. The IRB may waive or alter the parental permission process when the regulatory criteria for a waiver or alteration of informed consent are satisfied and such waiver or alteration is permitted under applicable federal regulations.

ii. Review Procedure

1. The PI makes a preliminary decision to seek waiver of parental or guardian permission for participation of children in accord with 45 CFR Subpart D 46.408 (c) or 45 CFR 46.116(e)(f). The PI includes justification for the waiver and a description of a substituted appropriate mechanism for protecting the children who will participate in the research.
2. The IRB may approve the request provided the conditions outlined for waivers of consent in A.2.a-e above are satisfied in addition to the following:

    a. The research is designed for conditions or for a participant

population for which parental or guardian permission is not a reasonable requirement to protect the participants.

b. An appropriate mechanism for protecting the children who would participate as participants in the research was substituted.

c. The research is not FDA-regulated.

3. If the IRB reviews the research at a convened meeting, HRPPD staff record the discussion on each criterion in the minutes.

4. If the IRB reviews the study using expedited procedures, the expedited reviewer documents on the expedited review documentation in ETHOS whether the research meets each of the criteria

f. Alternatives to informed consent for FDA Regulated studies:

i. Exceptions for informed consent requirements for planned emergency research: are approved if all of the requirements specified in 21 CFR 50.24 are met. See 2.5 Exception From Informed Consent For Planned Emergency Research.

1. At the convened meeting, the HRPPD staff provide the IRB Chair or designee with a copy of regulatory requirements explained in 21 CFR 50.24 and/or the HHS Secretarial waiver under 45 CFR 46.101(i). The individual chairing the meeting goes through each regulatory requirement. The IRB discusses whether the research meets each requirement and raises any applicable controverted issues. The outcomes of the review are the same as those listed in the 6.2 IRB Approval Of Research. HRPP D staff record the discussion in the minutes, following the procedures in 8.1 IRB Minutes.

ii. Emergency use of an investigational drug or biologic product (unapproved drug or biologic) or an unapproved medical device: exception from informed consent for emergency use is allowed if the investigator certifies

the requirements in 21 CFR 50.23(a) are met. It is recommended that investigators consult with the IRB Chair or IRB Director before using an investigational drug/biologic in an emergency without informed consent to review the requirements listed in 21 CFR 50.23. See 7.5 Emergency Use Of An Investigational Drug Or Device for more information.

g. Waiver of Documentation of Informed Consent - Federal regulations permit an IRB to waive the documentation requirements for obtaining informed consent under special circumstances. Waiver of documentation of informed consent is not necessary when informed consent has been waived by the IRB.

    i. Non-FDA regulated research

        1. The PI makes an initial request to waive the documentation requirements for obtaining informed consent, as specified in the IRB application.

        2. The IRB may waive the documentation requirements to obtain a signed consent if:

            a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject must be asked whether the subject wants documentation regarding the research and the participant's wishes will govern;

            b. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or

            c. The subjects or LARs 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.

3. When the IRB waives the requirement to obtain written documentation of informed consent, the IRB reviews a written description of the information that the PI will provide to the subjects (i.e., a cover letter or a phone script).
4. In cases in which the IRB waives the documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research.
5. If the IRB reviews the request at a convened meeting, HRPPD staff include the discussion on each of the criteria in the meeting minutes.
6. If the IRB reviews the protocol using expedited procedures, the expedited reviewer documents on the expedited review documentation that 45 CFR 46.111(4) has been appropriately satisfied.
7. When research involves children, the IRB may waive the requirement to document parental permission when the applicable regulatory criteria for waiver of documentation of informed consent are met.

ii. FDA regulated research:

1. The PI makes an initial request to waive the documentation requirements for obtaining informed consent, as specified in the IRB application.
2. The IRB may waive the requirement to obtain a signed informed consent document if the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. 21 CFR 56.109(c)(1)
3. When the IRB waives the requirement to obtain written documentation of informed consent, the IRB reviews a written description of the information that the PI will provide to the subjects.

4. In cases in which the IRB waives the documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research.
5. If the IRB reviews the request at a convened meeting, the meeting minutes include the discussion on each of the criteria.
6. If the IRB reviews the study using expedited procedures, the expedited reviewer documents on the expedited review documentation form whether the research meets each of the criteria.

IV. Definitions

See glossary of human research terms

V. References

a. 21 CFR 50: Protection Of Human Subjects
b. 45 CFR 46: Protection Of Human Subjects
c. 45 CFR 164: Security And Privacy (HIPAA Privacy Rule)
d. 21 CFR 56: Institutional Review Boards

VI. Revision and Review History

a. Revision Date: August 2026; Author: HRPP; Description: Clarified waiver and alteration procedures under the revised Common Rule and confirmed parental permission waiver processes consistent with federal requirements.
b. Revision Date: June 2026; Author: HRPP; Description: Reference to eIRB updated to ETHOS
c. Revision Date: June 2021; Author: HRPP; Description: Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.
d. Revision Date: January 2019; Author: HRPP; Description: Revision to reference 2019 common rule

e. Revision Date: August 2017; Author: HRPP; Description: New Policy Development

f. Revision Date: March 2012; Author: IRB Office; Description: IRB Written Procedures