

SOP 2.2.2

Waivers of informed consent and waivers of documentation of informed consent

General Description and Definitions:

Waiver or alteration of informed consent:

*HHS regulations allow the IRB to waive the requirement for obtaining informed consent or parental permission or to approve a consent procedure that leaves out or alters some or all of the elements of informed consent otherwise required under the regulations.

Research in general: an IRB may waive or alter the requirement of informed consent under 45 CFR 46.116(f), provided that all of the following five conditions are met:

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

Public benefit or service programs: an IRB may approve a consent procedure that alters some or all of the elements of informed consent, or waives the requirement to obtain informed consent under HHS regulations at 45 CFR 46.116(e), provided that the IRB finds and documents that both of the following conditions are met:

- the research could not practicably be carried out without the waiver or alteration; and
- the research or demonstration project is to be conducted by or 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.

Research in emergency settings: an IRB may also waive the requirement for obtaining informed consent if it finds and documents that the research meets the requirements 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.

Waiver of documentation of consent or signature:

HHS regulations (45 CFR 46.117 (c)), describe that documentation of informed consent may be waived partially (or entirely) by approval of the convened IRB or the IRB Chair or designee if:

1. The only record linking the participant and the research would be the consent form (and thus the principal risk would be potential harm resulting from a breach of confidentiality);
2. The research presents no more than minimal risk of harm to the participants (including risk of breach of confidentiality); and the research does not involve any procedure for which written consent is normally required outside 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Procedures:

Investigator Responsibilities

1. The Investigator will assess the proposed research to determine if it meets regulatory requirements for a waiver of informed consent or waiver of signature.
2. The PI will make an initial request to waive the requirements for obtaining informed consent or signature through the IRB application within IRBNet.

IRB Responsibilities

The IRB Reviewers will consider the request for a waiver of informed consent or waiver of documentation of consent and the Investigator's justification verifying and documenting that regulatory conditions are applicable to the proposed research activity.

- a. If the IRB Reviewer(s) agree with the Investigator's justification and documentation for waiver or alteration of the consent process, by approval of the proposed research procedure, this is documentation they agreed with the Investigator's justifications.
 - b. If the IRB Reviewer(s) do not agree with the Investigator's justification or if they do not agree that waiver or alteration of the consent process is allowable and appropriate, the IRB will request revisions to the protocol to require informed consent to be sought in its entirety.
2. When amendments are made to a currently approved research study which may impact the consent procedures, an approved waiver of informed consent is reassessed by the IRB, Chairperson or his or her designee, and a determination is made as to whether the conditions for the waiver have been altered, necessitating a removal of the waiver. If this occurs, the IRB will also determine whether currently enrolled participants must be re-consented.

Related Forms, Guidance, and SOPs:

- SOP 2.2.1 Informed Consent

Responsibility:

Principal Investigators
Research Team Members
Research Development, Integrity and Assurance
Institutional Review Board

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

References:

*Introductory material quoted directly from: 45 CFR 46.116 General requirements for informed consent
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>

45 CFR 46.117 Documentation of informed consent
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117>

Informed Consent Requirements in Emergency Research
<http://www.hhs.gov/ohrp/policy/hsdc97-01.html>

Recommendations Regarding the Provisions for Informed consent and waiver of consent)
<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2013-january-10-letter-attachment-d/index.html>

University of Arizona Human Subjects Protection Program. <http://orcr.arizona.edu/hspp>.

University of California Irvine Human Research Protections.
<http://www.research.uci.edu/compliance/human-research-protections/index.html>.

Date First Effective: March 26, 2014

Revision Date: January 21, 2019

Current Version #: 2

Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	January 21, 2019
Laurie Meamber	IRB Chairperson	January 21, 2019
