Human Subject Protection Program
Investigator Guidance
June 2, 2020

WAIVERS OF CONSENT AND DOCUMENTATION OF CONSENT

Overview

- This guidance document provides information about requesting waivers of informed consent and documentation of informed consent, as permitted by DHHS and FDA regulations.

- Investigators are required to obtain the legally effective informed consent of each participant or their legally-authorized representative, unless the IRB approves a consent procedure which does not include, or which alters, some or all of the elements of informed consent.

- For purposes of this guidance, “consent” includes parental permission and assent.

Waiver of Documentation of Informed Consent

Investigators may request a waiver for documenting signed informed consent in three situations:

Option 1 (Commonly Used):

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

Option 2 (Rarely Used):

- The only record linking the participant and the research would be the consent document;
- The principal risk of a signed consent document would be potential harm resulting from a breach of confidentiality;

- 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; and
- The research is not a clinical investigation subject to FDA regulations.

Option 3 (Rarely Used):

- The research is subject to the 2018 Common Rule;
- The subjects or legally-authorized representative are members of a distinct cultural group or community in which signing forms is not the norm;
- The research presents no more than minimal risk of harm to subjects; and
- There is an appropriate alternative mechanism for documenting that informed consent was obtained.
- The research is not a clinical investigation subject to FDA regulations.

Informed Consent Process

- When the IRB approves a waiver of documentation of consent, the IRB will often require Investigators to provide a study information sheet to participants.

- When a study information sheet is not required, the IRB requires a description in the IRB application about the planned consent process (i.e., how consent will be obtained from participants).

  ☐ An oral script or outline for obtaining consent may be submitted for review.

  ☐ Another alternative is the use of an introductory paragraph at the top of the study instrument (e.g., questionnaire) or an introductory letter attached to the study instrument.

IMPORTANT NOTES:

- Any study information sheets, introductory letters, oral scripts and outlines require IRB review and approval before they are used.

- Study information sheets, introductory letters, oral scripts and outlines must include the required elements of informed consent.

- A template research information sheet is available on the HSPP website.

Waiver or Alteration of Informed Consent

Investigators may request a complete waiver for obtaining consent (or an alteration of some or all of the elements of informed consent) in the following situations:

Option 1 (Commonly Used) – DHHS Waiver for Minimal Risk Research:

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- 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 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.
- The research is not a clinical investigation subject to FDA regulations.

Option 2 (Rarely Used) – FDA Waiver for Minimal Risk Clinical Investigations

- The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The clinical investigation could not practicably be carried out without the waiver or alteration, and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- The research is a clinical investigation subject to FDA regulations.

Option 3 (Rarely Used) - Waiver for Research Activities Designed to Study Certain Aspects of Public Benefit or Service Programs:

- 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; and
  - ☐ The research could not practicably be carried out without the waiver or alteration.
  - ☐ The research is not a clinical investigation subject to FDA regulations.

Option 4 (Rarely Used) - Waiver of Informed Consent for FDA-Regulated Research Involving Anonymous Tissue Specimens

- The research does not involve Human Subjects as Defined by DHHS;
- The study involves an in vitro diagnostic device investigation;
- The testing is noninvasive;
- The testing does not require an invasive sampling procedure that presents significant risk;
- The testing does not by design or intention introduce energy into a subject; and
- The device is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- The study **only** uses one of more of the following:

  - ☐ Specimens collected for routine clinical care or analysis that would have been discarded.
  - ☐ Specimens obtained from specimen repositories.
  - ☐ Leftover specimens that were previously collected for other research purposes.

- The identity of the subject is not known to the investigator or any other individuals associated with the investigation, including the sponsor.
- The specimens are not coded, and/or the Investigator nor any other individuals associated with the investigation or the sponsor can link the specimens to the subject from whom the specimens are collected directly or indirectly through coding systems.
- The samples are not accompanied by clinical information, or information that accompanies the specimens does not make the specimens identifiable.

IMPORTANT NOTES:

- When an IRB waives the requirement to obtain informed consent, it waives the entire requirement for informed consent.

- When the IRB approves an alteration of some or all of the elements of the informed consent (e.g., removes a required element of consent from the document), obtaining informed consent is still required.

- Alterations of informed consent are typically restricted to studies that involve deception or incomplete disclosure, both of which must be justified in the IRB application.

Waivers of Consent for Screening Recruiting, or Determining Eligibility

Screening activities may be performed before obtaining informed consent (with IRB approval) to identify potential research participants or to determine if basic eligibility criteria are met. Investigators do not need to request approval of waivers of informed consent for screening; however, IRB applications must still describe the screening procedures to be performed.

The 2018 Common Rule outlines the following conditions for IRB approval of a research proposal that involves screening procedures:

- 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:

  - ☐ The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

  - ☐ The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.