

## Guidance and Procedure: Requesting Waivers and Exceptions to Informed Consent (last updated July 28, 2011)

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## Introduction

This guidance document provides information about **requesting waivers and exceptions to informed consent**, as permitted by regulation. 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.

## Waiver of Documentation for Oral Consent

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

### Situation 1:

- 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.

### Situation 2:

- The only record linking the participant and the research would be the consent document;
- The principal risk would be potential harm resulting from a breach of confidentiality;
- Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern (a waiver of this requirement may be requested in webIRB); and
- The research is **not a clinical investigation** subject to FDA regulations.

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 an **oral script or outline** of the planned consent process. 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, which includes a statement that return of the questionnaire represents consent to participate in the project.

### IMPORTANT NOTES:

- 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. See OHRPP Guidance, [Obtaining and Documenting Informed Consent](#).
- Template [information sheets and scripts](#) are available on the OHRPP 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 two situations:

### **Situation 1 (Commonly Used): Waiver for Minimal Risk Research**

- The research involves no more than minimal risk to the participants; and
- The waiver or alteration will not adversely affect the rights and welfare of the participants; and
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.
- The research is **not a clinical investigation** subject to FDA regulations.

### **Situation 2 (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.

### IMPORTANT NOTES:

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

## Waiver Options for Screening Procedures

Access, use or collection of identifiable, private information from or about a person to conduct screening is a research procedure that is subject to informed consent requirements. Screening activities (with IRB approval) may be performed **before obtaining informed consent** to identify potential research participants or to determine if basic eligibility criteria are met.

### **Screening with No Participant Contact:**

This type of screening involves access to and use of private information to identify/recruit eligible participants without consent. Examples include:

- Reviewing medical records
- Using an existing data set or accessing a data repository

Investigators may request a **complete waiver for obtaining consent** if the minimal risk waiver criteria apply and are approved by the IRB. See “Waiver of Alteration of Informed Consent” section above.

#### **Screening with Participant Contact:**

This type of screening involves collection or recording of private information from or about a person with their oral consent. For example, screening interested people who respond to an advertisement to confirm basic eligibility.

Investigators may request a waiver for documenting **signed informed consent** if the minimal risk waiver criteria apply and are approved by the IRB. See “Waiver of Alteration of Informed Consent” section above.

#### **IMPORTANT NOTES:**

- A waiver is unnecessary if screening will occur **after** obtaining informed consent for participation.
- All screening procedures must be reviewed by the IRB to ensure appropriate informed consent is obtained.

For more information regarding screening activities, see [OHRPP Guidance and Procedure: Recruitment Methods and Tools](#).

## **Waiver of Informed Consent for *In Vitro* Diagnostic Device Studies Using De-Identified Specimens**

Under FDA regulations governing the conduct of in vitro diagnostic (IVD) device studies, the definition of “human participant” includes individuals on whose specimens an investigational device is used. Because these regulations require informed consent for FDA-regulated human participant research, except in limited circumstances specified in the regulations (emergency use of a drug or device, and planned emergency research) informed consent is required before specimens can be used in FDA-regulated research.

Informed consent may be difficult or impossible to obtain for use of specimens that are left over from clinical care or other research. The FDA has issued [guidance](#) to address this situation. The FDA will use its enforcement discretion so that informed consent requirements do not apply to IVD device studies meeting the criteria outlined in Section 4 of the FDA guidance.

Investigators wanting to conduct a study according to this FDA guidance should submit an application for IRB review. In addition to the information required by the application, the Investigator should also provide information or assurances that address the criteria in Section 4 of the FDA guidance. If the IRB determines that the research meets the criteria in Section 4 of the FDA guidance, the Investigator will not be required to obtain informed consent.

## **Exceptions from Informed Consent Requirements**

**Emergency Use of a Test Article (Drug/Device):** Emergency use of an investigational drug/device for patient care requires the treating physician to obtain the informed consent of the patient or a legally-authorized representative, **unless** the criteria in 21 CFR 50.23(a) are met. Because there is no equivalent provision in DHHS regulations, this exception may only be used for the emergency use of a test article for purposes of patient care, which is not “research”. For more information, see [OHRPP Guidance and Procedure: Emergency Use of a Test Article](#).

**Planned Emergency Research:** Conducting planned research in life-threatening situations may allow for exception from informed consent requirements as provided for in 21 CFR 50.24 (and in a corresponding waiver from the Secretary of HHS for research not regulated by the FDA). See the [OHRPP Guidance and Procedure: Research in an Emergency Setting](#) for more information.

## Regulations and References

### **DHHS**

- General Requirements for Informed Consent; Elements of informed Consent; Waiver or Alteration of Consent: [45 CFR 46.116](#)
- Documentation of Informed Consent; Waiver of Documentation of Informed Consent (Oral Consent): [45 CFR 46.117](#)
- [OHRP Guidance Documents on Informed Consent](#)

### **FDA**

- General Requirements for Informed Consent: [21 CFR 50.20](#)
- Waiver of Documentation of Informed Consent (Oral Consent): [21 CFR 56.109\(c\)](#)
- Exception from Informed Consent (Emergency Use of Test Article): [21 CFR 50.23](#)
- Exception from Informed Consent (Emergency Research): [21 CFR 50.24](#)
- [FDA Guide to Informed Consent Information Sheet](#)
- [FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable](#)