

Research Integrity Office

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Waiver or Alteration of Informed
Consent and HIPAA Authorization

Introduction

In certain situations, the IRB can approve a waiver or alteration of the informed consent process. There are generally four ways to alter the consent process:

1. A short form may be signed to document an oral consent process;
2. The requirement to document informed consent in writing may be waived;
3. Some required elements may be altered or waived; or
4. The requirement to obtain consent may be waived in its entirety.

The options available for your study will depend on a number of factors, including whether your study involves only minimal risk to subjects and whether it is FDA-regulated.

In addition, the IRB can approve a waiver or alteration to the HIPAA authorization process. These criteria are similar to some of the criteria for waiving or altering consent, but keep in mind that authorization is ultimately a separate requirement.

This Help Sheet is a supplement to:

- HRP-802 INVESTIGATOR GUIDANCE: Informed Consent
- HRP-803 INVESTIGATOR GUIDANCE: Documentation of Informed Consent
- HRP-300 CHECKLIST: Waiver of Consent HHS
- HRP-302 CHECKLIST: Waiver of Consent Leftover Specimens
- HRP-303 CHECKLIST: Waiver of Documentation of Consent
- HRP-428 WORKSHEET: HIPAA Waiver of Authorization

If you are requesting approval of a waiver or alteration of the consent process, be sure to describe your proposed process and justification clearly in your protocol. If you are requesting a waiver or alteration of HIPAA authorization, complete and upload a Waiver or Alteration of HIPAA Authorization form (available on our website) when you submit your study.

Click on a topic below to jump to that section:

1. [Minimal Risk Research](#)
2. [Greater than Minimal Risk Research](#)
3. [HIPAA Authorization](#)
4. [Example Modified Consent/Authorization Scenarios for Common Study Types](#)

1. Minimal Risk Research

Short Form Documentation

A short form is an abbreviated written consent document stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative (LAR). Instances when oral consent is appropriate include consenting subjects who are unable to read and comprehend the full written form due to language barriers, disability or other impediments. The IRB must approve a written summary (usually the long-form consent document) of what is to be said to the subject or the representative and the short form.

When this method is used, there shall be a witness (other than the LAR and the investigator) to the oral presentation. A copy of the summary and a copy of the short form shall be given to the subject or the representative. The following signatures are required:

1. The subject or the LAR signs: the short form
2. The person obtaining consent signs: the summary
3. The witness signs: the short form and the summary

For more guidance on informed consent of subjects with limited English proficiency, see the Quick Guide entitled, "Consent – Limited English Proficiency."

Waiver of the Requirement to Document Consent

For minimal risk research, if the research involves no procedures for which written consent is normally required outside of the research context, then the requirement to document informed consent may be waived. The IRB may require an information sheet, but not require a signature line. When the requirement to document consent is waived, there is still a complete informed consent discussion, and consent is given verbally. The only change is that no signature is obtained.

Waiver or Alteration of Consent

For minimal risk research, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent (**see HRP-400 WORKSHEET: Criteria for Approval**). When an alteration is approved, there will still be a modified consent process. The IRB may also entirely waive the requirement to obtain consent. In order for the IRB to approve waiver or alteration of the elements of consent, the following conditions must be true:

1. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
2. The research could not practicably be carried out without the waiver or alteration.

Whenever appropriate, the IRB will require that subjects be provided with additional pertinent information after participation. This may be in the form of an information sheet or other appropriate sources of information and may include references for services or counseling.

Partial Waivers/Alterations

A waiver or alteration of consent or waiver of documentation of consent may be granted for all or part of a study. For instance, it might apply only to the phone screening portion of a study, wherein subjects who meet eligibility criteria consent to the rest of the study in person via the typical process.

In the case of partial waivers/alterations, the entire study need not be minimal risk; only the portion of the study for which the waiver/alteration is being requested.

FDA-Regulated Minimal Risk Research

The IRB cannot waive or alter informed consent for any FDA-regulated human research. However, the FDA allows an exception to this rule for studies on in vitro diagnostic (IVD) devices that use only de-identified tissue samples or other specimens. See **HRP-302 CHECKLIST : Waiver of Consent Leftover Specimens** for details regarding this exception.

A waiver of documentation of consent is permitted for FDA-regulated minimal risk research as described above, including telephone screening for recruitment.

2. Greater than Minimal Risk Research

Short Form Documentation

The short form process is permitted for greater than minimal risk research and is carried out in the same manner as described above.

Waiver of the Requirement to Document Consent

For greater than minimal risk research, the requirement that a subject sign the consent document can only be waived if the following conditions are met:

1. The only record linking the subject and the research would be the consent document.
2. The principal risk of the study is harm from breach of confidentiality.

The IRB will require that an information sheet be made available to subjects. The information sheet will have an optional signature line. The investigator is required to ask each subject whether the subject wants to sign the consent, thus creating documentation linking the subject with the research, and the subject's wishes will govern.

3. Waiver or Alteration of HIPAA Authorization

In a typical consent and authorization process, HIPAA authorization language is integrated into the consent document, and the subject's signature is documentation of both informed consent and HIPAA authorization. Where the consent process is waived or altered, it is likely that the HIPAA authorization process will also need to be waived or altered.

The IRB can waive any or all of the HIPAA authorization elements (including the signature requirement) if it finds that the following criteria are met:

1. The research could not practicably be conducted without the waiver or alteration.
2. The research could not practicably be conducted without access to and use of the PHI.
3. The use or disclosure of the PHI involves no more than minimal risk to the privacy of the subjects as a result of:
 - An adequate plan to protect the PHI from improper use and disclosure;
 - An adequate plan to destroy any identifiers contained in the PHI at the earliest opportunity consistent with the research; and
 - Adequate written assurances that the PHI will not be reused or re-disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

The Waiver or Alteration of HIPAA Authorization form that you upload with your study contains questions that help the IRB determine whether your project meets these criteria.

Like a waiver or alteration of consent, the waiver or alteration of HIPAA authorization can apply to all or part of a study. If it applies to part of a study, only that part of the study must meet the above criteria.

There are other situations where HIPAA authorization is not required or another type of permission must be in place in order to use PHI for research purposes. See the IRB's [HIPAA and Research](#) website for more information.

4. Example Modified Consent/Authorization Scenarios for Common Study Types

Study Type	Consent Process	Authorization
Anonymous survey	Waiver of documentation of consent – information sheet or consent text included at start of survey; Waiver of consent if not all elements of consent are included	N/A – no PHI collected
Identifiable survey where no PHI or other sensitive information is collected	Waiver of documentation of consent – information sheet or consent text included at start of survey; Waiver of consent if not all elements of consent are included	N/A – no PHI collected
Identifiable survey where PHI is collected over the phone	Waiver of documentation of consent – verbal phone script with all required consent elements; Waiver of consent if not all elements of consent are included	Waiver of authorization
Focus group or interview	Signed consent or waiver of documentation of consent – information sheet; Waiver of consent if not all elements of consent are included	If PHI is collected, full authorization (if signed consent) or waiver or alteration of authorization
Retrospective chart review	Waiver of consent	Waiver of authorization
In vitro research on pre-existing specimens	Waiver of consent	Waiver of authorization if specimens are identifiable
Telephone screening	Waiver of documentation of consent for screening only – verbal consent; Waiver of consent if not all elements of consent are included	Waiver of authorization for screening only