Waiver to Document Informed Consent	Waiver/Alteration of Informed Consent	Waiver/Alteration Authorization of HIPAA
No signature is obtained but full consent process takes place with scripts including all required elements of consent	-**Waiver**: Consent is not obtained at all -**Alteration**: Consent is obtained but some of the elements of consent may be omitted or obscured	-**Waiver**: Authorization is not obtained at all -**Alteration**: Authorization is obtained but some of the elements of consent may be omitted or obscured (e.g. obtaining signature)
Each request must comply with the regulatory elements in order to be granted		

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Waiver of Documentation of Informed Consent

A waiver to obtain signed informed consent (commonly known as a waiver to document) is a consent process that does not require the signature of the participant but secures their affirmative agreement to participate via other means (e.g. verbal exchange, click to consent). This means that the study team must provide the participant with the required consent information, but the study team is not required to obtain the participant's signature on the informed consent form.

The Common Rule regulations at 45 CFR 46.117(c) allow an IRB to waive the requirement for signed informed consent for participation in a research study if it finds any of the following:

i. That the only record linking the subject and the research would be the informed consent form and the principal risk 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;

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

iii. 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.

If the research is **regulated by the FDA**, documentation of informed consent may be waived under 21 CFR 56.109 only when the IRB finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

For what purpose can a waiver to document informed consent be requested:

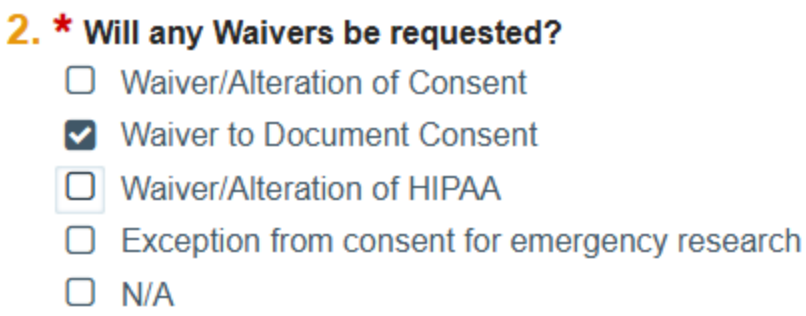
A waiver to document informed consent may be requested in situations where a study (or the activity under waiver) is minimal risk, meets one of the above criteria and it makes sense that signed informed consent would not be needed. For example:

- The study is being done over the phone or via videoconferencing, (e.g., Zoom) or other situation where the researcher and participant would not be in the same space
- When a participant is asked to “click to continue” to proceed to a survey or other online activity where no other validation of identity is required
- A study is collecting information about sensitive topics where linking the study to the person may put them at risk such as drug use, domestic violence, or immigration status
- A minimal risk study activity prior to obtaining written consent for a greater than minimal risk study. For example, requesting a participant fast for a blood draw prior to their first study visit

Remember: The waiver to document doesn't have to be for the whole study, but whatever activity it is related to needs to be minimal risk.

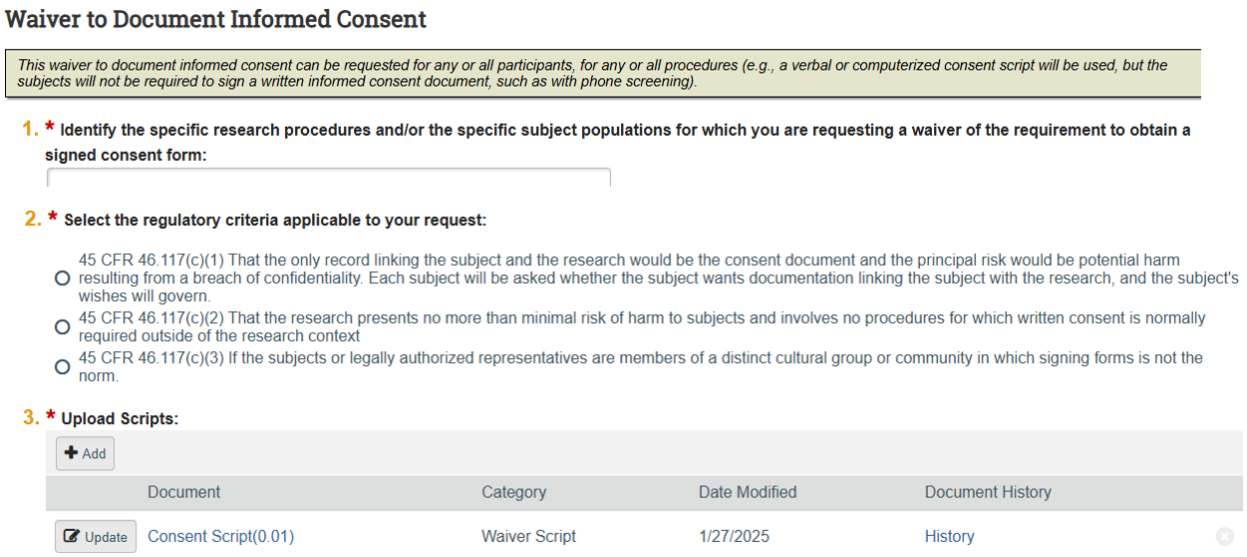
How is a waiver to document requested in PittPRO:

- **Study Scope #2**: Check Waiver to Document Consent



- **Consent Process Page**: The questions on the Consent Process page should be answered so that the IRB is able to understand how study teams will inform participants about the study and document their agreement to participate.
    - If the waiver is being requested because the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality, include the procedures for asking participants if they wish to have documentation linking them to the research.

- **Complete the Waiver to Document Informed Consent Page**: When a waiver to document consent is requested, all required elements of consent must be present and conveyed to the participant during the consent process. This may be done in the form of a consent script to be read, a consent cover page in the case of an online survey, or a cover letter for mailed materials.



Waiver or Alteration of Informed Consent

A waiver of informed consent allows a researcher to conduct human subject research without obtaining the informed consent of the participants. The waiver may apply to an entire study or specific parts of the study. Examples of situations where a waiver of informed consent may be allowed include:

- A medical record review with no interaction or intervention with participants
- Secondary analyses of existing information or specimens
- Enrollment of teens in a study when parental permission will not be sought

Alteration of Informed Consent: An IRB is permitted to approve an adjusted consent process that omits or modifies some or all the elements of informed consent without completely waiving informed consent. However, the informed consent process still takes place as approved in the protocol. This is most commonly used when the research design requires that participants be left unaware of a particular purpose of the research because the participants' responses might be biased if they know in advance what the investigators are seeking. To learn more about research involving deception, refer to Chapter 13, Policies and Procedures. If this type of alteration will be used, you must check "deception" in Study Scope #5, Other Requests

Justification of a Waiver or Alteration

Both the waiver and alteration of informed consent may be used for adult participants and for parental permission for a child to participate in research.

In order to approve a waiver or alteration of informed consent, the IRB must find and document the following (as per 45 CFR 46.116(f)(3) and 21 CFR 50.22):

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

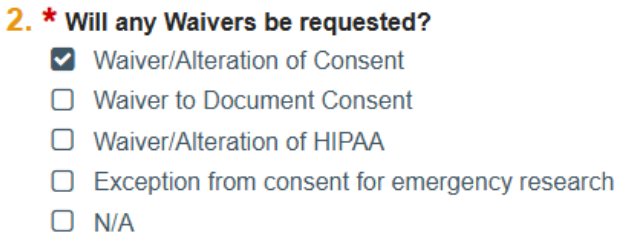
"Practicability" is an oft misunderstood concept. It is not a question as to whether it is possible to obtain consent from the subject or their legally authorized representative, but whether the study itself would be feasible to conduct without a waiver or alteration:

- Scientific validity would be compromised if consent was required:
    - The required sample size is so large that including the information of only those for which consent can be obtained would bias the sample

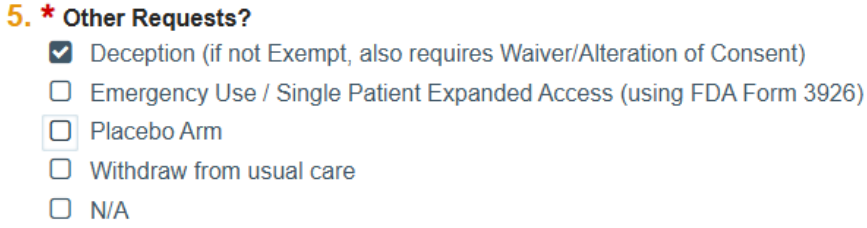
- The desired participant pool is no longer followed and may be lost to follow-up (e.g. relocation, death)

How is a waiver or alteration requested in PittPRO

Study Scope #2: Check Waiver/Alteration of Consent



Study Scope #5: if you are requesting a deception alteration, you must check "deception"

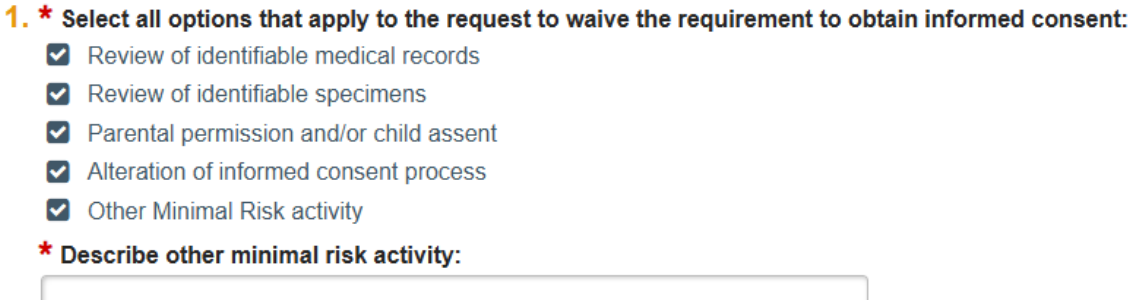


You will then need to complete the Use of Deception page which requires includes the following fields:

1. Describe the planned deception
2. Provide a justification for this planned deception
3. Describe when and how subjects will be debriefed
4. Attach the debriefing script

Consent Process Page: If a waiver of informed consent is requested, each section can be marked "not applicable". If an alteration of consent is being requested, the questions should be answered appropriately for procedures that will be used.

Complete the Waiver/Alteration Consent page: Select the purpose of the request in #1 and provide a justification, specific for the protocol, for each of the regulatory requirements. You MUST provide a justification addressing how each of the criterion are met for each option chosen in Item #1.



Waiver/Alteration of HIPAA Authorization for Protected Health Information (PHI)

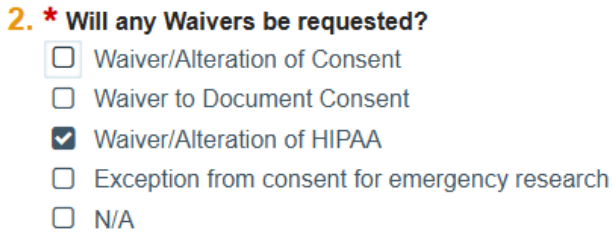
Researchers must obtain the participant's written authorization to access their PHI, but there are circumstances where a waiver or alteration of the authorization may be appropriate, for example, a medical record review under a waiver of consent or a situation where a participant will give verbal HIPAA authorization rather than written.

Studies requesting a full waiver of informed consent and that use PHI must request a waiver of HIPAA authorization. If a study seeks to obtain verbal HIPAA authorization rather than written, an alteration of HIPAA must be requested.

In order to approve a waiver or alteration of HIPAA, the IRB, acting as the HIPAA Privacy Board, must approve of the researcher's justification of the following criteria:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    a. an adequate plan to protect the identifiers from improper use and disclosure;
    b. an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    c. adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to and use of the PHI.

Study Scope #2 must check Waiver/Alteration of HIPAA



- If verbal authorization is being requested, the Waiver/Alteration of HIPAA Authorization page must clearly state that the study team is requesting an alteration of HIPAA so that a signature is not required.

Resources:

45 CFR 46.117 Documentation of Informed Consent

FDA 21 CFR 56.109(c)(1) IRB Review of Research

OHRP Informed Consent FAQs

SACHRP Recommendations related to waiver of informed consent and interpretation of "minimal risk"

A-Z Guidance: **E-consent**