

Waivers of Informed Consent, Waivers of Documentation of Informed Consent, and Waivers OF HIPAA Authorization: Guidance for Investigators

Both the Federal Policy for the Protection of Human Subjects (the “Common Rule”) and [FDA guidance](#) allow an IRB to approve an informed consent process that:

- Waives the requirement to obtain informed consent; or
- Alters some or all of the elements of informed consent; or
- Waives the requirement to document informed consent (i.e., to obtain a signature).

When should an investigator request a waiver?

- If you will not obtain subjects’ informed consent to use their identifiable data for research purposes, you must request a **Full Waiver of Informed Consent**.
 - Full waivers are most commonly approved for research involving only the review of medical records, in which investigators will not interact with subjects and therefore won’t have an opportunity to obtain their informed consent. They may also be approved for research involving deception.
- If you intend to only obtain *verbal consent* from subjects, you must request a **Waiver of Documentation of Informed Consent**.
 - There are a variety of circumstances under which you may wish to obtain a subject’s verbal consent in lieu of a signed consent form. For example, if you are doing minimal risk research involving only surveys/interviews conducted by telephone or online, it may not be feasible to document a subject’s consent via written signature. Or, if you are conducting research on a sensitive topic--such as domestic violence, illicit activities, etc.--the act of signing an informed consent document may place a subject at an unacceptable risk of loss of confidentiality. In these scenarios, COMIRB may approve a Waiver of Documentation of Informed Consent.
 - Under a Waiver of Documentation, you must provide subjects with the required consent information using a COMIRB-approved postcard consent/information sheet, but you are not required to obtain the subject’s signature on the informed consent document.
- Whether you request a Full Waiver or a Waiver of Documentation for the purposes described above, you may also need to request a **Waiver of HIPAA Authorization**.
 - The most common scenarios in which COMIRB may determine that a HIPAA waiver is appropriate are: 1) secondary research involving data accessed via the medical record; 2) studies in which investigators need access to PHI in order to identify potential subjects for recruitment/screening purposes; and 3) studies involving only surveys or interviews conducted via telephone, in which there will be no face-to-face interaction with between the subject and the study team.
 - When COMIRB grants a Waiver of HIPAA Authorization, it removes the requirement that investigators get a subject’s permission to access, use, and/or disclose their Protected Health Information (PHI) for research purposes. Unlike informed consent, investigators can only obtain HIPAA authorization via written signature; there is no such thing as “verbal HIPAA authorization.” Therefore, research activities that involve access to PHI should be conducted *whenever practicable* with HIPAA authorization. If you will have a meaningful opportunity—such as a face-to-face interaction—to obtain a subject’s signed HIPAA authorization, you must do so.

Regulatory Requirements

Full Waiver of Informed Consent

Per OHRP regulations at 45 CFR 46.116 and [FDA guidance issued in July 2017](#), COMIRB will only approve a full waiver if it determines that the research for which the waiver is sought:

1. Involves no more than minimal risk to subject(s);
2. Would not adversely affect the rights and welfare of the subject(s)
3. Could not be practicably carried out without the waiver;
4. Whenever appropriate, subject(s) will be provided with additional pertinent information after participation; and
5. If the research involves identifiable private information or identifiable biospecimens, the research could not be carried out practicably without using the information/specimen in an identifiable form.

Waiver of Documentation of Informed Consent

A Waiver of Documentation is permissible when:

- The signature on the informed consent document would be the only record linking the subject to the research, and the principal risk of harm to the subject would be a breach of confidentiality (e.g., for research on sensitive topics, such as domestic violence, illicit activities, etc.); **OR**
- The research involves no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context (e.g., minimal risk research that involves only surveys/interviews conducted via telephone or online); **OR**
- The subjects (or their legally authorized representatives) 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. This does not apply to FDA regulated research..

Waiver of HIPAA Authorization

COMIRB may approve a HIPAA Waiver if it determines that:

- The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - an adequate plan* to protect the identifiers from improper use and disclosure;
 - 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
 - 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;
- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted without access to and use of the PHI.

*Researchers provide these plans and written assurances in the COMIRB Application Forms. Requests for HIPAA Waivers must be submitted to and approved by COMIRB prior to accessing PHI.