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# Purpose:

To provide guidance about the informed consent process and documentation of consent procedures in research with human subjects:

* Suggested best practices in obtaining and documenting informed consent from prospective research participants
* Description of Regulatory and IRB requirements related to documentation of informed consent
  + Considerations when informed consent is to be sought remotely.
  + Requirements for electronic documentation of informed consent.
* Documentation of combined informed consent and HIPAA authorization documents.

# Documentation of Informed Consent Regulatory Requirements

* [Federal Policy](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html)[[1]](#footnote-1) requires that legally effective *informed consent to participate in research must be obtained and documented by investigators prior to involvement of participants in non-exempt human subjects research,* unless a waiver or alteration of informed consent is approved by an IRB.
* *Informed consent is a process* and involves providing a potential subject with adequate information about the research to allow for an informed decision about the subject’s voluntary participation in a research study.
* Consent must be sought under circumstances that allow the prospective subject, or their legally authorized representative, the opportunity to discuss and consider whether to participate.
* Language used should be understandable to the subject, organized and presented in a way that facilitates comprehension.
* All consent procedures (remote or otherwise) must be described in the Research Protocol. Consider whether the research plan can benefit from outlining both remote and in-person consent procedures to maximize flexibility.
* *Documentation of consent provides a record that the consent process took place.* The requirement to *document informed consent prescribes the use of a written form* approved by the IRB and *signed (handwritten or electronical signatures are acceptable) by the subject or the subject’s legally authorized representative (LAR)*.
  + Informed consent must include several basic elements (i.e., statement that study includes research, risks, benefits, alternatives, confidentiality, compensation, contact information, voluntary participation, statement about future use of information and/or biospecimens) and may also include other information as appropriate (unknown risks, termination of participation, costs to subjects, consequences of withdrawal, new findings, etc.). Any alterations to the required elements of informed must be approved by the IRB.
  + The most current UD consent form templates posted in IRBNet should be used in the development of informed consent documents. Researchers must check for updates of those templates every time they submit a new study for review to the IRB.
* In addition to the informed consent forms signed by the research participants (or their legally authorized representative or parent(s) when approved), researchers should keep record of the consent process having been completed. That documentation can be a cover page added to each participant record, or a consent process log documenting every subject consent process. Suggested templates for the consent process documentation forms are posted under IRBNet’s Forms and Templates section.

# Waiver or alteration of Documentation of Informed Consent

* If written documentation of consent is not required per the federal regulations, researchers can request a [waiver of documentation of consent[[2]](#footnote-2)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML&se45.1.46_1117) and, if applicable and approved by the IRB, obtain verbal consent remotely via phone or teleconference platforms such as Zoom.
* *A waiver or alteration of the requirement to document is not a waiver of the requirement to obtain informed consent*. An IRB may waive the requirement to obtain the subjects’ signature on the informed consent for some or all subjects if it finds any of the following:

1. *The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research, and the consent document is the only record linking the subject with the research. (e.g., collection of anonymous sensitive information).* 
   * + Under this criterion for waiver of documentation, each subject needs to be asked if they want documentation linking them with the research, and their wishes will govern. Informed consent document should include the signature line for subjects to sign as an option, if they wish to do so.
2. *The research presents minimal risk of harm and does not involve any procedures for which written consent would normally be required outside of the research context. (e.g., research that only involves non-sensitive surveys and questionnaires procedures could request a waiver to obtained signed informed consent documents).*
3. *The subjects are members of a distinct cultural group or community in which signing forms is not the norm provided the study is minimal risk and there is an appropriate alternative mechanism for documenting that informed consent was obtained.*

* In cases in which the signature requirement is waived or alteration approved, it is considered best practice for the investigator and study team to document that the consent process has occurred via a documentation of consent[[3]](#footnote-3) memo or note to file. The proposed plan for consent process documentation must be clearly described in the protocol form.
* Exempt human subjects research does not require written documentation of consent, nor a request for a waiver of written documentation. An informed consent process is still recommended, and the abbreviated Informed Consent Template for Exempt research is available in IRBNet’s Forms and Templates section.

# Remote Informed Consent Considerations

* *In cases in which investigators and research participants will not be in the same physical location the informed consent process can be done remotely* ensuring that:
  1. The remote consent procedures allow participants to experience a consent process as close to what it would be like in-person as possible (e.g., conversation with investigators allowing prospective participants to ask any questions they may have prior to giving informed consent). The participant should have ample time and opportunity to review the consent form in advance, and then discuss it and ask any questions together with the investigator
     + For an online survey where no direct interaction with the participant will occur, it is permissible to construct the survey with an embedded consent form at the beginning whereby completion of the survey indicates the participant’s consent.
  2. The IRB-approved and stamped consent form is used.
  3. The IRB-approved Research Protocol includes an accurate description of the entire consent process
  4. The physical location of the investigator and participant can be any place convenient to them but must provide adequate space for privacy and confidentiality. Remote conference tools can be used for online or on the phone conversations. Video conferencing (e.g., Zoom) is allowable. Regardless of the environment, the participant must be informed in advance if the consent process will be audio and/or video recorded.
* If written documentation is obtained remotely, the investigator must provide the person signing the consent form with a copy of the consent document unless this requirement is waived by the IRB. Copies can be sent via secure email, standard mail or document delivery service, fax, hyperlink for download on a secure website, etc. Enough copies should be provided that, if the participant is expected to return a hard copy, a second copy remains in their possession.
* If written documentation of consent (i.e., signature) is required, the participant can sign the consent during the remote consent process, as witnessed by the investigator, and it can be returned via one of the methods noted below.
* The regulations consider written documentation of consent to include electronic format. Acceptable options to obtain electronic signatures remotely are:

## If using a digital (e-consent) form:

* Consent document(s) can be provided on a secure online platform with an electronic signature collected at the end (e.g. REDCap, DocuSign, Google Forms, online survey using the [Signature option in Qualtrics](https://www.qualtrics.com/support/survey-platform/survey-module/editing-questions/question-types-guide/specialty-questions/signature/)[[4]](#footnote-4)). Should this method be used, it is preferable to use a platform that is easy to navigate, allows the participant to stop, save, and/or move forward and backward within the form.
  + Electronic signature - a computer data compilation of any symbol(s) executed, adopted, or authorized by an individual to be a legally binding equivalent of the individual’s handwritten signature. For studies under FDA oversight, electronic signatures must comply with 21 CFR 11.5 & 11.7 signature requirements:
    - The printed name, or handwritten signature executed to the electronic document, of the signee;
    - Date and time when the signature was executed;
    - Meaning (i.e., consent); and
    - Linked to their respective electronic records to ensure that it cannot be excised, copied, or otherwise transferred (i.e., tampered with).
* Consent language must be exactly as approved by the IRB in the most current version. When possible, the exact IRB approval stamp needs to be incorporated into the electronic version shared with the participants. If the electronic platform does not support the use of the IRB-stamped version of the informed consent, the e-version must include the IRB approval date and document version (Package IRBNet ID#)

## b) If using a paper consent form sent to a participant in advance of the consent discussion:

* Collect documentation as scanned copy or picture of the signed form sent back to investigators via secured email/file transfer.
* Collect a signed hard copy via fax or mail. Postage and mailing envelop/address should be provided by the investigator. In this case there should not be a place for the researcher to sign and date on the form itself. It is recommended to use a consent or enrollment log to capture this information instead.

# Documentation of Combined Informed Consent and HIPAA Authorization for research.

* The HIPAA Rules regulate how protected health information may be obtained and used for research purposes. *This is true whether the PHI is completely identifiable or partially de-identified in a limited data set.*
* To access and use PHI for research purposes appropriate HIPAA documentation must be obtained, including either:
* Individual patient authorization; or
* Approved waiver of authorization from an IRB or Privacy Board
* HIPAA authorizations for research purposes can be obtained on a separate document or combined with the Informed Consent document.
  + The UD IRB provides templates containing the required elements to be included in a HIPAA authorization. Signature of the individual and date are required as documentation of HIPAA authorization.
* *A waiver or alteration of HIPAA authorization can only be approved by an IRB or Privacy Board when the following criteria are met*:

1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
   1. An adequate plan to protect the identifiers from improper use and disclosure;
   2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of research, unless there is health or research justification for retaining the identifiers or such retention is otherwise required by law; and
   3. Adequate written assurances that the PHI will not be reused or disclosed 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 by the Privacy Rule;
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.

* The requirements overlap but are not the same as those for waiver of consent and waiver of documentation of consent. There are additional [requirements[[5]](#footnote-5) for HIPAA](https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/research/index.html) that are more stringent than for waiver under the Common Rule (research regulations).
* Even if documentation of informed consent can be altered or waived, HIPAA may still apply and authorization will need to be obtained if the requirements for a waiver of HIPAA are not met. In this situation, the investigator will need to obtain HIPAA authorization with a stand-alone HIPAA authorization form.

1. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html> [↑](#footnote-ref-1)
2. <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML&se45.1.46_1117> [↑](#footnote-ref-2)
3. See templates provided as resource in IRBNet under ‘Forms and Templates’ [↑](#footnote-ref-3)
4. <https://www.qualtrics.com/support/survey-platform/survey-module/editing-questions/question-types-guide/specialty-questions/signature/> [↑](#footnote-ref-4)
5. <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/research/index.html> [↑](#footnote-ref-5)