

Researcher Guidance for the Use of Electronic and Verbal Consent

Guidance provided by the University of Illinois at Urbana-Champaign ('Illinois') Office for the Protection of Research Subjects ('OPRS') to detail the use of electronic and verbal consent for research. This guidance may be updated with additional information as it becomes available.

Introduction:

Electronic or verbal consent can be a useful strategy for obtaining consent without a physical inked signature on paper. The federal regulations allow for a multitude of strategies and processes for the documentation of consent using virtual platforms, verbal acknowledgement, and information sheets. Electronic and verbal documentation of consent may be used when conducting research virtually or in-person for most types of minimal risk research.

Consent is best considered a process by which researchers fully inform potential subjects of the research parameters rather than a physical document. It is important to note that the use of electronic consent does not waive the responsibility of researchers to fully inform research participants and to affirm participant understanding prior to engaging in any research procedures. Please refer [here](#) for a guidance on the elements of informed consent.

Definitions:

Electronic Signature: *an electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.*

Informed Consent: *the process of providing participants information about the research, as well as the documentation that is used to ensure that consent for participation is fully informed.*

Waiver of Consent: *waives the requirement to obtain informed consent for research that meet the following conditions:*

- 1. involves no more than minimal risk to the subjects;*
- 2. could not practicably be carried out without the waiver;*
- 3. 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;*
- 4. the waiver will not adversely affect the rights and welfare of the subjects; and*
- 5. whenever appropriate, the subjects will be provided with additional pertinent information after participation*

Waiver of Documentation of Consent: *waives the requirement for the investigator to obtain a signed consent form for some or all participants if any of the conditions below are true:*

- 1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (Note: A waiver of documentation of informed consent is not permissible under this category if the research is subject to FDA regulations.);*
- 2. 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 consent;*
- 3. The subjects or 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.*

Electronic Signatures versus Waiver of Documentation of Consent:

The difference between collecting an electronic signature and a use of a [Waiver of Documentation of Consent](#) is an important distinction. The Waiver of Documentation of Consent is used for minimal risk research where there is no expected harm to participants or in research where the documentation of a signature is the only link to participation in a study and therefore elevates the risk level and impacts privacy of participants. Waivers of Documentation can also be used when the participants are members of a cultural group in which signing forms is not a normal/acceptable practice. Examples of consent where documentation of a signature can be waived include the following:

- Verbal consent in person, via telephone, or over a virtual platform
- Use of information sheets
- Implied consent via survey platforms

When a consent procedure will not include a written or e-signature, it requires a [Waiver of Documentation of Consent](#) form submitted with the IRB application.

Electronic signatures are an allowable form of consent whereby the potential participants are providing a legally valid signature in an electronic format. Electronic signatures can be used for research projects that otherwise would require a wet signature or the official documentation of consent. Examples of this type of consent include the following:

- Scanned copies of wet signatures
- E-signature services, such as Adobe EchoSign
- Typing one's name in an online text box
- Signing with a stylus in an electronic document

For these types of electronic signatures, a Waiver of Documentation of Consent is not needed.

Common Methods for Obtaining Consent:

Below is a short summary of the most commonly used methods of obtaining consent for various types of research projects. This guidance can be used as a general guide, but may not include all options or methods currently available. If you have any questions, please consult with an OPRS staff reviewer by emailing irb@illinois.edu.

Verbal Consent:

For studies where documentation of consent can be waived, verbal consent may be a viable option. Many studies that include telephone surveys/interviews, virtual surveys/interviews, or minimal risk research in-person qualify for verbal consent. Researchers using verbal consent should still give all potential participants access to the study information via an emailed or hard copy of the informed consent document. Additionally, it is useful to include various checks during the verbal consent process to affirm your potential participants fully understand and can repeat back key components of the study procedures.

To request use of verbal consent, please submit the [Waiver of Documentation of Consent](#) and a copy of your consent/verbal consent script with your new application or amendment. Please note that a complete description of the use of verbal consent must be documented in the IRB application form.

Information Sheets:

For studies where documentation of consent can be waived, researchers may consider developing information sheets to provide to potential research participants prior to their involvement in the study. Studies with minimal risk surveys/interviews are best served by this method of consent. Depending on the research procedures and recruitment methods, the use of informational sheets may be coupled with verbal consent.

To request use of information sheets, please submit the [Waiver of Documentation of Consent](#) and a copy of the information sheet with your new application or amendment. Please note that a complete description of the use of information sheets must be documented in the IRB application form.

Implied Online Consent:**UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN**

Many minimal risk survey research involves the use of virtual survey platforms such as Qualtrics, Survey Monkey, or MTurk. For these types of projects, consent is best conducted by using the first questions of the survey as the informed consent. The full text of the consent can be included with a “I agree” or “I do not agree” checkbox acknowledging the potential participant has read and understood the document. By clicking “I agree,” potential subjects will be directed to the rest of the survey. By clicking, “I do not agree”, the individual cannot move forward and is free to close out the platform. Any time consent is obtained with this approach, a print or email option should be available to the participant.

To request use of checkbox consent, please submit the [Waiver of Documentation of Consent](#) and a copy of your consent language with your new application or amendment. Please note that a complete description of the use of implied consent must be documented in the IRB application form.

Electronic Signatures (minimal risk research):

For minimal risk research where a Waiver of Documentation is inappropriate, researchers have the option to use e-signatures to obtain consent. There are many ways to collect e-signatures, depending on the nature of the research. Common methods of collecting e-signatures include use of scanned signatures, e-signature services (e.g. EchoSign from Adobe), typed signatures, and/or using a stylus to sign electronic documents. Any time consent is conducted in this manner, a print or email option should be available in case potential participants would like a copy of the signed consent document.

In order to approve the use of electronic signature on a consent form, guidance from the state and federal regulations indicates that the IRB will consider:

- If such signatures are legally valid within the jurisdiction where the research is conducted.
- How the electronic signature is created.
- Whether the signature can be verified to be legitimate. The electronic signature must uniquely identify the signer and must be under reasonable control of the signer; that is, it must be unlikely that any other unauthorized entity provided the signature.
- Whether the consent document can be produced in hard copy for review by the potential subject.

To request use of e-signatures for minimal risk research, please submit a copy of the consent form with your new application or amendment. Please note that a complete description of the use of e-signature consent must be documented in the IRB application form.

Electronic Signatures (higher risk research, FDA-regulated research, GDPR, or HIPAA Authorizations):

For those researchers who are conducting projects that must follow regulations that require additional levels of security and verification (e.g., FDA-regulated research, GDPR, or HIPAA), e-signatures need to be obtained using platforms that have demonstrated compliance. Currently, the University of Illinois at Urbana-Champaign has contracts with REDCap that provide the ability to collect e-signatures on these types of projects. REDCap is a resource provided to researchers at no cost. The Interdisciplinary Health

Sciences Institute (IHSI) is responsible for the administration and support of REDCap. Researchers can visit the [IHSI REDCap](#) page for more information.

To request use of e-signatures for special types of research, please submit a copy of the consent form with your new application or amendment. Please note that a complete description of the use of e-signature consent must be documented in the IRB application form.

References:

[OHRP Guidance on Electronic Signatures](#)

[IHSI REDCap](#)

[Elements of Consent](#)

[FDA E-Consent Guidance](#)