Rhode Island College IRB

Online Consent Recommendations

Before involving a person in research, an investigator needs to obtain and document that person's legally effective informed consent (45CFR46.116). Historically, documenting consent would mean a written signature on a paper consent form. With more and more research being conducted online, many researchers are unsure what constitutes a valid consent process for online studies. **The Office for Human Research Protections (OHRP)** has guidance that states that electronic signatures may be used to document informed consent. These electronic signatures must be obtained in a way that provides assurance that the person electronically signing the informed consent is the subject who will be participating in the research study. If this can not be verified then a waiver of consent may be requested for minimal risk studies. **The following is guidance for researchers at RIC who may be considering online consent.**

What fulfills the requirements for online consent?

To satisfy the regulatory requirements for written consent the following criteria must be incorporated into the electronic form:

- a valid electronic signature must be obtained (see definition below);
- the subject must be able to print (or save) a copy of the consent form (with or without signature) that they can retain for their records.
- The participant must be provided adequate opportunity to ask and have questions answered by the researcher before deciding to participate.

The consent authorization (when applicable) must, therefore, include instructions to print or save a copy of the page. Alternatively, the form could be emailed to the subject. Qualtrics has the option to allow participants to **download a copy** of the IRB stamped informed consent. Researchers should provide this option at the bottom of the consent page if using Qualtrics.

What constitutes an electronic signature?

An electronic signature can be used as a legally effective documentation of consent. To be legally effective, the electronic signature needs to be attributable to a verified identity. In other words, researchers must be sure that the person receiving and signing the consent, parent permission, or assent form is the intended individual.

Examples of this include:

- Having the potential study participant write their signature on a digital screen when in the presence of a member of the study team (either physically present or remote via a video conferencing platform).

- Typing of name to indicate electronic signature when the potential study participant is signed into a password-protected system.
- The potential study participant could orally agree on a digital recording to provide their consent by electronic signature.
- Sending an email to a school email address or text message to a phone number given by the potential participant with an individual link to access the electronic consent included in the message. Authentication can occur by linking Qualtrics surveys to specific email addresses. Qualtrics has a **guide** for linking surveys to specific email addresses.
- Having participants sign on Qualtrics. Qualtrics has an electronic signature option (for signing with a finger or a mouse, for example on an iPad or a laptop trackpad) if typing a name is not sufficient for documenting consent. Please review this tutorial provided by Qualtrics.

Please note. A participant clicking "I agree" after reading the informed consent does not constitute a legally effective documentation of informed consent. Always review your approved protocol to confirm whether documentation of informed consent is required or has been waived.

When might a waiver of online consent be warranted?

The Board can grant a waiver of documentation of consent for studies that have been determined to be no more than minimal risk. This means that the requirement to collect a written signature (documentation of consent) has been waived (is not required) and for that study, the study team is not required to document a written signature on the consent form. This type of consent process can be helpful for remote studies that have minimal risk. OHRP encourages investigators to apply a risk-based approach to the consideration of participant identity. For example, social behavioral minimal risk research will not typically warrant verification of consent. If asking for a waiver of consent, please choose the appropriate option in the TOPAZ application (Section 5.9 option D).