

Electronic Consent Processes for Minimal Risk Research*

Study teams may request electronic processes for obtaining informed consent in minimal risk research. Approvable options include web-based surveys and in-person consent processes that use laptops or mobile devices. The IRB considers the following criteria when evaluating these requests.

1. The IRB must be provided with the full content of documents, graphics, videos, help text, interactive questions and any other materials being viewed by the subject during the consent interview.
2. If the consent process does not involve an in-person interaction, the consent text must describe how subjects could contact the study team with questions.
3. The process to document the subject's agreement depends on the study details.
 - a. Anonymous surveys can inform the participant that completing the survey is considered evidence of informed consent.
 - b. The use of REDCap capabilities that obtain a 'signature' by finger, mouse or stylus is preferred. If this option is not feasible, the IRB will consider a process where the subject types their name and other confirming indications such as checking agreement boxes.
 - c. When the research involves protected health information or other sensitive information, there may be additional requirements to authenticate the individual's identity. These requirements are currently evaluated on a case-by-case basis.
4. The subject must be provided with a copy of the informed consent language.
5. Unless the study data are anonymous or unless the IRB has waived the signature requirement, the copy provided to the subject must be a signed version. It should also indicate the date the subject agreed to participation.
 - a. Preference is for the signed copy to be delivered at the time of consenting. REDCap offers the option to generate a pdf version of the document after the signature.
 - b. If the study involves protected health information, the subject must get a signed copy of the consent, either by secure email or sent by standard mail.
6. If the material provided to potential subjects includes one or more hyperlinks to information on the internet, the hyperlinks must be maintained and information must remain accessible until study completion.

*Studies that are more than minimal risk

The use of electronic consent for research that is more than minimal risk requires more extensive review to comply with FDA requirements and local data security standards. At this time, approval is granted on a case-by-case basis. Please consult with the IRB office to determine whether the request is approvable.