August 25, 2022

**BSPH IRB Frequently Asked Questions about Remote Consent and Electronic Consent (e-consent)**

**Definitions**

Remote consent (sometimes referred to as “teleconsent”) is a method of obtaining informed consent using a paper or electronic consent form where the study team and participant are not in the same physical location during the consent process.

Remote consent using a paper consent form (or remote paper consent) is a specific type of remote consent where a copy of the written informed consent form is provided to the participant via email, fax, mail or during a prior in-person visit. The informed consent process may be conducted over the phone or via video conference (e.g., Zoom). The participant signs and dates a hard copy of the consent form and returns it to the study team via email, fax, mail, or at the participant’s first in-person visit.

Electronic consent (e-consent) is a method of obtaining informed consent through the use of an electronic system instead of a paper consent form, e.g., in REDCap or DocuSign. Not all e-consent systems contain the ability to document legally effective signatures.

When an e-consent system is used, the consent process can occur **in-person** or **remotely**. An example of an **in-person** consent process that uses an e-consent system would be giving a potential participant an iPad that displays the consent form in REDCap, discussing the consent form in person, and then the participant agreeing to participate by tapping the appropriate button in REDCap. For a **remote** e-consent process, the study team may give the potential participant a link to the e-consent system and go over the consent information over the phone or via Zoom. The participant would provide their consent via the electronic platform.

Most electronic surveys do not require formal signed consent. Often the consent process is virtual, with no contact between the study team and the study participant. For example, in some cases the participant will read a consent statement on a screen and will be asked to check a box to indicate their consent.  Sometimes there is a statement explaining that completing the survey is evidence of their agreement.  The consent presented electronically can be shorter than an in-person version as some of the elements of informed consent don’t really apply to electronic survey studies. A simple consent paragraph with pertinent information will suffice, including: the voluntary nature of participation, what kind of information will be collected, how long the survey will take, risks, confidentiality protections, and how the data will be used to generate a social benefit. Please note that even though participants do not sign a consent form, you are still obtaining informed consent – just without a signature in most cases.

1. **What Electronic System can be used for Greater than Minimal Risk Research?**

REDCap may be used for greater than minimal risk research that is not FDA-regulated [e.g., research that involves an invasive biopsy] only if certain actions are incorporated into the electronic consent set-up and process to ensure the consent will qualify as legally effective documented consent. The requirements are the same for research conducted in Maryland, DC, or Florida.  Each of the following requirements must be addressed:

**How do you make sure the correct person signs the e-consent?**

**Authentication:**

When using REDCap or any other validated electronic system to document consent for greater than minimal risk research, the research team must incorporate a mechanism to verify that the person signing using the e-consent system is the correct person. One mechanism to do so is to provide a code during the consent conversation directly to the participant. This code must be unique and must be provided directly to the participant. A field to enter the authentication code must be added to REDCap as part of the e-consent build in REDCap for the study.

For FDA-regulated research that is greater than minimal risk, REDCap may not be used. DocuSign is the only system currently available at Hopkins that can document legally effective signatures and is Part 11 compliant (see question 2 below).

For FDA-regulated research, REDCap may be used only if the documentation of consent requirement has been waived. A waiver of documentation of consent may only be granted when the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

If documentation of consent is required for an FDA-regulated study, then REDCap may not be used since it is not 21 CFR Part 11 compliant. E-consent for FDA-regulated studies must use a compliant system, like DocuSign.

1. **What does it mean for consent to be 21 CFR Part 11 compliant?**

FDA requirements for electronic records and electronic signatures are set forth in 21 CFR Part 11 of the FDA regulations. When referencing a “Part 11 compliant” electronic consent system, the Office of Human Subjects Research (OHSR) is referring to use of a system that complies with FDA regulatory requirements for electronic records and electronic signatures. Compliance with these regulatory requirements is required for all FDA-regulated research that is greater than minimal risk and minimal risk research where the requirement for documentation of consent has not been waived. Please visit the [FDA’s guidance on electronic consent](https://www.fda.gov/media/116850/download) for additional information about the requirements set forth in 21 CFR Part 11 of the FDA regulations. DocuSign is the only Part 11 compliant system currently institutionally approved at Hopkins.

1. **What if my study falls under HIPAA?**

If your study falls under HIPAA, whether using JHM PHI or non-JHM PHI, you are required to obtain a signed Authorization from participants. The Authorization may be a free-standing document or, more commonly, incorporated into a Consent/Authorization document. If it is “impracticable” to obtain a signature, the IRB/Privacy Board is authorized to consider approving a HIPAA Waiver of the signature requirement.

1. **What consent document do I need to submit for e-consent or remote consent?**

If you want to have the option to obtain either paper written consent, oral consent, or e-consent, you should upload a Word version of the consent(s) to the consent form section of the PHIRST application. Note in your research plan how you plan to obtain consent and, if applicable, how you will document informed consent.

Please exercise good version control by carefully naming each document by title (Adult type? Parental permission? Assent?), version number, and date. You may only use Consent/Parent Permission/Assent forms approved by the BSPH IRB and finalized in the BSPH PHIRST system.

Please refer to the table to determine which consent form to use:

|  |  |  |
| --- | --- | --- |
| Participant Type | Form | Form Number |
| Adult | [ADULT CONSENT FORM FOR SIGNATURE](https://publichealth.jhu.edu/sites/default/files/2022-03/adult-signed-cfrcr-102mar2022.docx) | RCR1 |
|  | [ADULT ORAL CONSENT SCRIPT](https://publichealth.jhu.edu/sites/default/files/2022-05/adult-oral-cfrcr2-11may2022.docx) | RCR2 |
| Parent | [PARENT PERMISSION FOR SIGNATURE](https://publichealth.jhu.edu/sites/default/files/2022-03/parent-signed-pfrcr302mar2022.docx) | RCR3 |
|  | [PARENT PERMISSION ORAL](https://publichealth.jhu.edu/sites/default/files/2022-05/parent-oral-pfrcr4-11may2022.docx) | RCR4 |
| Minor | [ASSENT FORM – SIGNED AND ORAL](https://publichealth.jhu.edu/sites/default/files/2022-08/assentformrcr501aug2022.docx) | RCR5 |

If you have additional questions, send them to jhsph.irboffice@jhu.edu.

Resources:

Julie Blasingim. 2017. “Evaluating eConsent: Some Considerations from an IRB Perspective”  [https://www.advarra.com/blog/evaluating-econsent-considerations-irb-perspective/](https://nam02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.advarra.com%2Fblog%2Fevaluating-econsent-considerations-irb-perspective%2F&data=05%7C01%7Ctmcguin1%40jh.edu%7Cb54c1c0b6d204a1f759e08da3cdff4f7%7C9fa4f438b1e6473b803f86f8aedf0dec%7C0%7C0%7C637889229819185178%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=PFKNBsUqRygcoQMmtlSEcOS92%2BLoHaVt6gawScGpY%2BU%3D&reserved=0)

FDA Guidance Document: “Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers” 2016 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers>