Guidance for Obtaining Informed Consent Remotely

This document is meant to serve as a resource for investigators and research teams seeking to consent subjects in formats other than wholly in-person. The options available under the regulations vary based on the

Commonly Asked Questions

My project is multi-site, and the other participating institutions can utilize electronic consent and electronic signatures. Why can MCW not accommodate this?
For FDA-regulated research, there are additional requirements when consenting electronically. Although MCW does use several electronic platforms (e.g. RedCap), these are not compliant with the additional requirements for FDA-regulated projects at this time. Additional steps must be taken across a number of different departments to make our version of RedCap and other

though. For example, a subject who signs a consent form after a telephone consent process and emails the form back to the team does not need to be provided another copy since the subject would already have the copy he/she signed.

Of note, it is recommended by the FDA that the original, signed consent form be kept for project records.

The individual conducting the consent discussion is working remotely, but the subject is in-person. Another member of the research team or clinical staff will be handing the subject the consent form, and the individual conducting the consent discussion will speak with the subject via telephone or another approved electronic platform. Who signs the consent form as the individual obtaining consent? The member of the research team discussing the consent form with the subject via phone/electronic platform.

The Sponsor has provided me with documents stating that the electronic consent they wish to use is FDA Part 11 compliant. What should I do? It is best to contact the IRB Office with the documents for the specific project. The IRB Office will vet the documents with the appropriate institutional offices, and this method may be allowed in the specific project for which the documents were provided.

You were directed to this chart because you indicated your project is FDA-regulated and greater than minimal risk.

Type of Consent	Documentation Options	Notes
Telephone	Encrypted email, postal mail, fax, or delivered by subject at first research visit	The signed consent form must be received prior to beginning any research activities.
Zoom, WebEx, Skype, or Teams (these must be HIPAA-compliant)	Encrypted email, postal mail, fax, or delivered by subject at first research visit	The signed consent form must be received prior to beginning any research activities.

You were directed to this chart because you indicated your project is FDA-regulated and minimal risk.

Type of Consent	Documentation Options	Notes
Telephone	Encrypted email, postal mail, fax, or delivered by subject at first research visit	The signed consent form must be received prior to beginning any research activities.
Zoom, WebEx, Skype, or Teams	Encrypted email, postal mail, fax, or delivered by subject at first research visit	The signed consent form must be received prior to beginning any research activities.
Electronic	e-signature via an electronic consenting platform	This method may only be used for FDA-regulated research if the proposed platform has been vetted through the MCW IRB Office. Please reach out on a case-by-case basis.
Alteration of Consent	Documentation can be obtained but is not necessary. Generally, the MCW informational letter is recommended and does not include signature lines.	

Example 1: An unsigned consent form is emailed, mailed, or faxed to a potential subject. The consent discussion between the potential subject and a member of the research team occurs over the phone. The subject then signs the consent form and returns it to the research team via encrypted email, postal mail, or fax.

Example 2: The research team emails the potential subject the consent form. The consent discussion occurs over the phone. The subject brings a signed copy of the consent form at the subject's first research visit (the consent form must be received prior to any research activities occurring).

Example 3: A consent form is emailed to the subject and the consent discussion occurs via a HIPAA-compliant video platform. The subject signs the consent form provided to them, and the signed consent form is provided to the team prior to any research activities occurring.

You were directed to this chart because you indicated your project is *NOT* FDA-regulated and greater than minimal risk.

Type of Consent	Documentation Options	Notes
Telephone	Encrypted email, postal mail, or fax	The signed consent form must be received prior to beginning any research activities.
Zoom, WebEx, Skype, or Teams	Encrypted email, postal mail, or fax	The signed consent form must be received prior to beginning any research activities.
eConsent	eSignature via an electronic consenting platform	

research team electronically, and a copy of the consent form is provided to the subject electronically.

Example 5: A research team consents subjects to a research project in-person via REDCap using an iPad. The subject is emailed a copy of the consent form, and the research team receives the signed consent electronically via REDCap.

You were directed to this chart because you indicated your project is NOT FDA-regulated and minimal risk.

Type of Consent	Documentation Options	Notes
Telephone	Encrypted email, postal mail, or fax	The signed consent form must be received prior to beginning any research activities.
Zoom, WebEx, Skype, or Teams	Encrypted email, postal mail, or fax	The signed consent form

		consent is the only link between the subject and the project.

Example 1: An unsigned consent form is emailed, mailed, or faxed to a potential subject. The consent discussion between the potential subject and a member of the research team occurs over the phone. The subject then signs the consent form and returns it to the research team via encrypted email, postal mail, or fax.

Example 2: The research team emails the potential subject the consent form. The consent discussion occurs over the phone. The subject brings a signed copy of the consent form at the subject's first research visit (the consent form must be received prior to any research activities occurring).

Example 3: A consent form is emailed to the subject and the consent discussion occurs via a HIPAA-compliant video platform. The subject signs the consent form provided to them, and the signed consent form is provided to the team prior to any research activities occurring.

Example 4: A research team recruits a subject to participate in a project, but the project does not involve any in-person visits. The subject is sent a link to the consent form via REDCap and the subject signs electronically on his/her computer. The signed consent form is received by the research team electronically, and a copy of the consent form is provided to the subject electronically.

Example 5: A research team consents subjects to a research project in-person via REDCap using an iPad. The subject is emailed a copy of the consent form, and the research team receives the signed consent electronically via REDCap.