Guidance for Obtaining Informed Consent Remotely

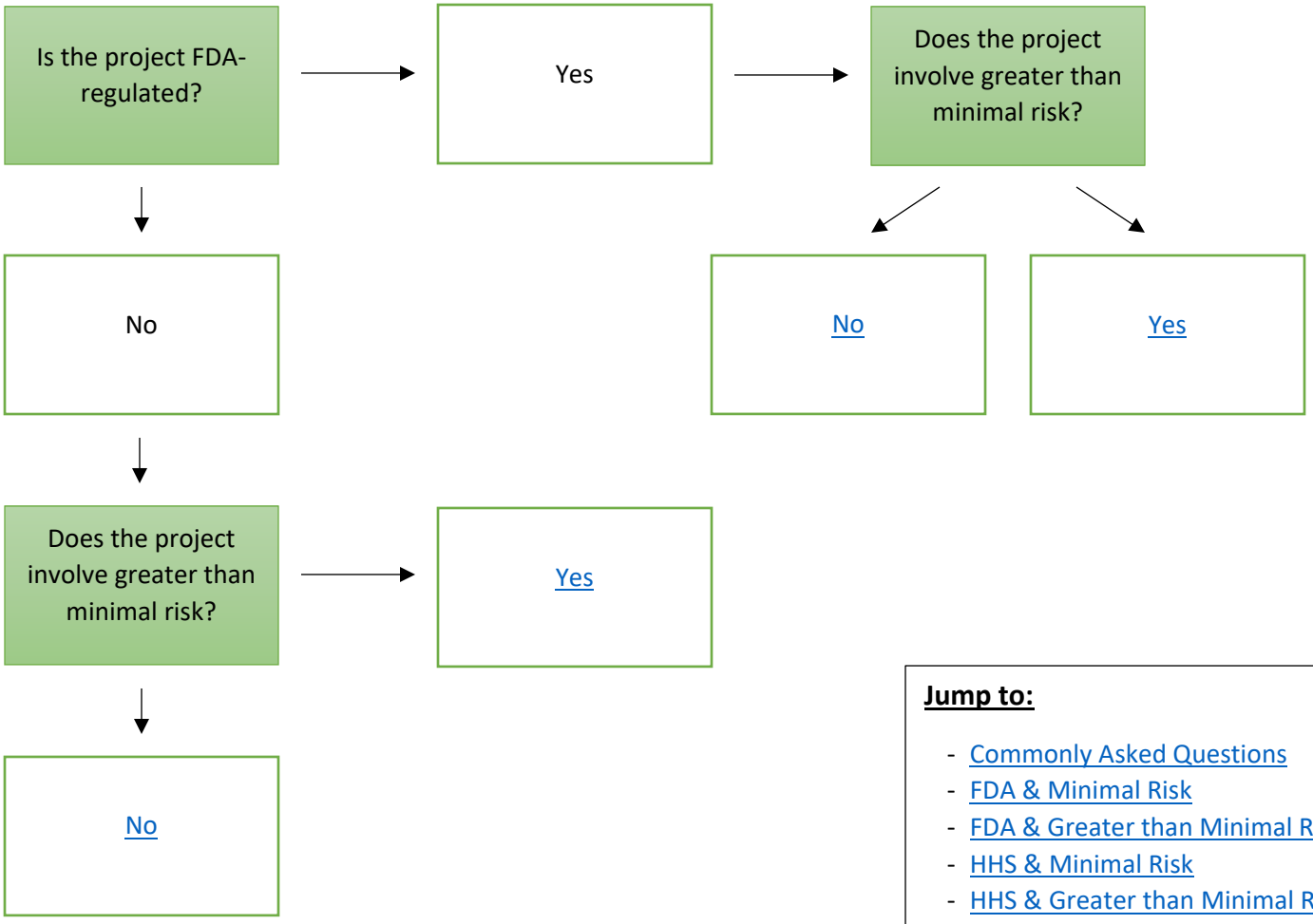
This document is meant to serve as a resource for investigators and research teams seeking to consent subjects in formats other than wholly in-person. The options available under the regulations vary based on the components of the specific project and the regulations that apply to it.

When determining whether a certain method generally can be utilized for your type of project, it is best to keep the following two question in mind:

1. Has the IRB classified the project as minimal risk or greater than minimal risk?
2. Is the project FDA-regulated?

With these questions is mind, this guidance has been crafted to lead you to a chart most applicable to your specific project.

Please note, the charts of options are not all inclusive. Also, just because an option is allowable for a project does not necessarily mean the IRB will grant the option for every project. The below is meant as a basic guide rather than a guarantee.



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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 electronic platforms FDA-compliant.

My project relies on another IRB for review. Do I still need to keep institutional consent requirements in mind? Yes! Even though your project is being reviewed by a different IRB, institutional requirements (such as those relating to electronic consent) must be followed.

Why do emails containing signed consent forms need to be encrypted? MCW consent forms contain an embedded HIPAA authorization, and once a subject signs a consent form, it contains PHI. Therefore, HIPAA regulations must be followed, which is why encrypted email must be utilized.

How do you handle a situation in which the subject will sign a different consent form than the consenter (a copy of the signed consent form is emailed to the research team)? Given the shift from in-person consenting procedures, it is common to have a situation in which a subject sends the research team a signed consent form that is then printed and signed by the team. The "wet ink signatures" of the subject and research team would not be on the same consent form, and this is acceptable. The research team should sign the signed document that is received from the subject.

How do you handle a situation where a subject signs the consent form on a different day than the individual obtaining consent (e.g. a subject delivers a signed consent form for their first research visit a week after signing it)? Given the shift from in-person consenting procedures, it is expected that different signature lines on the consent form may be completed on different days or in different ways (see above question). The key to handling these situations is to clearly document in the SmartForm and project files what is occurring and why.

Oftentimes, these situations can be anticipated when developing the consenting process for a project, so the process should be clearly defined in the SmartForm.

Does the subject need to receive a copy of the consent form with a wet signature? No. This is a commonly misunderstood component of the regulations governing human subject research. It is not a requirement of the HSR-related regulations to provide a subject with a signed copy of a consent form, but it is a requirement of HIPAA. **What does this mean for researchers at this institution?** For projects that use a HIPAA authorization embedded within the consent form, the subject should be provided with a copy of the consent form that they sign and date. It is not required that the copy containing all signatures be provided to the subject,

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.

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 FDA-regulated and minimal risk.

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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.	Please review the presentation titled **"Informed Consent Pathways for Minimal Risk Research"** for additional information about this pathway.
Waiver of Consent	N/A	Please review the presentation titled **"Informed Consent Pathways for Minimal Risk Research"** for additional information about this pathway.
Waiver to Document Consent	N/A	Please review the presentation titled **"Informed Consent Pathways for Minimal Risk Research"** for additional information about this pathway. This method is typically only allowable for projects collecting highly sensitive information where the consent is the only link between the subject and the project.

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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.

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eConsent	eSignature via an electronic consenting platform	REDCap is currently the only MCW-approved electronic platform for capturing electronic signatures. Florence is approved for use at Versiti, Inc. Any other proposed platform should be vetted through the IRB Office.

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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.

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