

IRB Frequently Asked Questions

The institutional requirements for obtaining a witness signature on the research informed consent document and obtaining a separate email authorization agreement changed effective February 23, 2023. Please read below to find out how this will impact your ongoing and new research studies.

Changes to Witness Requirements

How will this impact my existing/ongoing studies that were IRB approved prior to 02/23/2023?

You should continue to use your IRB approved consent form to consent participants. You do not need to obtain the witness signature on the consent form unless the IRB has specifically required a witness during the review process. The IRB would have documented this requirement in your IRB determination letter.

When you are ready to submit an amendment to the IRB, you may update your consent form to remove the witness line at that time.

How will this impact my new studies that will be IRB-approved after 02/23/2023?

Studies IRB approved after the effective date, will no longer require that a witness signature be obtained. Your consent form will not include a witness line. The IRB may require that you obtain a witness signature in special circumstances. If so, the requirement for obtaining a witness signature will be included in your IRB determination letter.

What if my study is already in the IRB queue for review?

The IRB team will revise your consent forms to be consistent with the revised changes. The team will reach out if there are questions.

What are the special circumstances when the IRB may require a witness?

The IRB will consider the type of research being conducted, and the population being studied. If the research is greater than minimal risk or sensitive in nature and the population represents one of the vulnerable categories (e.g., children, prisoners, economically or mentally disadvantaged), the IRB may require a witness to ensure the rights of the participant are protected, and that the participant fully comprehends the nature of the research and the research procedures.

My study is enrolling non-English speaking subjects and I do not have a translated consent. What are the procedures? Will I need a witness?

Using a Short Form: The human subjects regulations require that a participant be consented on a consent form in a language that is understandable to that participant. The regulations do allow for the use of a short form in conjunction with a written summary. When used, the short form, must be provided in a language understandable to the participant, include information about the required elements of consent, and information the subject will hear during the consent process. The short form must be signed by the subject and a witness that is fluent in both languages.

Using a Translated Consent Document: If you are using a consent form that has been translated into the language of the participant, you are not required to obtain a witness signature.

I thought the witness signature helped to verify that the consent process occurred properly. If I no longer need a witness, how do I verify that I conducted the consent process properly?

The consent form is only one part of the consent process. The consent process begins when a subject receives information about the study or is approached about the study. It also includes the interaction between the subject and the study team before, during and after the consent document has been signed. It may include providing new information or updates to the subject while they are participating on the study. The process ends once the subject is no longer participating in the study. During the process, the research team provides details about the study, responds to the subject's questions and checks for subject comprehension. The entire process should be summarized in the subject's medical or research record at the time of initial consent, and anytime there is a re-consent. Many research teams utilize standardized language and consent checklists to ensure the consent process is documented appropriately.

Does this FAQ apply to external IRB studies?

The witness signature is no longer required by the institution. However, a witness signature must be obtained if required by the external IRB of record.

Change to Email Authorization Agreement requirement

How will this impact my existing/ongoing studies that were IRB approved prior to 02/23/2023?

You should continue to use your IRB approved consent form to consent participants. If a subject has a signed Email Authorization agreement on file, you should continue to maintain that document as part of your study records. For new patients, you no longer need to ask subjects to sign a separate Email Authorization Agreement. However, since your consent form has not yet been updated, you will need to verbally inform participants that the research team may contact them regarding the study. You should document this discussion as part of your consent process. If the subject is unable to receive emails, consider alternative communication methods if allowed by the study.

When you are ready to submit an amendment to the IRB, you should add the new emailing language.

How will this impact my new studies that will be IRB-approved after 02/23/2023?

Studies IRB approved after the effective date, will no longer require the use of an Email Authorization Agreement. Your consent form will include the IRB-approved emailing language.

Change to Texting requirements

How will this impact my existing/ongoing studies that were IRB approved prior to 02/23/2023?

Texting language has been updated in 2 sections of the consent (ie, “How we may contact you?” and “ClinCard”). You should continue to use your IRB approved consent form to consent participants. If a subject has indicated a choice in the “Texting” section of the informed consent document, you should continue to honor the wishes of the subject. For new patients, you no longer need to ask subjects to select “yes/no”. However, since your consent form has not yet been updated, you will need to verbally inform participants that the research team may contact them via text regarding the study. You should document this discussion as part of your consent process. If the subject is unable to receive texts, consider alternative communication methods if allowed by the study.

When you are ready to submit an amendment to the IRB, you should add the new texting language.

How will this impact my new studies that will be IRB-approved after 02/23/2023?

Studies IRB approved after the effective date, will no longer require the subjects to indicate their choice (ie, yes or no) in the texting section of the consent. Your consent form will include the IRB-approved texting language.

Responding to Sponsors

What do I do if my Sponsor/CRO or other auditing entity requests written confirmation from the IRB about any of the new changes?

You should refer the Sponsor/CRO or auditing entity to the updated IRB Informed Consent Policy and Procedure, the Consent Forms, and the IRB SOP for Obtaining Informed Consent that were all revised and effective on 02/23/2023. The policy, consent forms, and the SOP remove the requirement for a witness unless specifically mandated by the IRB or the Sponsor, and the requirements to obtain additional documentation for communicating with subjects via email or text.