Sabai IRB Informed Consent Guidelines

As each new Study and/or Principal Investigator is submitted to the IRB, submitters are prompted to attach materials, including any informed consent documents (ICF) for IRB review.

IRB Approved ICF Version Dates

Once approved, final IRB-approved ICFs will be issued for use in the study/with research participants. These will be "Protected" Microsoft Word documents with Sabai IRB version dates included on the document, for example:

> Approved by Sabai IRB October 01, 2025
> Template Only: Not approved for Use by Participants
> IRB Version: 1.0
>
> Sites have the middle line removed:
>
> Approved by Sabai IRB October 01, 2025
> IRB Version: 1.0

Sabai IRB uses the IRB approval date as the "Approved by" Version Date. For the IRB Version, Sabai IRB uses 1 for the first IRB approved version, 2 for the next version, etc.

For sites using the template ICFs without site-specific changes, the ICF will show a .0 version, for example 1.0, 2.0, etc. Sites with site-specific changes will reflect a .1 version, for example 1.1, 2.1, etc.

An "alpha-numeric" version is issued to correct an error made in a previously issued ICF. The corrected ICF version increases by a lower-case letter beginning with the letter "a" (i.e. Version 1.0a, Version 1.1a, Version 2.0b, etc.). The date of the alpha-numeric ICF is the same date of the previously issued form which contained the error.

Translated ICFs will have the same version number and date as the English version.

ICF Submission Requirements for Sites on Multi-site Studies

For multi-site studies, "Protected" Microsoft Word versions of study-level template ICFs will be provided for use.

If a site only requires revisions to placeholder sections, such as site contact information (PI name, site name, address and phone numbers) and participant payment/reimbursement information, there is no need to submit ICFs. For those sections, the IRB team will insert the details from the IRB application into the consent form and route for sponsor/CRO review, if applicable, prior to IRB review.

If information/sections beyond the placeholder language is required for a site, use the "Protected" IRB approved template version of ICFs to insert any site-specific changes (this will automatically track any changes that are made) and submit for IRB review. Please refrain from any attempts to unlock, reformat, or alter the protected file structure. This includes converting between Microsoft Word and PDF file formats. Sabai IRB cannot accept ICFs created on the wrong ICF version/format. Sponsors/CROs may need to approve any ICF changes made ***prior to*** *IRB review.*

How to Revise/Update ICFs

The IRB requires submission and review of any proposed changes to ICFs prior to use with participants.

For any future ICF updates, the current "Protected" IRB-approved ICF versions should be used. As changes are made, they will automatically be tracked, and the tracked version should be submitted for IRB review. Please refrain from any attempts to unlock, reformat, or alter the protected file structure. This includes converting between Microsoft Word and PDF file formats. Sabai IRB cannot accept ICFs created on the wrong ICF version/format.

Note: Sabai IRB will follow the same procedure noted above for multi-site studies; however, if study level ICFs are being revised, once approved at the study level, these changes will be carried over to all active participating site ICFs regardless of whether the site uses template or site-customized ICFs.