

Memo to File

Subject: Use of Protected Microsoft Word format for IRB-Approved Informed Consent Forms (ICFs)

Date: 02Feb2026

Purpose:

This memo provides clarification regarding Sabai IRB’s use of the protected Microsoft Word format for Informed Consent Forms (ICFs), finalized and issued via the MySabai portal. The purpose of this control is to maintain compliance with 21 CFR Part 11, ensure document integrity, and support accurate site ICF customization under sponsor workflows.

Background:

Sabai IRB is standardizing document handling practices across divisions. As part of this alignment, Sabai IRB will issue final IRB-approved ICFs in a protected Microsoft Word format.

Rationale (Operational & Compliance Considerations):

The protected Microsoft Word format was selected to improve transparency and reliability in document management. Using a protected file maintains full revision history, reduces formatting issues that can occur when converting between Microsoft Word and Adobe PDF, and ensures that any editing is clearly marked for IRB review. This practice safeguards approved content from inadvertent changes and ensures every distributed version corresponds precisely to the IRB-approved record stored within the validated MySabai portal.

Guidance:

Under this process, IRB-approved ICFs are finalized and released as protected Microsoft Word files in the MySabai portal. The IRB team uses site application data to populate the designated placeholders, and if a site has no other customization, then no additional steps are required. If a site has customization outside of those defined placeholder sections, then the site must route any additional edits through the IRB for review and approval before use. The protected format prevents unauthorized changes to approved sections while maintaining visibility of permitted site-level insertions. If a sponsor or site encounters technical limitations using this format, Sabai IRB will coordinate an alternative secure method to ensure consistent document control.



This approach aligns with Sabai IRB's document control and data integrity standards and supports 21 CFR Part 11 principles by maintaining the authoritative record within the validated system while ensuring distributed files remain traceable and controlled.

Recommended Action:

- Retain this memo in study regulatory documentation to document Sabai IRB's process for protected ICF issuance.
- Utilize the IRB-approved *protected* Microsoft Word file for all site-specific insertions or tracked revisions.
- Refrain from any attempts of unlocking, reformatting, or altering the protected file structure. This includes converting between Microsoft Word and PDF file formats.
- Notify the IRB if technical limitations prevent use of the protected format.
- Maintain the IRB-issued file as the reference source for any audit or inspection purposes.

Contact:

For any questions, please contact Sabai IRB at 888-442-2472 or clientservices@sabaiglobal.com.

