Clean vs Tracked & Add vs Update

Know when tracked versions are needed and how to include the document properly in a JHM SOM IRB Application

What are Clean and Tracked Documents?

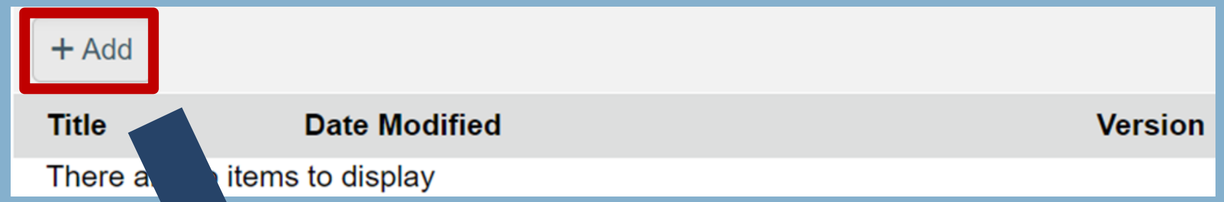
A clean document is free from edits, comments, and redlines.

A tracked document allows the reviewer to clearly observe the modifications made to the document.

A clean document should be added when the document is new and has never been reviewed by the IRB or the IRB requires a clean and tracked version of the document.

Tracked versions are required once the Board has reviewed the document and has required changes or the PI is submitting a Change in Research to update the document.

Add vs Update



New documents that have never been reviewed should be uploaded to the appropriate section using the 'Add' Function. This should be a CLEAN document.

If the document is a revised version of a previously uploaded document that has been reviewed, use the 'UPDATE' function to upload the revised document.

The UPDATE function allows the document to be "stacked" to maintain a record of previous versions. Do NOT delete previous versions of documents - "stack" them to maintain the history of the document

DOCUMENTS THAT CAN BE UPLOADED AS ONLY A TRACKED VERSION. THESE DOCUMENTS WILL BE STAMPED ONCE APPROVED:	Documents that require Clean versions "stacked" over a Tracked version:	Documents that require separate Clean and Tracked versions submitted in separate fields:
Recruitment Materials (e.g. flyers, brochures, screening scripts) - section 13	Supplemental study documents - section 20, questions 1 and 2. *Section 20, question 3 does NOT require a tracked version.*	Protocol (e.g. sponsor protocols, eForm A, eForm S) - Sections 4 - 6
HIPAA Form 4 - section 13 HIPAA Form 3 - section 19	Investigational Drug Data Sheet - section 21	Investigator's Brochure - section 21
Informed Consent Documents - sections-15 - 17	Data Safety Monitoring Plans - section 32	

Things to Keep in Mind

Upload tracked changes documents when file format permits (not PDF, JPG, etc.). If the document is from a sponsor who has not provided a tracked-changes version, the study team is expected to make a tracked changes version or can upload a summary of changes if unable to provide a tracked version.

Things to Keep in Mind

When preparing a tracked changes document, avoid inserting large blocks of text directly. This is crucial, particularly when revising the Hopkins informed consent document from industry-sponsored consents. It's essential to carefully review the consent form line by line to preserve Hopkins-approved language and to allow for individual changes to the text to be tracked.

It’s important to use the last approved WORD version of the Hopkins Informed Consent document when making changes. Please avoid converting the PDF copies of stamped consent documents to a Word document to create tracked versions. Inconsistent formatting makes it difficult to distinguish the changes from the last approved version in such cases.

Things to Keep in Mind

Documents that may be revised but do NOT require tracked versions:

- **Sponsor Recruitment ads**
- **International Research Supplemental Form**
- **Risk Tier Calculator**
- **Supplemental study document(s) that will be provided to the participants or are participant facing in section 20, QUESTION 3.**
- **Biospecimen Transfer Committee Documents in Section 23**
  - **The Biospecimen Transfer Information (BTI) Form-Although it is helpful to the Biospecimen Transfer Committee to highlight any substantive changes.**
  - **Although tracked versions are not required, it is standard practice to provide a copy of the consent form(s) associated with the IRB protocol under which the biospecimens were collected, with language appropriate to the transfer highlighted.**

Need More Help?

JHM IRB Request a Consult Service

Need help navigating the IRB review process? Use the QR code or visit the IRB Website to request a consult and be matched with IRB staff who will address your needs.

Sample topics we can help with:

Uploading clean and tracked documents
Protocol planning
Determining IRB review type & forms
IRB regulations and policies
Recruitment & consent
Responding to IRB Review

Consult requests will receive a response within 24 hours!

Contact Us

IRB Help Desk
E-mail: jhmeirb@jhmi.edu
IRB Help Desk Phone: 410-502-2092

Watch our instructional video on this topic!