

Stacking Guidance Document for Investigators 10.30.2023

What is “Stacking”?

“Stacking” is a term that IRB analysts communicate to investigators about documents within in USC iStar system. Stacking leaves a digital footprint in the iStar system.

Why do I have “stack” my documents?

Stacking documents is necessary to properly keep track of documents in iStar. Stacking helps the IRB with record keeping. Stacking makes sure all documents are stored in iStar in an individual file folder. This folder will track the versions and dates that documents were uploaded. Stacking documents allows for proper record keeping in iStar.

What documents do I need to stack?

Any documents that you change after the initial submission: For example, protocols, Informed consent forms, recruitment materials, surveys, interview schedules, and Investigator Brochures.

When do I stack my documents?

Documents are stacked when a new/revised version is available.

Should the documents I upload contain the tracked changes in MS Word?

YES! Please make sure that all documents that can be ‘tracked changed’ are tracked changed (i.e., Protocol, informed consent form, recruitment, etc.

Is stacking optional?

No. You must do it. An IRB application might be sent back to you to ‘fix’ if you do not follow these directions.

Should I delete previously approved documents when I submit amendments/continuing review?

NO! Please do not delete any previously approved documents. Please do not delete any previously approved stacks. Please ‘stack’ your documents, you may add to the current stack.

If I uploaded the incorrect documents, should I delete them?

It depends! **Do not delete a ‘stack’ or everything will be lost.** You *may delete* extraneous documents that are not in a stack.

How should I name the documents that I stack?

Please provide a “Revised Version Date” for all documents (Protocol/Informed consent) that are added. This helps both study teams and the IRB members and analysts keep track of documents.

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[Click here to watch a video on how to stack documents.](#)

Diagram of how to stack a document.

How to “stack” Documents in iStar

Tip: The IRB must review the correct document. In this example, the document name has different dates. The IRB will not make assumptions, and this would be sent back to the investigator to correct.

1. The IRB asks that you stack documents so only the most current document shows in iStar. In this example, we see two interview question sets uploaded – not stacked. This is a common error that investigators make when adding in revised documents to the iStar System. Both documents are version “1”. These documents must be “stacked”.

19. Methods and Procedures

This screen is required if you include questions in your protocol.

19.1. Attach copies of any scripts and/or questions that will be used to guide the interviews/groups.

Name	Version	Modified
Interview questions 10-20-23.docx(0.01)	0.01	10/24/2023 3:18 PM
Interview questions 10-24-23.docx(0.01)	0.01	10/24/2023 3:20 PM

19.1. Attach copies of any scripts and/or questions that will be used to guide the interviews/groups.

Name	Version	Modified
Interview questions 10-24-23.docx(0.02)	0.02	10/24/2023 3:26 PM

2. To stack a document, start by clicking on the “...” by the title of the oldest file.

5.2. Attach the protocol here. All studies require a fully developed protocol.

+ Add Drag and drop files to upload

Name	Version	Modified
Social-Behavioral-Protocol (1).docx(0.02)	0.02	6/13/2022 7:10 AM
Social-Behavioral-Protocol.docx(0.01)	0.01	6/3/2022 10:57 AM

For investigators here: https://www.fda.gov/oc/ohrt/and-protocol-writing-tips-are-available

5.3. Attach the protocol here.

+ Add

- Download Copy
- Upload Revision
- View History
- Delete

3. This shows the choices that will appear. Select “Upload Revision” and then you will be able to stack the new document on top of the old one.

4. See? By stacking, we know it’s version 2!

Tip: The IRB must have the correct version date as this is printed on approval letters.

History:

Compare	Date	Version	Person	Action	Notes	Uploaded File
<input type="checkbox"/>	10/24/2023 3:26 PM	0.02	Janet Morris	File Uploaded & Edited		Interview questions 10-24-23.docx
<input type="checkbox"/>	10/24/2023 3:18 PM	0.01	Janet Morris	Created		Interview questions 10-20-23.docx

1-2 of 2

5. Above, you can see what version history looks like. To see the version history, select “View History,” also from the “...” option.