



Review of Informed Consent Documents (ICD) in PROTECT

- An IRB shall require that information given to subjects (or legally authorized representatives [LAR], when appropriate) as part of informed consent is in accordance with [§ 46.116](#). ([45 CFR 46.109\(b\)](#))
- The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. ([45 CFR 46.116\(a\)\(4\)](#))
- Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate. ([45 CFR 46.116\(a\)\(5\)\(i-ii\)](#))

In reviewing the consent form, IRB members should promote disclosure of information that will help facilitate subjects' understanding of the study and voluntariness of their subsequent decision to participate.

- Confirm that the consent is consistent with information in the protocol and, if applicable, the IB or package insert.
- Level and complexity of information in the ICD should be appropriate and culturally sensitive for proposed subjects.
- Key information section should communicate material most relevant from potential subjects' perspective.
- Required template language should be included appropriately.
- Procedures should be accurately described in an understandable manner.
- Risks are disclosed in a clear and understandable manner. (If the study is an interventional trial, does the risk section accurately reflect reasonably foreseeable risks included in the IB, package insert or device information?)
- Potential for direct benefit (if any) is realistically described.
- As applicable, the ICD should describe appropriate reward, compensation, or non-monetary incentive in such a way that undue influence is avoided.
- Consent form must be free of exculpatory language meaning it must not waive or appear to waive the rights of the subject or release or appear to release those conducting the study from liability for negligence.
- When enrolling minors, confirm there is an age-appropriate assent form, as applicable, with information conveyed in a meaningful manner. (Investigators should use the [OHSRP assent template](#).)

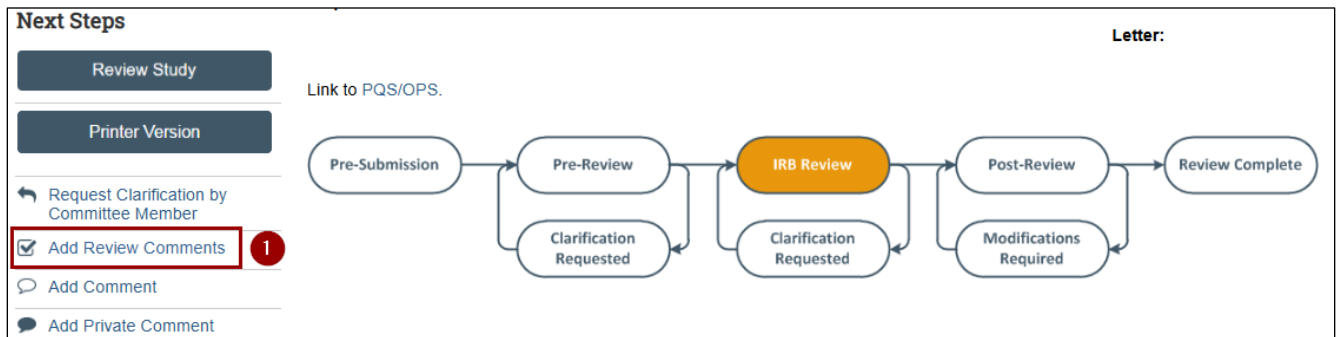
What if you have proposed edits to the consent/assent document(s) based on your pre-meeting review?

- First check the "Reviews" tab to see if other members have already uploaded a consent with edits as part of their review. If yes, then download the most recently uploaded version and make your changes in the same document.

Committee Member Review Comments

Person	Role	Notes	Checklists Supporting docs	Date submitted
	Secondary Reviewer	Added Monday: Feb 10. Sorry to do this in multiple messages ~ I've not had much experience with the use of "deception" pages 22, 36 in protocol, and participant memo. What do others think about thi... read more	IRB002341_Consent_22Jan2025 [redacted].docx	2/10/2025
		study is approvable, category 9. study involves deception. Suggested edits made to the consent; I used [redacted] consent and added edits to that version, attached. No other proposed stipulations.	IRB002341_Tracked_Consent_22Jan2025 [redacted].docx	2/10/2025
		See my additional edits and comments in the informed consent document. Additionally, there is a statement on page 40, Section 5.7. I recommend be removed by the study team.	IRB002341_Consent_22Jan2025 [redacted].docx	2/10/2025

- Download and edit the consent and/or assent documents using “tracked changes” during your pre-meeting review.
- If the document needs a major re-write, it is fine to just insert comments and not re-write the ICD for the investigator.
- While Board members should not rewrite the proposed ICD based on personal preferences, check to see if it is targeted at the recommended 6th-8th grade reading level using lay terms instead of technical words. See [instructions to check readability statistics in Microsoft Word](#) and “Additional Resources for Consent Forms” on the [Consent Templates and Guidance OHSRP website page](#) for tips to simplify consent terms.
- When you have completed your review, upload the tracked consent(s) with your review in PROTECT. All the combined suggested edits of the members will be reviewed and discussed at the IRB meeting.



Add Review Comments

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i All committee members and IRB staff can view your comments in the Reviews tab.

i All comments and attached files will be removed from the system upon the submission's approval.

1. Notes:

2

2. Checklists: (attach relevant checklists from the IRB Library) ?

3 + Add

Name

There are no items to display

3. Other supporting documents:

4 + Add

Upload tracked version of the consent with IRB reviewer's comments/edits here.

Name

123456_Standard Consent.1_tracked_20250207(0.01) ...