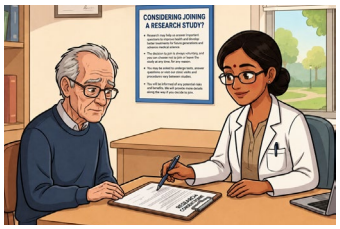
IRB Member Review of the Informed Consent Document (ICD) in PROTECT



Federal regulations for protection of human subjects relating to the consent document and process (45.CFR 46.116) require the following:

- Unless the IRB waives this requirement, an investigator must obtain legally effective informed consent from the prospective participant before involving the individual in research. This tip sheet also refers to the individual's legally authorized representative (LAR), if applicable.
- The prospective participant/LAR must be given the information a reasonable person would want before deciding whether to participate. They must also have a chance to discuss that information.
- Informed consent must begin with a concise, focused summary of the key information most likely to help a prospective participant understand why they may or may not want to participate in the research. This section must be organized in a way that supports understanding. The ICD must give adequate detail about the research and clearly explain the reasons a person may or may not want to participate, rather than simply listing separate facts.

When reviewing the consent form, IRB members should make sure information is accurate and clear so prospective participants can understand the study and freely decide whether to participate. The IRB should confirm that:

- The ICD matches the protocol and, when applicable, the Investigational Brochure (IB) or package insert.
- The level and complexity of information in the ICD are appropriate and are culturally sensitive.
- The key information section explains what is most important from the prospective participants' point of view.
- Required template language is included appropriately.
- Procedures are described accurately and in a way that is easy to comprehend.
- Risks are explained clearly and in understandable language. For example, in an interventional trial, does the risk section accurately describe the reasonably foreseeable risks listed in the IB, package insert, or device information?
- Any potential for direct benefit is described realistically.
- When applicable, payment or other incentives are described appropriately and do not create undue influence.
- The ICD does not contain exculpatory language. This means it must not waive, or appear to waive, the prospective participant's rights, or release, or appear to release, those conducting the study from liability for negligence.
- When minors are being enrolled, an age-appropriate assent form is used when applicable, and the information is presented in a way they can understand. Investigators should use the OHSRP assent template.

How do you propose edits to the consent/assent document(s) during your pre-meeting review?

- First, check the "Reviews" tab to see whether other members have already uploaded an edited consent as part of their review. If so, download the most recently uploaded version and make your changes in that same document.

Committee Member Review Comments

Person	Role	Notes	Checklists	Supporting docs	Date submitted
[redacted]	[redacted]econdary [redacted]eviewer	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
[redacted]		study is approvable, category 9. study involves deception. Suggested edits made to the consent; I used [redacted] and added edits to that version, attached. No other proposed stipulations.		IRB002341_Tracked_Consent_22Jan2025[redacted].docx	2/10/2025
[redacted]		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

- During your pre-meeting review, download the consent/assent documents and edit them using “tracked changes.”
- If the document needs a major rewrite, you may insert comments instead of rewriting the ICD for the investigator.
- Board members should not rewrite the proposed ICD based on personal preferences. Check that it uses plain language instead of unnecessary technical terms and is written at the recommended 6th-8th grade reading level. See instructions to check readability statistics in Microsoft Word and the OHSRP webpage on Consent Development, including Related Resources, for tips on making consent language easier to understand.
- After your review, upload the consent document(s) with tracked changes along with your review in PROTECT. (See screenshot below.) The IRB will review and discuss the combined suggested edits at the IRB meeting.