10-1. Informed Consent

Hide

10-1.1* All documents related to consent, assent, permission, and or debriefing documents, including oral scripts must be uploaded here. If you are requesting a waiver of documentation of informed consent, upload a copy of any written materials to be provided to participants, and provide a written description of any information to be provided orally.

+ Add

Name		Version
Adult Consent brief 7-29-2013(0.02)	•••	0.02

IRBMED studies: Edit the most recent ve of the clean informed consent document f in 10-1.1. **Use the Upload Revision butt stack the new tracked-changes docume on top of the tracked-changes stack.** Us the standard naming conventions for stack from the Statement of Practice on "Versior Control of Informed Consent Documents".

IRB-HSBS/Dearborn/Flint studies: Uploa "clean" version in 10-1.1; upload "tracked-changes" in 44.1. Click here for more deta

Please see important information about naming, editing, uploading, and downloadi documents. Upload consent documents in or .docx format. Please DO NOT delete previously uploaded documents: add a ma such as "X-NOT IN USE" to the file name any obsolete document.
See the Additional Help for links to templa and guidelines.

Additional Help

10-1.1.1* Does the Informed Consent use the sentences required for Applicable Clinical Trials: "A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."?

○ Yes ● No Clear

Note: This question is not asking whether is an Applicable Clinical Trial. It is asking whether the informed consent document d actually use these specific sentences. Guidance for whether or not to use these sentences appears in Section 9.2 of the Informed Consent Template Instructions o IRBMED website. It is also available on th Regulatory Affairs website, or by contactin the Office of Regulatory Affairs at UMMS-RegAffairs@med.umich.edu or by calling (1576.

10-1.2* Will the subjects be audiotaped, videotaped, or photographed (identifiable images of subject) during the research?

○ Yes ● No Clear

Note: If yes, any required informed conser document(s) and/or debriefing document(s must seek explicit permission (e.g., separa signature) to record the subjects and/or us the materials for the purpose of this resea

Additional Help

10-1.3* Is there a substantial likelihood that the research will be conducted among a non-English-speaking population?

● Yes ○ No Clear

Department of Health and Human Service regulations for the protection of human subjects require that informed consent information be presented "in language understandable to the subject" and, in mos situations, that informed consent be documented in writing.

For more information, see Obtaining and Documenting Informed Consent of Subjec Who Do Not Speak English on the OHRP website.

Additional Help

10-1.3.1* Identify the language(s) expected to be encountered:

+ Add

Language	Translation Detail
There are no items to display	

10-1.4* Indicate which anticipated costs could be the full or partial responsibility of the

Exit Save Continue

subject.

Check all that apply:

- [ ] Cost of routine health care that would be incurred for this condition if the subject were not participating in the research study
- [x] No anticipated costs
- [ ] Parking
- [ ] Travel
- [ ] Lodging
- [ ] Research-related services/procedures
- [ ] Research-related counseling
- [ ] Drugs, biologics, or devices
- [ ] Other

If other, please specify:

10-1.5* Is the study designed to collect identifiable information from primary research subjects about other individuals, including family members?

● Yes ○ No Clear

Third parties may become human subjects the course of a research study if identifiab private, information about them is obtainec the researcher. Guidance as to when rese involving private information is or is not 'research involving human subjects' is pro by the OHRP. When collecting identifiable information from primary research subject about other individuals, this guidance is us in determining whether or not those other individuals should provide their consent fo data collected about them.

Additional Help

10-1.6* At the conclusion of this study, will specimens and/or data be retained for future research use?

● Yes ○ No Clear

The Informed Consent Document(s) gover permissible future uses.

10-1.7* Does the informed consent document explicitly notify subjects that their data and/or specimens will be stored for future research?

○ Yes ● No Clear

10-1.8* Are subjects required to agree to retention of their data and/or specimens as a condition of participating in the research?

○ Yes ● No Clear

GENERALLY, subjects SHOULD be able t "opt-in/opt-out" of unspecified future use o data/biospecimens generated during a research study. OHRP views embedding f use of samples in a main study without giv subjects this option as coercive.