eResearch M REGULATORY MANAGEMENT SAND

Edit: Application - HUM00009240

Note *(0 Notes Total)*

Hide Help

10-1. Informed Consent

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	
Upload Revision	res_irbmed_waiver IC-auth.doc | History	0.01	Delete

IRBMED studies: Edit the most recent version of the clean informed consent document found in 10-1.1. Use the Upload Revision button to stack the new tracked-changes document on top of the tracked-changes stack. Use the standard naming conventions for stacks from the Statement of Practice on "Version Control of Informed Consent Documents".

IRB-HSBS, IRB Dearborn and IRB Flint studies: Upload "clean" version in 10-1.1; upload "tracked-changes" in 44.1. Click here for more detail.

Please see important information about naming, editing, uploading, and downloading documents. Upload consent documents in .doc or .docx format. Please DO NOT delete previously uploaded documents: add a marker such as "X-NOT IN USE" to the file name for any obsolete document.
See the Additional Help for links to templates 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 this is an Applicable Clinical Trial. It is asking whether the informed consent document does 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 on the IRBMED website. It is also available on the Regulatory Affairs website, or by contacting the Office of Regulatory Affairs at UMMS-RegAffairs@med.umich.edu or by calling 647-1576.

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 consent document(s) and/or debriefing document(s) must seek explicit permission (e.g., separate signature) to record the subjects and/or use the materials for the purpose of this research.

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 Services regulations for the protection of human subjects require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing.

For more information, see Obtaining and Documenting Informed Consent of Subjects

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

Additional Help

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 in the course of a research study if identifiable, private, information about them is obtained by the researcher. Guidance as to when research involving private information is or is not 'research involving human subjects' is provided by the OHRP. When collecting identifiable information from primary research subjects about other individuals, this guidance is useful in determining whether or not those other individuals should provide their consent for the 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) govern 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 to "opt-in/opt-out" of unspecified future use of data/biospecimens generated during a research study. OHRP views embedding future use of samples in a main study without giving subjects this option as coercive.

10-1.8.1* **Provide a justification for this requirement.** ***If the information is included in the attached protocol, please indicate section.***

because

Continue >>