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.

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<th>Name</th>
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<td>Adult Consent brief 7-29-2013(0.02)</td>
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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

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

- [ ] Yes
- [ ] No

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

- [ ] Yes
- [ ] No

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

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<th>Language</th>
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10-1.4* Indicate which anticipated costs could be the full or partial responsibility of the

Additional Help
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 used in determining whether or not those other individuals should provide their consent for data collected about them.

Additional Help

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

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.

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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
- No anticipated costs
- Parking
- Travel
- Lodging
- Research-related services/procedures
- Research-related counseling
- Drugs, biologics, or devices
- Other

If other, please specify:

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

- Yes
- No

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

- Yes
- No

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

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