# Consent Process

The informed consent process meets one of these sections or checklists

- Section 5: Consent Process
- Waiver or alteration of consent process (HRP-410)
- Permanently closed to enrollment

- The informed consent documentation meets one of these sections, worksheets, or checklists
- Section 6: Long Form
- Short Form (HRP-317)
- Waiver of documentation (HRP-411)
- Waiver or alteration of consent process (HRP-415)
- Permanently closed to enrollment

- The criteria in the corresponding checklist are met when the research involves: ("N/A" if none involved)
  - Pregnant Women (HRP-412)
  - Non-viable Neonates (HRP-413)
  - Uncertain Viability Neonates (HRP-414)
  - Cognitively Impaired Adults (HRP-417)

## Additional Considerations

- Does the research involve no more than Minimal Risk to subjects?
- Based on risk should review take place more often than annually? If so, specify period.
- Is verification needed from sources other than the investigator that no material changes have occurred since prior IRB review? (Implement when the veracity of the information provided is questioned.) ("N/A" if initial review)
- Is there information that needs to be provided to current or former subjects because it may affect their willingness to continue participation? ("N/A" if initial review)

Advertisements meet WORKSHEET: Advertisements (HRP-315) criteria ("N/A" if no advertisements)

Payments to subjects meet WORKSHEET: Payments (HRP-316) criteria ("N/A" if no payments)

## Primary Reviewer Criteria for Initial review

- The research has the resources necessary to protect subjects. (Time to conduct and complete, staff, facilities, subject population, and medical/psychosocial resources for subjects.) ("N/A" if not initial review)
- There are no inconsistencies between the DHHS grant and protocol. ("N/A" if there is no DHHS grant.)
- The plan for communication of information among sites is adequate to protect subjects. ("N/A" if not a multicenter trial, the investigator is not the lead, or not initial review)

## Consent Process

- The investigator will obtain the legally effective informed consent of the subject or LAR.
- Consent will be obtained only under circumstances that provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.
- Consent will be obtained only under circumstances that minimize the possibility of coercion or undue influence.
- Information to be given to the subject or LAR will be in language understandable to the subject or LAR.
- There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.
- Consent will disclose the elements in Section 7: Elements of Consent Disclosure

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**WORKSHEET:** Criteria for Approval and Additional Considerations

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### Required ("Starred elements can be omitted if there are none."

- **A statement that the study involves research.**
- **An explanation of the purposes of the research.**
- **An explanation of the expected duration of the subject's participation.**
- **A description of the procedures to be followed.**
- **Identification of any procedures, which are experimental.**
- **A description of any reasonably foreseeable risks or discomforts to the subject.**
- **A description of any benefits to the subject or to others, which may reasonably be expected from the research.**
- **A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.**
- **A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.**
- **An explanation of how to contact the research team for questions, concerns, or complaints about the research.**
- **An explanation of how to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.**
- **An explanation of whom to contact in the event of a research-related injury to the subject.**
- **A statement that participation is voluntary.**
- **A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.**
- **A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.**

### Required for Research Involving More than Minimal Risk

- **An explanation as to whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.**
- **An explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.**

### Required for Clinical Trials

- **The approval of the IRB.**
- **The probability for random assignment to each treatment.**
- **The subject's responsibilities**
- **When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.**
- **The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.**
- **When there is no intended clinical benefit to the subject, a statement to this effect.**
- **A statement that monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.**
- **If the results of the trial are published, the subject's identity will remain confidential.**

### Required for FDA-Regulated Research

- **A statement that notes the possibility that the Food and Drug Administration may inspect the records.**
- **The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.**
- **The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.**
- **For FDA-regulated non-Phase I controlled trials: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”**

### Additional: (Include when appropriate.)

- **A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.**
- **A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.**
- **Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.**
- **Any additional costs to the subject that may result from participation in the research.**
- **The consequences of a subject's decision to withdraw from the research.**
- **Procedures for orderly termination of participation by the subject.**
- **A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.**
- **The approximate number of subjects involved in the study.**
- **The amount and schedule of all payments.**