

# Motion Prompter

## Initial

- Level of Risk: Minimal Risk or Greater than minimal risk
- Motions: (1) Approve, (2) Approve with Modifications, (3) Defer, (4) Disapprove, (5) Table
- Period of Approval (1 Year or 6 Months)
- Criteria for Approval Met (yes/no)
  - Vulnerable Population Determinations: See Vulnerable Populations Info
  - Device Determination: Significant Risk or Non-significant Risk
  - Partial HIPAA Waiver for Recruitment Purposes Granted/Needed (yes/no)

## Continuing Review

- Level of Risk: Minimal Risk or Greater than minimal risk
- Motions: (1) Approve, (2) Approve with Modifications, (3) Defer, (4) Disapprove, (5) Table
- Period of Approval (1 Year; 6 Months)
- Criteria for Approval Met (yes/no)
- Vulnerable Populations: IRB determined there was no change to the previous vulnerable population determination(s)

## Modification

- Motions: (1) Approve, (2) Approve with Modifications, (3) Defer, (4) Disapprove, (5) Table
- No change to level of risk
- No change in review frequency
- Re-Consenting (or notification) recommendations:
  - Not Applicable-No ICF revision as part of the modification
  - Not required-ICF revisions present do not require already enrolled subjects to be re-consented
  - Not required, no local subjects currently enrolled- If no subjects are enrolled at time of modification submission. If subjects have been enrolled prior to IRB review then they should be re-consented
  - Required for all subjects on active treatment- ICF revisions present do require already enrolled subjects that are receiving active study interventions to be re-consented
  - Required for all subjects -ICF revisions present do require all already enrolled subjects to be re-consented
  - Accept the study teams specific re-consent plan
  - Notifying enrolled subjects without use of the consent form via other means to be specified by the convened IRB

## RNI's

- Motion: (1) Serious Non-Compliance; (2) Continuing Non-compliance; (3) Unanticipated Problem Involving Risks to Subjects or Others (4) Non-Compliance that is neither serious nor Continuing, (5) Defer, (6) Table
- If the convened IRB determines that the New Information does not meet any of the motions above then the IRB can acknowledge the New Information and investigator's action, if any. They can recommend additional actions including:

Actions to consider:

- Modify the protocol
- Modify the information disclosed during the consent process;
- Provide additional information to current subjects;
- Provide additional information to past subjects;
- Have current subjects re-consent
- Increase the frequency of continuing review
- Observe the research
- Observe the consent process
- Require additional training of the investigator
- Transfer subjects to another investigator
- Make arrangements for clinical care outside the research
- Allow continuation of some research activities under the supervision of an independent monitor
- Require follow-up of subjects for safety reasons
- Require adverse events or outcomes to be reported the IRB & Sponsor
- Obtain additional information
- Any review of additional communication to study participants and the date and manner for review of this communication should also be documented in the minutes and letter, where appropriate.
- Suspend or terminate IRB Approval

**Device Determination:**

**Significant Risk:** Intended as an implant and presents potential for serious risk to subjects or; Used for supporting or sustaining human life plus potential for serious risk to subjects or; Used to diagnose, cure, mitigate, or treat disease plus potential for serious risk to subjects or; otherwise presents potential for serious risk to subjects

**Non-Significant Risk:** Any device that does not meet the above definition of significant risk

## Pediatric Determinations:

- (1) CATEGORY 21 CFR §50.51/45 CFR §46.404: *(No greater than minimal risk)*
- (2) CATEGORY 21 CFR §50.52/45 CFR §46.405: *(Greater than minimal risk but presenting the prospect of direct benefit to individual subjects)*
- (3) CATEGORY 21 CFR §50.53/45 CFR §46.406 *(Involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition)*
- (4) CATEGORY 21 CFR §50.54/45 CFR §46.407 *(Not otherwise approval that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Must have opportunity for public review and comment)*
  
- **Adequate provisions for Soliciting the Permission of Parents or Guardians:**
  - (1) Permission is to be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
  - (2) Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. **(Cannot be selected for 21 CFR §50.53, 54/45 CFR §46.406, 407)**
  - (3) Parental permission is waived under 45 CFR §46.116(c).
  - (4) Parental permission is waived under 45 CFR §46.116(d).
  - (5) Parental permission is waived under 45 CFR §46.408(c).
  
- **Assent will be obtained from:**
  - (1) All Children
  - (2) None of the children
  - (3) Some of the Children
    - Reason Why Assent is Not Necessary *(One or more may be true, note all that are applicable):*
      - (1) The capability of these children is so limited that they cannot reasonably be consulted
      - (2) The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research
      - (3) Assent is waived under 45 CFR 46.116(d)
      - (4) Assent is waived under 45 CFR 46.116/21 CFR 50.55(c)
  
- **Documentation of Assent:**
  - (1) Investigator will document assent in the consent signature block
  - (2) Other – the application needs to describe the process of assent documentation

## **Pregnant Women/Fetus Determination (Subpart B):**

### Minimal Risk Research

The research is no more than minimal risk to pregnant women and fetuses

### Greater than Minimal Risk Research (46.204)

Confirm the following are met:

- Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.
- The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; OR, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- Any risk is the least possible for achieving the objectives of the research;
- If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent regulations
- If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent regulations, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- For children who are pregnant, assent and permission are obtained per the regulations in subpart D
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- Individuals engaged in the research will have no part in determining the viability of a neonate.

## **Cognitively Impaired Adults**

### Greater than Minimal Risk Research with Direct Benefit

Confirm the following are met:

- Risks to subjects are reasonable in relation to anticipated benefits to subjects.
- The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
- Subjects will be particularly closely monitored.
- Subjects will be withdrawn if they appear to be unduly distressed.
- The subject will be informed about the research to the extent compatible with the subject's understanding (i.e., assent), if applicable.

### Greater than Minimal Risk Research without Direct Benefit

Confirm the following are met:

- A review of the objectives of the trial cannot be met by means of study of subjects who can give consent personally.
- How the negative impact on the subjects well-being is minimized to the extent possible.
- Subjects will be particularly closely monitored.
- Subjects will be withdrawn if they appear to be unduly distressed.
- The proposed plan for the assessment of the capacity to consent is adequate.
- The subject will be informed about the research to the extent compatible with the subject's understanding. (i.e., assent), if applicable.
- Additional protections based on the complexity of the study and risk level, such as appointment of a patient advocate, an assessment by an independent assessor, observation of the consent process, or review by an expert consultant.

**Assent determination must be made for both categories above/Assent will be obtained from:**

- (1) All Adults
- (2) Adults with the cognitive capacity to consent
- (3) None of the Adults (if this is selected – study team should provide the reason why assent is not able to be obtained)

**Documentation of Assent:**

- (1) Investigator will document assent in the consent signature block
- (2) Other – the application needs to describe the process of assent documentation