Please refer to this checklist as necessary when reviewing amendments and revisions.. A list of the required and additional elements of informed consent is included. There is a one page summary form to be filled out with your comments based on these guidelines.

The reviewer is expected to have the scientific or scholarly expertise, the representational experience, knowledge of the local context, and other expertise needed to review this research. (If you do not feel you have this expertise please ask for additional consultation or ask for review by another IRB member)

If Amendment proposes changes that impact risks and benefits you need to be sure that:

Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

- *Consider physical, psychological, social, legal, and economic risks.*
- *Has the appropriate departmental scientific review occurred?*
- *Are the aims and objectives clearly defined?*
- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*
- *Are medical or psychological resources available that participants might require as a consequence of the research?*
- Are adequate references provided

Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

- *Consider physical, psychological, social, legal, and economic risks.*
- *Are procedures that will answer the scientific question being performed anyway?*
- *If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm?*
- *Is there a clear differentiation between research and standard of care procedures*

Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

- *Consider physical, psychological, social, legal, and economic risks. Are the risks and benefits adequately described?*
- *Does the investigator have access to a population that will allow recruitment of the necessary number of participants?*
- *Does the investigator have sufficient time to conduct and complete the research?*
- *Is the research and timeline for completion feasible?*
- *Does the knowledge expected to result have importance?*
- *Are there adequate plans to notify the subjects about the research results (clinical issues, suicidal, referrals*

If Amendment proposes changes that impact eligibility/exclusion or recruitment procedures you need to be sure that:

Selection of participants is equitable.

- Consider the purpose of the research.
- Are the inclusion and exclusion criteria adequately defined and equitable?
- Are there populations vulnerable to coercion and undue influence and has this been addressed?
- Are there acceptable procedures for screening subjects prior to recruitment?
- If there is exclusion of women, minorities, and other vulnerable populations are they justified

Recruitment procedures are appropriate

- Are the setting, location and timing of recruitment appropriate for the research being conducted?
- Are recruitment methods well defined and appropriate for the population?
- Are all recruitment materials non coercive, and easily understood

If Amendment proposes changes that impact how the research and data are collected , analyzed or monitored you need to be sure that:

The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants. *(Not applicable if the research involves no more than minimal risk.)*

- *Does the protocol adequately specify:*
  Who will monitor the data?
  What data will be monitored?
  How frequently will data be monitored?
  What analyses will be performed on the data?
  What decision rules (e.g., stopping rules) will be considered?
- *Is there a plan to promptly detect unexpected harms or an increase in frequency or severity of harms?*
- *Is there an adequate plan to stop the protocol if benefits are proven to outweigh harms or harms are proven to outweigh benefits*

If Amendment proposes changes that impact respect for privacy and maintenance of confidentiality you need to be sure that:

There are adequate provisions to protect the privacy of participants.

- *Will participants have an expectation of privacy?*
- *Will participants think that the information sought is by the investigator is appropriate?*
- *Will participants be comfortable in the research setting?*
- *Are there adequate provisions to consider and assure the privacy of the subject*?

There are adequate provisions to maintain the confidentiality of the data.

- Will confidentiality be pledged?
- Are there adequate provisions to protect the confidentiality of the data?
- Are there legal/ethical requirements to breach confidentiality and is this well described and addressed?
- Will data release cause risk of harm?

- Are appropriate techniques being used to protect confidentiality (storage, coding, use of identifiers)
- Does the protocol and consent specify where the data and consent form will be stored?

Other considerations

If this is multi-site research, is the management of information that might be relevant to the protection of subjects still adequate

If Amendment proposes changes that impact involvement of vulnerable subjects you need to be sure that:

- **Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence.**

- **If the research/amendment involves pregnant women, fetuses, please review the *Research Involving Pregnant Women and Fetuses* OR *Research Involving Neonates* checklist.**

- **If the amendment/research involves prisoners review Research *Involving Prisoners* checklist.**
- **If the amendment/ research involves children review section of new protocol reviewer worksheet that addresses determinations *for Children*.**
- **If the research involves other vulnerable populations, please make sure additional safeguards remain appropriate**.

If the Amendment proposes changes that impact informed consent you need to be sure that:

The investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.

- *Has the investigator indicated whether consent will be obtained from the participant, from a legally authorized representative, or both?*
- *Are steps taken to help the participants or representatives understand the facts?*
- *Are adequate steps taken to help the participants or representatives understand the research and associated ramifications?*
- *Does the investigator adequately address how he/she will determine that a subject understands the research prior to providing consent/assent?*

The circumstances of consent provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.

- *Is adequate time devoted to the consent discussion and decision making process?*
- *Do the circumstances of consent minimize the possibility of coercion or undue influence?*
- *Have all issues regarding the capacity to make a decision been addressed*

The circumstances of consent minimize the possibility of coercion or undue influence.

- *Are consent procedures well defined?*
- *Are there excessive motivating factors?*
- *Are the timing, location and setting of obtaining consent acceptable?*
- *Are payment arrangements acceptable?*
- *Will parents and children be compensated and if so is the amount fair and distributed appropriately between parent and child?*
- *If study procedures are not complete or a subject withdraws is there any pro-rating of compensation*?
- *Are there plans so families avoid out of pocket expenses in order to participate*

The information that will be given to the participant or the representative will be in language understandable to the participant or the representative.

- *What language do the participants or representatives speak?*
- *Can the research team communicate in understandable language to the participants or representatives*?
- *Will written information be in the language understandable to the participants or representatives*

No information will be provided to the participant or the representative that waives or appears to waive any of the participant's legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

All required and appropriate additional disclosures will be provided to the participant or the participant's Representative.

The consent document embodies the basic and appropriate additional elements of disclosure. *(See Elements of Informed Consent Disclosure)*

The participant or the participant's legally authorized representative will sign (and date for FDA-regulated research) the consent document.

A copy of the consent document will be given to the person signing the consent document.

The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed

If the Amendment proposes a new or changes a alteration or wavier of consent process:

One of the criteria must be met:

- The consent form would be the only record linking the subject with the research, and a potential risk would be a breach in confidentiality. In such case, each subject should be asked if they want documentation and their wishes would govern (**cannot apply to FDA regulated research)**

or

- Study is no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

And the following apply to both sets of waiver criteria

- If informed consent documentation is waived, consider whether subjects should be provided with a written statement regarding the research?
- If written statement is required, is the statement appropriate and can it be approved?

If the Amendment involves a new or change in waiver of written documentation, the following criteria need to be met:

- The research involves no more than minimal risk to the subjects
- The waiver/alternation will not adversely affect the rights and welfare of the subjects
- The research could not practicably be carried out without the waiver or alteration, and
- When appropriate, the subject will be provided with pertinent information after participation.
- The research is not FDA-regulated.

If the Amendment involves a new or change to a short form of consent:

- The consent document states that the elements of disclosure required by regulations had been presented orally to the participant or the participant's legally authorized representative.
- A written summary embodies the basic and appropriate additional elements of disclosure.
- There will be a witness to the oral presentation.
- For participants who do not speak English, the witness is conversant in both English and the language of the participant.
- The participant or the participant's legally authorized representative will sign (and date for FDA-regulated research) the consent document.
- The witness will sign both the short form and a copy of the summary.
- The person actually obtaining consent will sign a copy of the summary.
- A copy of the short form will be given to the participant or the representative
- A copy of the summary will be given to the participant or the representative

Other considerations for amendments and revisions:

- If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?

Informed Consent Document

The following are the required and additional elements of consent, please refer to this list as necessary to make sure all elements are still appropriately addressed

- ❑ A statement that the study involves research.
- ❑ An explanation of the purposes of the research.
- ❑ An explanation of the expected duration of the participant's participation.
- ❑ A description of the procedures to be followed.
- ❑ Identification of any procedures that are experimental. *(May be omitted if there are none.)*
- ❑ A description of any reasonably foreseeable risks or discomforts to the participant. *(May be omitted if there are none.)*
- ❑ A description of any benefits to the participant or to others, which may reasonably be expected from the research. *(May be omitted if there are none.)*
- ❑ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. *(May be omitted if there are none.)*
- ❑ A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. *(May be omitted if confidentiality will not be maintained.)*
- ❑ A statement that notes the possibility that the Food and Drug Administration may inspect the records. *(May be omitted for research that is not FDA-regulated.)*
- ❑ An explanation as to whether compensation is available if injury occurs. *(May be omitted if the research involves no more than minimal risk.)*
- ❑ If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. *(May be omitted if the research involves no more than minimal risk.)*
- ❑ An explanation as to whether any medical treatments are available if injury occurs. *(May be omitted if the research involves no more than minimal risk.)*
- ❑ If medical treatments are available when injury occurs, an explanation as to what it consists of or where further information may be obtained. *(May be omitted if the research involves no more than minimal risk.)*
- ❑ An explanation of whom to contact for answers to pertinent questions about the research.
- ❑ An explanation of whom to contact for answers to pertinent questions about the research participants' rights.
- ❑ An explanation of whom to contact in the event of a research-related injury to the participant. *(Note: May not be omitted just because the research involves no more than minimal risk.)*
- ❑ A statement that participation is voluntary.
- ❑ A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- ❑ A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Additional

- ❑ A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. (*Look for when research involves investigational drugs/devices, novel procedures involving risk, or where a goal of the research is to define safety.)*
- ❑ A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. (*Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.)*
- ❑ Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. (*Look for when the protocol mentions this as a possibility.)*
- ❑ Any additional costs to the participant that may result from participation in the research. (*Look for when additional costs are expected.)*
- ❑ The consequences of a participant's decision to withdraw from the research. (*Look for when withdrawal from the research will have adverse consequence.)*
- ❑ Procedures for orderly termination of participation by the participant. (*Look for when such procedures are part of the protocol.)*
- ❑ A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. (*Look for on long-term clinical trials.)*
- ❑ The approximate number of participants involved in the study.

Other

- ❑ No statements similar to "Compensation will not be provided."
- ❑ No signature line for legally authorized representative or parent, when the research is not approved for cognitively impaired adults or children.