IRB Reviewers 8-Point Analysis Form
Reviewer's Additional 6-Point Analysis Form for Children
Based on Federal Policy for the Protection of Human Subjects,
Criteria for IRB Approval of Research (45 CFR 46.111)

Protocol ID #/Title:

Date of Review:

IRB Reviewer:

(Type inside gray boxes, cells will expand)

Instructions: The criteria for reviewing research involving children are listed below in Parts A, B, and C. Please complete all sections.

A. EIGHT POINT CRITERIA for IRB Review

In accordance with 45 CFR 46.111, the protocol must meet the following IRB approval criteria:

1. Risk Identification and Minimization (physical, psychological, social, economic, legal)

- **Are risks to subjects minimized by (i) the use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and (ii), whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes?**

☐ **Yes** ☐ **No**

Comments: (cell will expand)

2. Risk /Benefit Assessment

- **Are risks to subjects reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result from the study?**

☐ **Yes** ☐ **No**

Comments: (cell will expand)

3. Equitable Selection of Subjects

- **Is the selection of the subjects equitable, taking into account the purposes of the research and the setting in which the research will be conducted?**

☐ **Yes** ☐ **No**

Comments: (cell will expand)

4. Obtaining Informed Consent

- **Informed consent is sought from each prospective subject or subject's legal representative in accordance with and to the extent required by the Federal Policy.**

Place a checkmark in front of each of the following elements appropriately expressed in each submitted ICF:

☐ **Explanation of the purposes of the research, expected duration of the subject's participation, and description of procedures to be followed**

☐ **Description of any reasonably foreseeable risks or discomforts to the subject**

☐ **Description of any benefits to subject or others which may reasonably be expected**

☐ **Disclosure of appropriate alternative procedures or courses of treatment (for bio-medical research)**

☐ **Statement describing how confidentiality of records identifying subject will be maintained**

☐ **Contact information regarding questions about the research (PI) and about rights (IRB Chair)**

☐ **Statement of voluntary participation**

☐ **If a survey instrument contains questions that individuals might find invasive, subjects must be forewarned. Studies about sexual behavior, childhood abuse, use of psychotropic medications, and other personal topics should include a disclosure in the consent form about the nature of the questions**

- **If you find that the project presents greater than minimal risk to subjects, then additional elements would be applicable in concert with full board review.**

Comments:

- **Does the protocol request alteration to or waiver of informed consent?**
  ☐ **Yes** ☐ **No**

If yes, the request is accompanied by information documenting consistency with conditions required by the federal regulations.

Place a checkmark before each condition documented in the protocol:

☐ **The research is designed to study, examine or evaluate a public benefit or service program; focuses on procedures for obtaining benefits or services, changes or alternatives to programs or changes to or procedures for methods or levels of payment for benefits or services; and, is conducted by or subject to the approval of state or local government officials.**

☐ **The research involves no more than minimal risk to subjects.**

☐ **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

☐ **The research could not practicably be carried out without the waiver or alteration.**

☐ **Whenever appropriate, the subjects will be provided with additional pertinent information after participation.**

Comments:

- **The informed consent requirements of the Federal Policy are not intended to preempt any applicable Federal, State or local laws. Does the protocol raise any issues about other matters that might need to be disclosed in order for informed consent to be legally effective?**

☐ **Yes** ☐ **No**

Comments: (cell will expand)

5. Appropriate Documentation of Informed Consent

- **Will the informed consent be appropriately documented by the use of a written consent form approved by the IRB and signed by the subject or subject's legally authorized representative?**

☐ **Yes** ☐ **No**

Comments: (cell will expand)

- **Will a copy of the informed consent be provided to the person signing the form?**

☐ **Yes** ☐ **No**

Comments: (cell will expand)

- **Does the protocol raise any concerns about how, when and by whom the informed consent will be administered?** ☐ **Yes** ☐ **No**

Comments: (cell will expand)

6. Data Monitoring

- **Where appropriate, does the research protocol make adequate provisions for monitoring the data collected to ensure the safety of participating subjects?**

☐ **Yes** ☐ **No**

Comments: (cell will expand)

7. Privacy of Subjects and Confidentiality of Data

- **Are there adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data?**

☐ **Yes** ☐ **No**

Comments: (cell will expand)

8. Vulnerability to Coercion or Undue Influence

- **Where subjects are likely to be vulnerable to coercion or undue influence, have additional safeguards been included to protect the rights and welfare of those subjects?**

☐ **Yes** ☐ **No**

Comments: (cell will expand)

B. Additional Protections Criteria for Research Involving Children

Definition: Children are persons who have attained the legal age (often 18) to give consent to treatments or procedures under the applicable law of the jurisdiction in which the research will be conducted. The Secretary pf DHHS has set 18 as the age of adulthidd in the absence of other guidelines.

Please identify the applicable category of the research involving children and determine whether the special criteria have been met.

☐ **Category 1: Minimal Risk:** The risks of harm to children anticipated in the proposed research are no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

If the research involves only minimal risks, please determine the following:

1. Does the project make adequate provisions for soliciting both Child Assent from the minors (taking into account the ages, maturity and psychological state of the children involved) and parental consent?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

2. Are the Child Assent and Parental Consent forms written at the appropriate reading level (*i.e.* 6th-8th grade for parents, and age appropriate for children)?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

☐ **Category 2: Greater than Minimal Risk with Direct Benefits:** The research involves a procedure or intervention that presents greater than minimal risk to children, but the research offers the prospect of direct benefit to the individual participants, or involves a monitoring procedure that is likely to contribute to the participant's well being.

If the research involves greater than minimal risk, but offers the prospect of direct benefit(s) to the individual, please determine the following:

1. Is the risk justified by the anticipated benefits to the participant?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

2. Is the relation of the anticipated benefit to the risk at least as favorable as that presented by currently available alternative approaches?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

3. Does the project make adequate provisions for soliciting both Child Assent from the minors (taking into account the ages, maturity and psychological state of the children involved) and parental consent?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

4. Are the Child Assent and Parental Consent forms written at the appropriate reading level (*i.e.* 6th-8th grade for parents, and age appropriate for children)?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

☐ **Category 3: Greater than Minimal Risk with No Direct Benefits:** The research involves a procedure or intervention that presents greater than minimal risk to children, and offers no direct benefit(s) to the individual participants, or involves a monitoring procedure that is not likely to contribute to the participant's well being, but the research is likely to yield generalizable knowledge about the participant's disorder or condition.

If the research involves greater than minimal risk and no prospect of direct benefit(s) to the individual but is likely to yield generalizable knowledge about the particinpant's disorder or condition, please determine the following:

1. Does the risk represent only a minor increase over minimal risk?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

2. Does the intervention or procedure present experiences to the child participants that are reasonably commensurate with those inherent in actual medical, dental, psychological, social or educational situations?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

3. Is the intervention procedure likely to yield generalizable knowledge about the child participants' disorder or condition or information which is of vital importance for understanding or ameliorating the disorder or condition?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

4. Does the project make adequate provisions for soliciting both Child Assent from the minors (taking into account the ages, maturity and psychological state of the children involved) and parental consent?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

5. Are the Child Assent and Parental Consent forms written at the appropriate reading level (*i.e.* 6th-8th grade for parents, and age appropriate for children)?

☐ **Yes** ☐ **No**

Comments: (cell will expand)

☐ **Category 4: Research not Otherwise Approvable:** Research that does not fall within one of the above categories cannot be approved by the IRB.

Comments: (cell will expand)

C. Final Recommendation

In accordance with USM Policies and Procedures for Human Subject Research and federal regulations for human research protections, I have reviewed this protocol using an expedited review procedure; I recommend

Protocol Approved: ☐

Protocol Approved with Changes: ☐

Changes required:

Modifications and Further Review: before Approval: ☐

My specific recommendations for required modifications and/or clarifications are:

Recommend Full Board Review ☐

Justification for recommendation:

Not Approved: ☐

Additional Comments: