Section D. Research Involving Minors Under 18

The IRB is required to consider the benefits, risks and discomforts of the research and assess the justification for minor's participation in light of the benefits to the minor or to society as a whole. In calculating the risks and benefits, the IRB must consider the circumstances of the minors under study, the magnitude of risks or discomforts that may result from participating in the research, and the potential benefits the research may provide to the minor or to other minors with the same disease or condition.

"Minimal risk" is defined as a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations or tests. Please complete "Section C - Minimal Risk Eligibility Checklist".

I. Risks and Benefits to Minors

Does the proposed research pose no greater than minimal risk? ◯ **Yes** ◯ **No**

If "YES," complete Item 1 below. If "NO," begin with Item 2.

1. Explain how this protocol poses no more than minimal risk and indicate the category number from "Section C - Minimal Risk Eligibility Checklist" into which this research falls.

STOP HERE AND GO TO PAGE 3 IF YOUR RESEARCH POSES NO GREATER THAN MINIMAL RISK.

2. If this research poses greater than minimal risk, please explain the nature of the risks.

Does the proposed research offer potential benefits to subjects? ◯ **Yes** ◯ **No**

If "YES," complete Items 3 and 4 below. If "NO," go to Item 5.

3. If the research poses greater than minimal risk, explain how the potential benefits to the subjects themselves might outweigh the risks. If the benefits to the subjects do not outweigh the risks, complete #5 on the next page.

4. If the research poses greater than minimal risk, explain how the benefit-to-risk assessment at least as favorable as that presented by alternative approaches.

Complete the items below if the proposed research poses (a) greater than minimal risk to subjects and (b) no potential for direct benefit to subjects

5. Is the proposed research likely to yield generalizable knowledge about the subjects' conditions? ◯ **Yes** ◯ **No**
   If yes, please explain the nature of the potential benefits in the box below.

6. How is the risk of the protocol an increase over minimal risk?

7. How does the procedure present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected situations?

8. How is the knowledge to be gained of vital importance for the understanding or amelioration of the condition?

OBTAINING PARENTAL PERMISSION AND ASSENT OF MINORS

Unless a waiver is granted, parental permission must be obtained.

Is a waiver of parental permission requested? ◯ Yes ◯ No

If "yes," please complete Section F – Consent Waiver Form
If "no," please complete the "Parental Permission" item below.

PARENTAL PERMISSION

Describe procedures that will be used to obtain permission from parents including (a) how and where permission will be obtained (b) who will obtain the permission, and (c) how the parents' informed consent will be documented.

Note the following:

- The parental permission form must be attached to this document.
- If the proposed research poses a greater than minimal risk with no potential for direct benefit to the children, then permission from BOTH parents is required.

ASSENT OF MINOR

Adequate provisions must be made for soliciting the assent of children when in the judgment of the IRB the children are capable of providing assent and for soliciting the permission of their parents or guardians.

Is a waiver of child assent requested? ◯ Yes ◯ No

If "yes," please complete Item 1 below.
If "no," please complete Items 1 and 2 below.

1. Please indicate whether all, some, or none the children you will study are generally capable of providing assent. Evaluate age, maturity and psychological state of the minors involved.

2. Describe procedures that will be used to obtain assent from the subjects including (a) how and where assent will be obtained (b) who will obtain the assent, and (c) how the subjects' informed consent will be documented.
