Cleveland Clinic Akron General

FOR IRRB USE ONLY
IRRB Number:_____
IRRB Reviewer:_____
☐ Exempt ☐ Expedited ☐ Full

Institutional Research Review Board Akron General Medical Center
Research Involving Children and Minors

Please type all of the required information. HAND WRITTEN FORMS WILL NOT BE ACCEPTED. Submit the completed form with all required attachments to the Institutional Research Review Board (IRRB) IRRB@akrongeneral.org. Questions regarding IRRB submissions can be directed to (330) 344-6947, or by emailing IRRB@akrongeneral.org.

Project Title:

I. CHILDREN SUBJECT POPULATION

A. Age range (Check all that apply)

☐ Newborn to 2 years of age
☐ 3-6 years
☐ 7-12 years
☐ 13-15 years
☐ 16-17 years

B. Identify the federally-defined category for this research and justify the rational for inclusion of children in this category.

☐ **45 CFR 46.404** (FDA 21 CFR 50.51)

- Research involves no greater than minimal risk to children, and
- Adequate provisions are made for soliciting assent of the child and permission of the parent/guardian

Please explain why the research involves no more than minimal risk.

Please explain how assent from the child and permission of the parent/guardian will be obtained.

☐ **45 CFR 46.405** (FDA 21 CFR 50.52)

- Research involves greater than minimal risk to children, but
- Presents the prospect of direct benefit to the child, and
- Anticipated benefit justifies the risk, and
- Anticipated benefit versus the risk is at least as favorable as that of alternative approaches, and
- Adequate provisions are made for soliciting assent of the child and permission of the parent/guardian

Please explain why the anticipated benefit justifies the risk.

Please explain why the anticipated benefit versus the risk is at least as favorable as that of an alternative approach.

Please explain how assent from the child and permission of the parent/guardian will be obtained.

☐ **45 CFR 46.506** (FDA 21 CFR 50.53)

- Research provides greater than minimal risk to children, and
- Presents no prospect of direct benefit to the child, but
- The risk represents a minor increase over minimal risk, and
- Interventions and procedures present interventions that are reasonably commensurate with those inherent in the child's actual or expected medical, dental, psychological, social, or educational situations, and
- Interventions and procedures are likely to yield generalizable knowledge about the child's disorder or condition that is of vital importance for the understanding or amelioration of the child's disorder or condition, and
- Adequate provisions are made for obtaining assent from the child and permission of both parents or guardian.

Please explain why the risk represents a minor increase over minimal risk.

Compare the actual or expected experiences of the child with those due to the research intervention.

Please explain why the research is likely to yield generalizable knowledge about the child's condition that is of vital importance for understanding or amelioration of the disorder.

Please explain how assent from the child and permission of both parents (unless deceased, incompetent, unknown, reasonably unavailable, or only one parent has guardianship of the child) or from one legal guardian will be obtained.

☐ **45 CFR 46.507** (FDA 21 CFR 50.54)

- Research not otherwise approvable under one of the above categories, but
- Presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, and
- Adequate provisions are made for obtaining assent from the child and permission of both parents or guardian

Please explain why the research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Please explain how assent from the child and permission of both parents (unless deceased, incompetent, unknown, reasonably unavailable, or only one parent has guardianship of the child) or from one eligible legal guardian will be obtained.

II. RE-CONSENT PROCESS FOR MINORS WHO BECOME ADULTS DURING THE STUDY

Will any of the children reach the age of consent (18 years) during the course of the study?

☐ Yes ☐ No

If 'yes', explain how these subjects will be identified and informed consent will be obtained.