

**GREENVILLE HOSPITAL SYSTEM  
INSTITUTIONAL REVIEW COMMITTEE  
PEDIATRIC RISK GRADING FORM**

For IRC Use Only

Title (*Do not exceed space provided*):

Principal Investigator: \_\_\_\_\_

**TYPE OF SUBMISSION – Please check only one box.**

<input type="checkbox"/> <i>CFR 46.404 Research not involving greater than minimal risk</i>	A) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
<input type="checkbox"/> <i>CFR 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects</i>	A) The risk is justified by the anticipated benefit to the subjects. B) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. C) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
<input type="checkbox"/> <i>CFR 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.</i>	A) The risk presents a minor increase over minimal risk. B) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations. C) The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition. D) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
<input type="checkbox"/> <i>CFR 46.407 Research not otherwise approvable which present any opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children</i>	A) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. B) The Secretary (of DHHS), after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: 1) That the research in fact satisfied the conditions of 46.404, 46.405 or 46.406, or 2) The following: i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. ii) The research will be conducted in accordance with sound ethical principles. iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

\_\_\_\_\_  
Typed Name of Investigator

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date