GUIDELINES FOR SCIENTIFIC REVIEW OF A RESEARCH PROTOCOL

PLEASE USE THIS GUIDE TO PREPARE YOUR REVIEW:

1. Briefly summarize the research study.

2. Express a definite opinion (yes or no) as to whether the research strategy is appropriate, taking into consideration the selection and recruitment of subjects and current standards of care. Will the study lead to an answer to the questions posed in the hypothesis? A project which is unlikely to achieve useful data must not be approved simply because physical harm is unlikely to occur to the subject.

3. Express an opinion whether the risks are minor or substantial and whether they are justified by the objectives of the project.

   For studies that involve children please mark the appropriate box and return this sheet along with your review:

	Research/Clinical investigations not involving greater than minimal risk. Permission of at least one parent is required. (§ 46.404, § 50.51)
	Research/Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. Permission of at least one parent is required. (§ 46.405, § 50.52)
	Research/Clinical investigations 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. Permission of both parents is required. (§ 46.406, § 50.53)
	Research/Clinical Investigations that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children. (§ 46.407, § 50.54)

4. Give recommendations for change. These may be major or minor. Frequently, investigators find this helpful and may re-design protocols, make changes to procedures and methods or re-word consent documents.

5. Give an overall opinion or recommendation. Express an opinion whether you would approve the study as written, approve the study with changes and/or clarifications as requested in the review, or not approve the study. **If you would like to review the changes submitted to the IRB by the investigator in response to your review, please state this.**