**Instructions: To justify the inclusion of human subjects in research, and to assess the balance between any risks that may be imposed upon human subjects, an assessment is required to evaluate the scientific question and appropriateness of the methods planned to answer the scientific question. Attestation from a Scientific/Scholarly Reviewer is required upon IRB submission. This completed form should be uploaded to eIRB as an “Institutional Approval.”**

|  |
| --- |
| **Protocol Title:** |
| **Principal Investigator Name:** |
| **Scientific/Scholarly Review (please select ONE):**  Nationally based, federally funded organization (i.e., NIH, NSF) subject to full peer review  **\*No signature required for Scientific/Scholarly Review**  Nationally based, non-federally funded organization (i.e., March of Dimes, American Academy of Pediatrics) subject to peer review  **\*No signature required for Scientific/Scholarly Review**  Locally constituted peer review  **\*Signature required on this form unless UACC SRC approval applies** |
| **If Locally Constituted Peer Review, Reviewer Name:** |

**Locally Constituted Peer Review Attestation**

When a locally constituted peer review is required, the local scientific/scholarly reviewer should consider the following:

* Is the rationale for the study clearly stated and is the rationale scientifically sound?
* Are the aims and corresponding hypothesis clearly stated?
* Is the primary outcome (and secondary outcomes, as appropriate) clearly defined?
* Are there adequate preliminary data in the literature (or from the investigator) to justify the proposed research?
* Has an adequate literature review been done to support this study?
* Is the question or hypothesis being tested providing important knowledge to the field?
* Is the design of the study appropriate for the questions that are posed?
* Have the validity and reliability of measures been established or are there methods proposed for establishing validity and reliability?
* Is the proposed subject population appropriate?
* Are statistical considerations, including sample size and justification, estimated accrual and duration, and statistical analysis clearly described and adequate to meet the study objectives?
* Are all the proposed tests or measurements requested necessary to answer the scientific question?
* Are the investigators well qualified to conduct this study?
* Is the proposed research novel and new?

I am the local scientific/scholarly reviewer for this protocol. By my signature, I certify that I have reviewed the protocol and believe that it is scientifically sound. Furthermore, I believe that risks are adequately balanced, and the scientific question(s) and methods are appropriate.

