ATTACHMENT 2: APPLICATION FOR PHERRB REVIEW

Date (DD/MM/YYYY):	
Name and Address of Institution:	
Lead Principal Investigator: **Work Phone:** **Work E-mail:**	**Work Address:**
Title of Protocol:	
List Study Co-investigators and key personnel, including any contractors engaged in the research: **1.** **2.** **3.** **4.** **5.**	
Do all investigators and key research personnel have current human subject protections training? **Yes** ☐ **No** ☐	

PROJECT DESCRIPTION

List five keywords that describe your project:

1.

2.

3.

4.

5.

Has scientific review taken place for this protocol? Yes ☐ No ☐

If yes, what institution was responsible for the scientific review and when did it occur? Please attach documentation of scientific review.

Has funding been secured for this protocol? Yes ☐ No ☐
If yes, what is the funding source(s) or sponsor?

What is your risk assessment of the entire protocol?

Minimal risk ☐ Minor increase over minimal risk ☐ Greater than minimal risk ☐

Please list study sites where research will be performed:

When will the study commence?

Primary aims of study:

Secondary aims:

Briefly describe the scientific rationale for the study (500 words or less):

Briefly describe the proposed research design (750 words or less):

Will this Study use any FDA regulated drug/biologic or device?
Yes ☐ No ☐

If yes, has an application for an IND/IDE been submitted to FDA? Yes ☐ No ☐

If yes, provide any additional details if applicable, such as IND/IDE number.

List participating pharmaceutical, biologic or device manufacturing companies (if any):

Subject selection criteria:

Inclusion Criteria -

Exclusion Criteria -

Proposed number of subjects to be enrolled:

Indicate if any of the following vulnerable populations will be included:

- ☐ **Children**
- ☐ **Pregnant Women, Neonates, Human Fetuses**
- ☐ **Cognitively Impaired**
- ☐ **Prisoners**

Please describe the informed consent process (500 words or less).

What other committee approvals will be required by your institution? (e.g., radiation safety, pharmacy)

Institutional Signatory Official
(Name and Title)

Work Address:

Work Phone:

Work E-mail:

Please attach curriculum vitae of PI and all co-investigators.

Please e-mail the completed application and attachments to PHERRB@mail.NIH.gov

Please call the NIH Office of Human Subjects Research Protections (OHSRP) with any questions at 301-402-3444.

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx*). Do not return the completed form to this address.