**ATTACHMENT 2: APPLICATION FOR PHERRB REVIEW**

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| **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** [ ]  |

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| **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.