

**ATTACHMENT 1: 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 <input type="checkbox"/> No <input type="checkbox"/>	

Collection of this information is authorized under 42 U.S.C. 241. The primary use of this information is to determine the eligibility of your protocol for review by the Public Health Emergency Research Review Board (PHERRB). The PHERRB is a network of National Institute of Health (NIH) Institute/Center (IC) Institutional Review Boards (IRBs) that conducts human subjects research protections review of public health emergency protocols. The NIH Office of Human Subjects Research Protections (OHSRP) reviews and summarizes the information you provide about the research project and the investigators' qualifications as part of the evaluation of the PHEP-PSA. The information you provide may be disclosed to those who will determine the eligibility of your research project or review your application (i.e., OHSRP Staff, Deputy Director for Intramural Research). Submission of this information is voluntary. However, in order for us to evaluate your application, you should complete all fields.

Public reporting burden for this collection of information is estimated to average 180 minutes 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 (XXXX-XXXX). Do not return the completed form to this address.

---

## 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):
<p>Subject selection criteria:</p> <p>Inclusion Criteria -</p> <p>Exclusion Criteria -</p>
<p>Proposed number of subjects to be enrolled:</p> <p>Indicate if any of the following vulnerable populations will be included:</p> <p><input type="checkbox"/> Children</p> <p><input type="checkbox"/> Pregnant Women, Neonates, Human Fetuses</p> <p><input type="checkbox"/> Cognitively Impaired</p> <p><input type="checkbox"/> Prisoners</p>
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)
<p>Institutional Signatory Official (Name and Title)</p> <p>Work Address:</p> <p>Work Phone:</p> <p>Work E-mail:</p>

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

**Please e-mail the completed application and attachments to  
[PHERRB@mail.NIH.gov](mailto:PHERRB@mail.NIH.gov)**

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