



**INSTITUTIONAL REVIEW BOARD
RESEARCH PROPOSAL APPLICATION**

1. Title of Protocol:
2. Investigators involved in the Protocol (All investigators and co-investigators must submit or have on file a certificate of required training):
<http://phrp.nihtraining.com/users/login.php>

Principal Investigator:	Signature:
Department/Division:	Phone:
Co-Investigator(s):	Signature:

3. How will the study be funded? Attach a budget.
4. Are any non-CHMCA faculty or facilities involved?
- No Yes

If yes, please list:

5. Do any of the investigators have an interest in a drug or device to be studied or in the design, conduct or reporting of research, that might lead to a conflict of interest?
- No Yes

If Yes, please detail:

Have all the investigators completed the Conflict of Interest training and forms, including the Financial Disclosure form?

No Yes

If No, please detail:

6. What is the purpose of the research?

7. a. What experimental drugs and devices will be used?

b. If a drug is used, is there an IND number? Yes ___ No ___, if not explain.

Question: consult - FDA Drug Information Branch – HFD-210
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
301-827-4573

c. If a device is used, is there an IDE? Yes ___ No ___, if not why does the investigator consider the device NSR.

12. What alternatives exist to the experimental procedures?

13. Who are the subjects to be studied? (List inclusions and exclusions)

14. What method(s) will be employed to select or recruit subjects?

15. How many subjects will be in the study? _____

16. Population to be studied (check all that apply):

- Male Only
- Female Only
- Male and Female
- Pregnant Women/Fetus/Nonviable neonate _____
- Minors
- Disabled or Mentally Retarded
- Other (explain) _____

If vulnerable subject (for example: minors, pregnant women, or disabled/retarded individuals) will be included, how are the additional requirements met?

17. How will you ensure that the subjects understand the risks of participation in the study (check all that apply):

- Informed consent will be obtained
- An assent will be obtained (include a copy of Readability Statistics - Flesch-Kincaid Grade Level)
- Waiver of consent is requested (please document why)
- Delayed consent (emergency research) is requested (please document why) and obtain and complete extra documentation such as plans for community consultation
- No assent is needed (please specify why)

18. How will subject confidentiality be protected?

19. How will you address HIPAA requirements?

20. Will data be recorded in such a manner that subjects remain identifiable?

Yes No

If yes: initially throughout project after project

21. How will the safety of subjects be assured?

As individuals (safety monitoring on each individual subject)?

As a cohort, check and complete A, B or C below:

A. If the study is a Phase III randomized clinical trial, a data safety monitoring committee is required and a charter must be attached.

B. For other trials, IRB may still require a data safety monitoring committee or allow an alternative safety program. Please supply answers to all of the following if an alternative safety program is proposed.

1. Who is the designated safety monitor?
2. What relationship does the monitor have to the study sponsor?
3. Is the monitor able to independently act to recommend changes and stopping of the trial?
4. Does the monitor perform review of subjects to assure they meet inclusion/exclusion criteria prior to application of research interventions?
5. Is there a well defined monitoring of reported severe unexpected events and severe expected adverse events frequency such that they are appropriately reported to sponsors, federal agencies, investigators and IRBs?
6. Are reports of adverse events provided with analysis and context?
7. Are there appropriate stopping rules with interim analyses at appropriate frequencies to allow for stopping or modifying the study in a prompt manner? Please specify.

8. Does the monitor review and approve any proposed changes to assure they are consistent with optimal safety of the study?

C. The study is minimal risk and only requires technical safety measures as noted:

22. Will the subjects be offered any compensation? Yes No

If yes, please detail:

23. Will any recruitment materials be used? Yes No If yes, please attach examples

24. What is the duration of the subjects' participation? _____

25. Support of your Departmental Chairman/Research Director

Signature: _____ Date: _____

26. Indicate Cooperating Departments:

Responsible Signature(s)

Pharmacy _____

Laboratory _____

Radiology _____

Nursing Research Center _____

Information Services _____

Other (List) _____

27. Date of Application: _____

Please attach appropriate HIPAA, informed consent and assent documents, a complete budget for this application, a complete research protocol and investigator's brochure if provided. Incomplete submissions will be returned.