PRINCIPAL INVESTIGATOR: _____________________________ Date: _____________________________

TITLE & DEPARTMENT: _____________________________ Phone: _____________________________

PROJECT TITLE: _______________________________________________________________________

PROPOSED SPONSORING AGENCY: _____________________________ Project Start Date _____________

Check one: ___ New Proposal

___ Old Proposal With Changes )

___ Old Proposal Without Changes )

Previous CHS # ____________

1. SUMMARIZE YOUR PROPOSED RESEARCH. OUTLINE OBJECTIVES AND METHODS.

2. SUMMARIZE ALL INVOLVEMENT OF HUMANS IN THIS PROJECT (Who, How Many, Age, Sex, Length of Involvement, Frequency, etc.) AND THE PROCEDURES THEY WILL BE EXPOSED TO:

3. RESEARCH INVOLVING HUMANS EXPOSES THE SUBJECTS TO RISKS:
For the purpose of this application, “risk” is defined as exposure of any person to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

CHECK ALL RISKS TO HUMANS TO BE INVOLVED IN YOUR PROJECT:

___ Physical trauma or pain  ___ Experimental diagnostic procedures
___ Side effects of medications  ___ Experimental treatment procedures
___ Contraction of disease  ___ Deception
___ Worsening of illness  ___ Loss of privacy
___ Psychological pain  ___ Loss of legal rights
___ Other

CHECK ALL PROCEDURES THAT WILL BE USED TO PROTECT HUMAN PARTICIPANTS FROM RISKS:

___ M.D. or other appropriately trained individuals in attendance
___ Sterile equipment
___ Precautions in use of stressor or emotional material (explained below)
___ When deception used, subjects fully informed as to nature of research at feasible time (explain below)
___ Procedures to minimize changes in self-concept (explain below)
___ Anonymity of subjects maintained via code numbers and protected files
___ Other

EXPLANATIONS:

4. DESCRIBE MECHANISM FOR SAFETY MONITORING. How will you detect if greater harm is accruing to your subjects than you anticipated? What will you do if such increased risk is detected?

5. Briefly describe the benefits that will accrue to each human subject or to mankind in general, as a result of the individual’s participation in this project, so that the committee can assess the risk/benefit ratio.
6. INDICATE HOW YOU WILL OBTAIN INFORMED CONSENT:

- Subject (or Parent/Guardian) reads complete consent form & signs (“long” form)
- Oral briefings by PI or project personnel, with simple consent form (“short” form)
- Other (explain)

PARTICIPATION MUST BE VOLUNTARY; THE PARTICIPANTS CANNOT WAIVE LEGAL RIGHTS, AND MAY WITHDRAW AT ANYTIME WITHOUT PREJUDICE. ATTACH CONSENT FORMS TO BE SIGNED BY EACH PARTICIPANT (THESE MUST REMAIN AS PART OF YOUR PROJECT RECORDS, SUBJECT TO COMMITTEE REVIEW). ATTACH A SUMMARY OF ALL VERBAL INFORMATION TO BE GIVEN TO EACH SUBJECT. ALL SUBJECTS MUST RECEIVE A COPY OF THE CONSENT FORM UNLESS WAIVED BY CHS.

7. IF UNDER #3, YOU HAVE CHECKED RISK FOR INJURIES FOR WHICH MEDICAL TREATMENT MAY BE REQUIRED, AND IF THE RESEARCH SUBJECT SUSTAINS SUCH AN INJURY, HAS PROVISION BEEN MADE TO ASSURE THAT THE RESEARCH SUBJECT WILL BE INDEMNIFIED FOR EXPENSES INCURRED IN TREATING THESE INJURIES?

Not applicable  ____ No  ____ Yes  Explain:

If the answer to #7 is “no” the following language shall appear in the written consent form:

I UNDERSTAND THAT IF I AM INJURED IN THE COURSE OF THIS RESEARCH PROCEDURE I, ALONE, MAY BE RESPONSIBLE FOR THE COSTS OF TREATING MY INJURIES.

8. Are there non-therapeutic tests that the research subject may be required to pay?
   - No  _____  Yes  ____ If yes, explain:

IF “YES” ADD TO THE CONSENT FORM, I UNDERSTAND THAT I MAY BE RESPONSIBLE FOR THE COSTS OF PROCEDURES THAT ARE SOLELY PART OF THE RESEARCH PROJECT.

9. Are there any local IRB’s reviewing this proposal also? Location:

10. I affirm that the attached drug sheet(s) submitted to CHS for this project have been checked and confirmed to be accurate and current. If changes in a CHS-approved drug sheet have been made to insure accuracy and currency, these changes have been listed on the attached.

   Signed ______________________ Date ____________________
   (Principal Investigator)

   Prepared by ____________________ Phone _____________

Submit the original plus 10 copies of this form with the following attachments:
   3 copies of proposal
   11 copies of all consent form
   11 copies of verbal information to be given if short consent form is used.