ATTACHMENT B

CHS # _____

APPLICATON FOR APPROVAL OF STUDIES INVOLVING HUMAN SUBJECTS
University of Hawai‘i, Committee on Human Studies (CHS)
Spalding Hall 253, 2540 Maile Way, Honolulu, Hawai‘i 96822
Telephone: 948-8658

PRINCIPAL INVESTIGATOR: _____ Date: _____

TITLE & DEPARTMENT: _____ Phone: _____

PROJECT TITLE: _____

PROPOSED SPONSORING AGENCY: _____ Project Start Date _____

Check one: __ New Proposal

__ Old Proposal With Changes)
) Previous CHS # _____
__ Old Proposal Without Changes)

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:

CHECK WHETHER ANY SUBJECTS OF YOUR RESEARCH WILL BE SELECTED FROM THE FOLLOWING CATEGORIES:__ Minors,__ Fetuses,__ Abortuses, __ Pregnant Women, __Prisoners,__ Mentally Retarded,__ Mentally Disabled.

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, develop ment, 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
___ Side effects of medications
___ Contraction of disease
___ Worsening of illness
___ Psychological pain
___ Other
___ Experimental diagnostic procedures
___ Experimental treatment procedures
___ Deception
___ Loss of privacy
___ Loss of legal rights

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.