A Survival Guide for Conducting International Collaborative Research in Thailand

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Fogarty AIDS International Training and Research Program (AITRP)
University of California, Berkeley (UCB)
University of California, San Francisco (UCSF)

FOREWORD

Dear AITRP scholar-

The design and conduct of international collaborative research is a challenge. There are several administrative, logistical and technical hurdles to overcome before a study can be initiated and completed in a country like Thailand. International research may also raise unique ethical issues and dilemmas.

This survival guide on conducting research in Thailand, compiled by a current Fogarty scholar and a Thai official, is the third in a series of country-specific survival guides intended to assist Fogarty AITRP scholars planning collaborative research projects in developing countries. The guidelines provided are not comprehensive and are, naturally, subject to change. You are advised to check with relevant Thai agencies, and the AITRP team for any new developments, prior to starting your research project.

With best wishes,

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1. APPROVALS REQUIRED BEFORE STUDIES CAN BE INITIATED IN THAILAND

Committee for the Protection of Human Subjects Approval from University of California, Berkeley:

All research involving human subjects requires approval from the Committee for the Protection of Human Subjects (CPHS), University of California, Berkeley (UCB): http://cphs.berkeley.edu:7006. According to CPHS, "The political or social climate in a foreign country may be such that normal methods for protecting the confidentiality of research data and the identity of subjects are not adequate. Researchers should address this problem in their protocols. Except under unusual circumstances, the procedures to be employed should not be less stringent than those required by the CPHS for research in this country, even if those customary in the foreign country are less restrictive."

Graduate students are required to submit the CPHS approval letter to the Graduate Division at the time of filing their dissertation. There are no provisions for retroactive approval of research projects. Approval must be obtained *before* the study is begun. If research is begun without CPHS approval, upon discovery of the error, the student must stop the research and notify the CPHS immediately. The student must then submit a protocol to the CPHS along with a detailed explanation as to why the protocol was not submitted at the appropriate time. A detailed letter from his or her faculty advisor must accompany the materials submitted to the CPHS.

There are no submission deadlines for new protocols. The time required for CPHS approval varies greatly, and depends on the level of review: exempt, expedited, and full committee review. Certain types of research studies (e.g., interviews where responses are recorded anonymously) may qualify as exempt from full CPHS review. For exempt research, approval might take 3-4 weeks. Certain "low-risk" projects (e.g., no interventions or vulnerable populations involved), might quality for "expedited" review by a sub-committee of CPHS, and this process can take up to 8 weeks.

A small portion of projects are judged by the CPHS Chair to need full Committee review, which can only happen at the CPHS monthly meeting. Full Committee review is required for: (1) most physiological or medical research; (2) research involving certain vulnerable populations; and (3) research "where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing" and either there is a non-trivial risk that confidentiality could be violated, or the consequences of a loss of confidentiality would be severe. Full committee reviews might take a longer time (8-12 weeks). Full committee meetings are held once a month. The complete application package (including consent forms, recruitment materials, conflict of interest forms, etc.) must reach CPHS 4 weeks before the next full committee meeting.

Getting Your CPHS Approval Faster **Box 1**

1. Contact and develop a rapport with the CPHS staff assigned to handle your protocol. Follow-up with them on a regular basis. Telephonic and personal contacts are likely to be more effective than emails.
1. Respond to CPHS requests/calls immediately.
2. Read the CPHS guidelines and instructions very carefully. Use the sample CPHS protocol and consent form [available at: http://cphs.berkeley.edu/content/sample.htm] as templates for your own protocol and consent. This will ensure that you address all the ethical issues that CPHS requires. The consent form, in particular, is critical. Get your adviser and colleagues with IRB experience to critique your draft consent form.
3. Get your faculty adviser to critique your draft protocol. Make sure the CPHS cover sheet is signed by your faculty adviser.
4. Submit your protocol with a cover letter, describing the key issues involved in your research. Every item in the cover sheet should be completed and checked for accuracy.
5. Check if your research qualifies for the "exempt" research. For example, analyses of unlinked secondary data (without personal identifiers such as name, address, etc.) might qualify as exempt research. Exempt research applications take less time for approval.
6. If your project is low-risk (e.g., no interventions or vulnerable populations involved), you could talk to the CPHS staff about sub-committee reviews (likely to be quicker).
7. CPHS (unlike the UCSF IRB) might defer to other IRBs that have approved the project. For example, if the UCSF IRB has already approved your protocol, then CPHS might grant you an approval on the basis of the 'reciprocal agreement' it has with other IRBs.
8. If your project has already been approved by the IRB of your Thai institution, attach the approval note to your CPHS protocol. This might help to speed up things a bit. Also, obtain a "letter of support" from the Thai institution and attach this to your CPHS protocol. The letter of support should briefly describe the project and state that the Thai institution is willing to collaborate with UCB and support your project.
9. Try and avoid submitting protocols during summer - the CPHS full committee does not meet during all of the summer months and this can delay your protocol review.

Institutional Review Board Approval from the Collaborating Thai Institution(s):

All collaborative research projects require Institutional Review Board (IRB) approval from the collaborating Thai institution(s). The first step would be to check if the Thai institute has a functioning IRB in place. Many Thai institutions and research centers already have IRBs (see **Appendix 1**). Check with your Thai collaborators about this and the time they usually take for the review process. Some Thai institutions (small non-governmental organizations (NGO), for example) may not have IRBs. This can pose problems. In these situations, you could 1) use an existing IRB from another Thai institution; or, 2) convince the Thai institution/NGO to first constitute a new IRB. However, you should note that the latter can be a lengthy and cumbersome process.

If the collaborating Thai institution decides to use an existing IRB from an external institution, then you will have to ensure that 1) the external IRB is registered with the Office for Human Research Protections (OHRP) - see section 2 on IRB registration and OHRP assurances, and 2) the arrangement between the two institutions is documented as an "IRB Authorization Agreement." See the OHRP guidelines: http://www.hhs.gov/ohrp/assurances/index.html.

If the collaborating Thai institution decides to constitute its own IRB, then OHRP guidelines (see **Box 2**) may be used to decide on IRB composition, role, etc: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.107. In addition, the World Health Organization (WHO) has also provided operational guidelines for ethics committees that review biomedical research: http://www.who.int/tdr/publications/publications/ethics.htm. These guidelines are available in English, French, German, Spanish, Russian, Turkish, Thai, Japanese, Chinese, Laotian, Korean, and Vietnamese.

Once the IRB is constituted as per guidelines, you might need to provide the new IRB some guidelines/training on how to review protocols. The OHRP offers educational materials for IRBs (including videos and CDs). Please check their site: http://www.hhs.gov/ohrp/education/#materials. OHRP also offers an online IRB Guidebook: http://www.hhs.gov/ohrp/irb/irb_guidebook.htm. A more detailed list of education materials are provided at the end of this document (section 14). You could also contact Dr. Rutt Chuachoowong, Medical Research Scientist at the Thailand MOPH - US CDC Collaboration and member of Siriraj Hospital Ethical Review Committee for assistance/advice regarding IRB establishment and ethics training in Thailand.

After this process is complete, request the Thai IRB to review and approve your protocol. Most of the Thai IRB's meet regularly. If the IRB does not meet regularly, you will need to request your Thai collaborators to convene an *ad hoc* IRB meeting to specifically review your protocol. Obtain a written, signed copy of the approval letter (you may need to send the Thai IRB a sample IRB approval letter - you could use the CPHS letter as a template).

US Guidelines on IRB Composition and Role **Box 2**

The IRB shall:

a. Have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
b. Be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.
c. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
d. Include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
e. Include at least one member who is not otherwise affiliated with the institution operating the IRB and who is not a part of the immediate family of a person who is affiliated with it.
f. Make every nondiscriminating effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

US Guidelines on IRB Composition and Role (continued)

g. Have no member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
h. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.
i. All IRB members are required to undergo ethics training through an NIH-approved program such as NIH's online training program: http://cme.nci.nih.gov/.

Institutional Review Board Approvals from External US or International Institution(s):

In addition to UCB and Thai IRB approvals (these are called primary IRBs), you might need IRB approvals from all the external (secondary) US/international institutions involved in your research project. Often funding agencies have requirements for IRB approvals, some even have their own.

For example, if you have co-investigators or collaborators from University of California, San Francisco (UCSF), you will need approval/exemption from their Committee for Human Research (CHR): http://www.research.ucsf.edu/chr/index.asp. Again, it will help a great deal if you submitted your protocols to the external IRBs along with copies of the CPHS and Thai IRB approval letters.

If the UCSF (or any other) collaborator is involved only as a "consultant" or "technical adviser" you might want to consider applying for an exemption (wherein you state that your collaborator is only a consultant, and will not have access to data with identifying information). This might save you several weeks of delay.

Multiple IRBs and Time Delays **Box 3**

If your project involves multiple institutions, you might need approvals from all of them. The time required for these external IRB approvals varies by institution. For example, the CHR at UCSF meets every week and has a much faster turn around time as compared to CPHS. However, agencies like CDC and WHO might take a long time to complete their reviews.

Overall, you will have to budget for adequate time (3 months or even longer) for all approvals to come in. It is a good strategy to apply to the external IRBs after the primary IRBs (CPHS and the Thai IRB) approvals are obtained. In your submission, emphasize that your protocol has been approved by the primary IRBs. Some external IRBs might defer to the UCB IRB approval.

As always, email/telephonic follow-up is required for getting external IRB approvals faster. Be sure to get hard copies of all IRB approvals for your records and also for the AITRP folder in Dr Reingold's office. If your project will take longer than a year, remember to submit renewal applications to all the IRBs involved, well *before* the expiration of approval. Sometimes, external IRBs will not renew their approvals unless the primary IRBs have done so. It is therefore important to renew CPHS and the Thai IRB approvals first and subsequently apply for external IRB renewals. Note that some IRBs may require that you provide a summary of study activities for the past year along with the renewal applications. Be sure to check with your IRBs for this requirement and prepare it beforehand.

2. INSTITUTIONAL REVIEW BOARD REGISTRATION AND ASSURANCE FROM OFFICE FOR HUMAN RESEARCH PROTECTIONS FOR THE THAI INSTITUTION

What is an Assurance and Why is it Needed?

Under the Department of Health and Human Services (DHHS) human subjects protection regulations, every institution engaged in human subjects research supported or conducted by DHHS (which includes National Institutes of Health (NIH)-funded grants such as AITRP) must obtain an assurance of compliance approved by the OHRP: http://www.hhs.gov/ohrp/assurances/assurances_index.html. Also, as per AITRP regulations, the Thai institution involved in collaborative research must:

a. Register its IRB with the OHRP
b. Obtain a Federalwide Assurance (FWA; also called “assurance”) from OHRP.

The Federal Policy (Common Rule) for the protection of human subjects requires that each institution "engaged" in Federally-supported human subject research file an "Assurance" of protection for human subjects. The Assurance formalizes the institution’s commitment to protect human subjects. The requirement to file an Assurance includes both "awardee" (e.g., AITRP) and collaborating "performance site" institutions (e.g., Thai collaborating sites).

Under the Federal Policy (Common Rule) awardees and their collaborating institutions become "engaged" in human subject research whenever their employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain, release, or access individually identifiable private information for research purposes.

In addition, awardee institutions are automatically considered to be "engaged" in human subject research whenever they receive a direct DHHS award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award. The awardee is also responsible for ensuring that all collaborating institutions engaged in the research hold an OHRP approved Assurance prior to their initiation of the research.

Steps in Obtaining a Federalwide Assurance:

Before applying for a FWA, check if your collaborating Thai institute has already filed an assurance. Check: http://ohrp.cit.nih.gov/search/asearch.asp#ASUR. At present time, many Thai research centers, hospitals and medical colleges (including some NGOs) already have FWAs (see **Appendix 2**). If the institute/NGO you are working with has not filed a FWA, they will need to do the following:

a. The first step is to register the Thai IRB with OHRP. This involves submission of a short application form (with details about the IRB, composition, etc.). This form can be submitted to OHRP via email, fax, or completed online. Instructions and forms: http://www.hhs.gov/ohrp/humansubjects/assurance/regirb.htm. The form has to be submitted by the Thai institution (although you can help in completion of the form and following-up with OHRP). If the Thai IRB conforms to the OHRP requirements, the application for registration is usually approved in 2-3 weeks.

b. Once the IRB registration is complete, the Thai IRB is assigned a unique ID number. The Thai IRB information also gets posted on the OHRP website: http://ohrp.cit.nih.gov/search/asearch.asp#ASUR.
c. The last step is to submit an application for FWA. This application form needs to be submitted by the Thai institution and signed by the head of the institution. The form [http://www.hhs.gov/ohrp/humansubjects/assurance/filasur.htm] can be submitted via mail or completed online (in which case the page with the Thai institution head's signature has to be sent separately to OHRP via mail). If the FWA application is in order, approval is usually given in 2-3 weeks. After approval, the Thai institute is given a unique FWA# and this information is posted on the OHRP website. A hard copy of the assurance is sent via mail to the Thai institution. The FWA is valid only for a limited period (usually, 3 years); it has to be renewed periodically.

Steps to Register a New IRB or IEC **Box 4**

Paper-Based IRB/IEC Registration

1. Download or print the Instructions and the Registration form and membership roster

- Instructions: http://www.hhs.gov/ohrp/humansubjects/assurance/regirbi.htm
- Registration form and membership roster (HTML): http://www.hhs.gov/ohrp/humansubjects/assurance/regirb.htm
- Registration form and membership roster (RTF): http://www.hhs.gov/ohrp/humansubjects/assurance/regirb.rtf

2. Read the Instructions.
3. Review and fill out the Registration form and membership roster.
4. Fax the completed Registration form and membership roster to OHRP at: 301-402-0438 or mail the registration form and membership roster to: Office for Human Research Protections, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852

Electronic IRB/IEC Registration (for NEW registrations only)

1. Download or print the Instructions for registering an IRB/IEC.

- Instructions: http://www.hhs.gov/ohrp/humansubjects/assurance/regirbi.htm

2. Read the Instructions.
3. Go to the website: http://ohrp.cit.nih.gov/efile to create electronic IRB/IEC Registration.
    a. Click "Enter New IRB Registration".
    b. Request electronic registration number, which will be e-mailed to you.
    c. Return to website and enter data to complete registration. All areas marked with an * must be completed. You may work on the registration, exit, and return as many times as you would like.
    d. Review your entries carefully before clicking the "Submit IRB/IEC Registration" button.
    e. Print a copy of the IRB/IEC registration for your file.

Steps to File an International (non-US) Federalwide Assurance (FWA) **Box 5**

International Paper-Based Assurance

1. Download or print the Instructions, Terms of Assurance and the FWA form.

- Instructions: http://www.hhs.gov/ohrp/humansubjects/assurance/ifilasuri.htm
- Terms of Assurance: http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm
- FWA form (HTML): http://www.hhs.gov/ohrp/humansubjects/assurance/ifilasur.htm
- FWA form (RTF): http://www.hhs.gov/ohrp/humansubjects/assurance/ifilasur.rtf

2. Read the Instructions and the Terms of Assurance.
3. Review and fill out the FWA form.
4. (*Signatory Official*) Sign and date the FWA form.
5. Fax the completed FWA form to OHRP at: Office for Human Research Protections, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852

International Electronic Assurance (for NEW submission only)

1. Download or print the Instructions and Terms of Assurance.

- Instructions: http://www.hhs.gov/ohrp/humansubjects/assurance/ifilasuri.htm
- Terms of Assurance: http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm

2. Read the Instructions and the Terms of Assurance.
3. Go to the website: http://ohrp.cit.nih.gov/efile to create electronic FWA submission
    a. Click "Enter New FWA".
    b. Request electronic submission number, which will be e-mailed to you.
    c. Return to the website and enter data to complete the FWA form. All areas marked with an * must be completed. You may work on the FWA, exit, and return as many times as you would like.
    d. Review your entries carefully before clicking the "SUBMIT" button.
    e. Print a copy of the FWA form for your file and for signature.
4. (*Signatory Official*) Sign the Assurance form.
5. In order to process the electronic submission, you must FAX a copy of the signed FWA form to OHRP at: 301-402-0438 or mail the FWA form to: Office for Human Research Protections, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852

3. MINISTRY OF PUBLIC HEALTH GUIDELINES FOR RESEARCH IN HUMAN SUBJECTS IN THAILAND

The Ethical Review Committee for Research in Human Subjects (ERC), Ministry of Public Health (it is called MOPH ERC) is Thailand's apex organization for scientific research involving human subjects. In 1993, the ERC proposed its ethical guidelines for research on human subjects to form the basis for conducting ethical research in Thailand. The guidelines, revised in 1995, are currently in use. Documents in Thai language may be obtained by writing to the following address:

The Office of Secretary
Ethical Review Committee for Research in Human Subjects
Department of Medical Services
3rd Floor of Building 4, Ministry of Public Health,
Tiwanon Road, Nonthaburi 11000, Thailand
Tel: +66-2591-8251, +66-2590-6172
Fax: +66-2591-8251
Email: porntiva@health.moph.go.th.

Ethical Criteria **Box 6**
The Ethical Review Committee for Research in Human Subjects
Ministry of Public Health, Thailand
1993 (revised 1995)

1. The Ministry of Public Health (MOPH) is responsible for reviewing ethical issues in the medical research which meet the following criteria:
   - 1.1 Research to be conducted by MOPH's personnel or organizations, or to be conducted in geographical areas under responsibility of MOPH;
   - 1.2 Research to be conducted by non-related organizations but requesting ethical review by MOPH;
   - 1.3 Research (both those funded by Thai and foreign funding sources) requiring approval by national authority.

2. The proposed research should meet the following criteria:
   - 2.1 Be based on Thai legislation and merit considerations;
   - 2.2 Be conducted by adequate number of investigators who are knowledgeable and have experience in the areas related to the research. The investigators should be competent and understand the research process, benefits and potentially harmful risks that may be incurred by participating in the research;
   - 2.3 Have at least one licensed medical officer of Thai nationality on the team. This officer is to be responsible for treatment of any adverse effect that may occur upon the participants' physical or mental health as the result of the research;
   - 2.4 Have clearly stated feasible objective(s);
   - 2.5 Lead to new and useful findings and knowledge;
   - 2.6 Justify the needs to conduct human subject research;
   - 2.7 Have adequate and qualified scientific evidences to substantiate its safety based on animal experiments or previous knowledge;
   - 2.8 Be restricted to the minimum number of participants as determined by statistical techniques;
   - 2.9 Be ethically sound and clearly state the alleviative measures and facilities required for the safe and efficient treatment of the participants as well as the compensation should the adverse effects occur;
   - 2.10 Have a clear statement regarding inclusion, exclusion and discontinuation criteria;
   - 2.11 Be translated into Thai (for proposal originally in foreign language);
   - 2.12 Have a clear statement regarding the benefit(s) to the participants, investigators, organization(s) and the nation(s);
   - 2.13 Estimated expenditure of the proposed research, including source of fund(s) must be provided using the Estimated Expenditure form recommended by ERC.

Ethical Criteria (continued)

3. After being properly informed, and if the prospective participants agree to participate in the research, written consents must be obtained from the participants. For minors or those who are not able to consent legally, written consent must be obtained from their legal guardians. The consent form should follow the MOPH requirement.

4. Investigators have an obligation to clearly explain to potential participants, the following:
    - 4.1 Methodology of the research, including the procedures to be conducted on the participants and those in which the participants are expected to follow;
    - 4.2 Potential hazards or discomfort that may occur during and after the research is finished, including preventive measures;
    - 4.3 Benefit(s) to the participants, investigators and the nation(s);
    - 4.4 The participants' rights and freedom to withdraw from the research;
    - 4.5 Related information to ensure that the participants have no doubt regarding any aspects of the research, to ensure full agreement, and to avoid misunderstanding and coercion.

5. Methodology to be conducted in the research must be that which will cause minimal impact on the participants' physical and mental health. This is of particular concern for research to be conducted among children, elderly, pregnant woman or those incapable to make the decision consciously.

6. Each activity involving human subjects must be conducted under caution based on medical standards. Methods found to indicate potential hazards to the participants must be ceased immediately.

7. Research participants or their legal guardians are free to withdraw from the research at any time without penalty or loss of benefits to which they are entitled.

8. Investigator must report to the ERC or the Principal Investigator any serious adverse event as determined in the Guidelines for Good Clinical Practice.

9. Investigator should provide the ERC progress report(s) and upon the completion of the research, a final report within 6 months after research is completed.

10. The ERC has the right to set any future guidance or regulation as deemed necessary.

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Note: *The information contained herein was translated from the latest guidelines written in Thai language. The translator made every effort to ensure that the content was most up to date and as accurate as possible at the time it was being translated. However, this information should be used as guidelines only. Should there is any question or discrepancy, please refer to the Thai version.*

In addition, ERC also released special guidelines to govern HIV/AIDS vaccine-related research in Thailand and *Guidelines for Preparation of a Research Protocol*. All AITRP scholars planning studies in Thailand should be familiar with these guidelines.

Ethical Considerations for AIDS Vaccine Trials/Studies in Thailand **Box 7**
The Ethical Review Committee for Research in Human Subjects
Ministry of Public Health, Thailand
1993

The Ethical Review Committee for Research in Human Subjects (ERC), Ministry of Public Health, Thailand, has realized the necessity of promoting research on AIDS vaccines. The committee has developed guidelines for AIDS vaccine studies which will serve to: 1) help increase understanding among investigators/institutions involved regarding the ethical assessment of research proposals; 2) facilitate the review process; and 3) ensure protection of volunteers/research participants in terms of health, human rights and compensation. The research proposal will be reviewed according to the following criteria:

1. All proposed research should be accompanied with the following documents or meet the following criteria:
    - 1.1 Letter of approval to conduct Phase I, II or III issued by the national authorities from the vaccine's country of origin or from the nation where the vaccine was developed such as Investigational New Drug (IND), Food and Drug Administration (FDA) or National Institutes of Health (NIH);
    - 1.2 Certificate of Good Manufacturing Practice (GMP);
    - 1.3 Letter of approval from the institute(s) with which the investigators are affiliated and letter of approval to conduct the proposed research at the location/institution where the research will take place;
    - 1.4 Detailed list of budget and itemized expenditures as well as sources of funds using Estimated Expenditure form recommended by the ERC;
    - 1.5 Measures to safeguard the following ethical aspects:
        - Confidentiality concerning personal information of research participants;
        - Methods of data collection, processing and dissemination;
        - Investigators' responsibilities to research participants ensuring adequate medical treatment and care should the adverse effects or reactions which, in some cases may be fatal, occur; and preventive measures against such events as well as the measures to protect the research participants from social discrimination;
        - Provision of appropriate compensation to be given to the research participants or to their heirs in the event of harmful effect(s);
        - Provision of adequate education and HIV risk reduction counseling to the participants through out the length of research;
        - Right and freedom of the participants to withdraw from research at any time;
    - 1.6 Clear statement of the benefits of the study to the investigations, institution(s), and the nation(s);
    - 1.7 Sample of informed consent to be used in the research.

2. The existing ethical criteria currently used to assess proposals for biomedical research in human subjects will also be applied to evaluate AIDS vaccine proposals.

3. The committee will meet once a month to review submitted proposals and has the right to consult experts from other institutions such as NIH or Centers for Disease Control and Prevention (CDC). The review process will take approximately 3 months.

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4. CLEARANCES FROM THE ETHICAL REVIEW COMMITTEE FOR RESEARCH IN HUMAN SUBJECTS OF MINISTRY OF PUBLIC HEALTH AND GOVERNMENT OF THAILAND

All research projects involving foreign assistance and/or collaboration (e.g., NIH-funded grants in Thailand) have to be cleared by MOPH ERC and the Government of Thailand.

Submission of Research Protocol to Ethical Review Committee for Research in Human Subjects of Ministry of Public Health:

Applications for research projects involving foreign assistance/collaboration in health research are to be submitted to MOPH ERC for approval of the Government of Thailand through the Office of the Secretary (please see list of contacts for contact information). This application must be submitted by the collaborating Thai institution. The ERC will not communicate with the US investigators. The application process involves submission of the protocol containing 17 sections (see **Box 9**) and other materials such as Thai and US IRB approvals, budget, and consent form.

MOPH ERC meets approximately once a month and there are four result reviewing categories which are:

1. Those approved without any condition;
2. Those approved with conditions, i.e., with some recommendations for protocol's revision;
3. Pending (research protocol has not been reviewed);
4. Those not approved.

In order to expedite and facilitate the review process of research proposal and protocol submitted to MOPH ERC, proposed research should comply with the guidelines set by the ERC. For HIV/AIDS vaccine-related research, proposed research should also comply with the guidelines set by Subcommittee on HIV/AIDS Vaccine Development[1] (SHAVD). Research proposal and protocol should be prepared as per the *Guidelines for Preparation of a Research Protocol Submitted to the Ethical Review Committee for Research on Human Subjects, Ministry of Public Health* (see **Box 9**). Generally, a total of 23 copies (1 original and 22 collated copies) of the proposal and protocol are needed and must be directed to the Office of Secretary, Ethical Review Committee for Research in Human Subjects, Department of Medical Services, 3rd Floor of Building 4, Ministry of Public Health, Tiwanon Road, Nonthaburi 11000, Thailand. For proposal and protocol pertaining the conduct of HIV/AIDS vaccine-related research in Thailand, a total of 25 copies (1 original and 24 collated copies) of the proposal and protocol must be first submitted to the AIDS Vaccine Coordinating Unit[2] (AVCU) (see list of contacts for contact information). Proposal and protocol recommended for approval by AVCU will further be submitted for ethical review by the ERC.

[1] The SHAVD was established by the National AIDS Committee (NAC) in December 1995 and is responsible for review research proposals and protocols submitted for approval and/or funding on behalf of NAC.

[2] The AVCU serves as secretariat and functional arms of SHAVD to co-ordinate protocol review for recommendation and authorization.

Once copies of the proposal and protocol are received at the ERC office, they will be screened and forwarded to at least 2 technical peer reviewers. For HIV/AIDS vaccine-related research, there will be at least 3 reviewers. The initial technical peer review will take approximately 2-3 weeks to complete while the overall process (from protocol submission until notification of reviewing result to Principal Investigator) will take up to 3 months. At the ERC's monthly meeting, the reviewers will present to the ERC the summary of the protocol, ethical concerns and relevant comments. The committee members will discuss ethical and scientific aspects of the proposed research and express its opinion on terms of recommending approval, recommending modification of the proposal, or not recommending of the proposal. If there are major concerns on the research protocol, the investigator may be invited to the following ERC's meeting for clarification. The investigator will be required to give a presentation of the proposed research and answer inquiries to the satisfaction of the committee. At the end of the meeting, the Principal Investigator or his/her representative will be verbally informed of the initial result. The result of the ERC's consideration will be reported to the ERC's chairman by the secretary and subsequently to the Permanent Secretary for Public Health. Approval Certificate signed by the Permanent Secretary for Public Health will be forwarded to the Principal Investigator and responsible organization(s).

If the proposed research is approved *without condition*, the research can be conducted at once. If the research is approved *with conditions*, the proposal will be returned to the Principal Investigator, with comments and recommendations justifying the decision. Principal Investigator can resubmit a modified proposal for a second review. Revised proposal with a slight modification will be checked by the secretary and, if agreeable, Principal Investigator will be informed and the research can be initiated. If there is any significant modification, the secretary will forward the revised proposal to the reviewers for comments and then submit further to the ERC for consideration. Principal investigator may be invited to give additional clarification, if deemed appropriate. The investigator will be notified of the ERC's consideration.

Pending research protocol (research protocol that has not been reviewed) is protocol that needs to be completely revised. To submit the revised protocol, the investigator is required to start the submission process all over. Note that due to the high workload of ERC, the investigator should be aware that proposals that do not comply with the *Guidelines for Preparation of a Research Protocol* may easily result in either refusal of acceptance upon submission or pending status after accepted (even though methodology of the proposed research may be ethically and scientifically sound). A check list recommended by the ERC (see **Appendix 3**) may be used to ensure that proposal and protocol comply with these guidelines. There is a requirement that this checklist accompanies the copies of proposal and protocol upon submission.

Approved research can be initiated as soon as investigator is verbally informed of approval, though the Approval Certificate will be made available to the investigator in days or weeks later. While waiting for Approval Certificate, Principal Investigator may request a temporary letter of approval from the ERC's secretary to enable him/her to process a request for importation of essential products/equipment to be used in the research work, if needed.

It is very important that Thai investigators establish a relationship with key personnel at ERC. Before submitting formal proposal and protocol, Principal Investigators are

encouraged to establish early interactions with the ERC, through the secretary to facilitate the formal process or review and approval.

Do AITRP students need MOPH ERC clearance for their field training/research conducted as part of their graduate studies? Yes; all research involving human subjects to be conducted in the geographic areas under supervision of MOPH must be cleared by MOPH ERC. MOPH ERC needs to clear all foreign collaborative research projects (such as NIH RO1, the United States Agency for International Development (USAID) funded grants, etc.) for which they have bilateral agreements in place. Those planning to work with governmental agencies (such as Mahidol University, Thai NIH, etc.) may also have to obtain ethical clearance from the IRBs of those agencies. Thai nationals who plan to return to Thailand for field work as part of graduate or doctoral training are advised to tackle this issue on a case-by-case basis in consultation with Dr. Reingold and their Thai collaborators.

Time Delays and Other Constraints **Box 8**

AITRP scholars who submit their protocols to MOPH ERC and related IRBs for review will have to be prepared for very long delays. The approval process could take anywhere from 3 months to 1 year. Protocols have also been denied approval (rarely). It might be a good idea to submit the protocol early during the Ph.D. program and budget for a 6 month to 1 year delay. Having alternative (backup) plans for dissertation may also be prudent. Issues that may cause delays or denial of approval include export of biological specimens and raw data (intellectual property concerns). Some IRBs (including MOPH ERC) may be reluctant to approve researches involving exporting biological specimens (and, may be, raw data). If investigators can assure the committee that they will now be used to serve the purpose other than those specified in the protocols, IRBs will have no reasons to deny them. Several institutions have already prepared Material Transfer Agreement to accommodate such projects. This document could help a lot in IRB reviews.

Guidelines for Preparation of a Research Protocol Submitted to The Ethical Review Committee for Research in Human Subjects Ministry of Public Health, Thailand **Box 9**

Research protocol (1 original and 22 collated copies) must be submitted in the Thai language and should include the following content:

1. Title: Proposed research must have a Thai title. The title must be concise and informative. If accompanied by an English title, the meanings of both titles must be exactly the same.

2. Name and address of Principal Investigator and institution.

3. 2-page summary of proposed research.

The full protocol should include the following content:

4. Introduction: The introductory section should include background information, rationale and justification, and expected benefit from the proposed research.

5. Objective(s).

6. Location and duration of the proposed research.

Guidelines for Preparation of a Research Protocol (continued)

7. Methodology. The methodology outlining the following should be included:
   - 7.1 Study population (both experimental and control groups) with details of sex, age, other characteristics, disease or specific sign/symptom and number of study participants;
   - 7.2 Inclusion criteria;
   - 7.3 Exclusion criteria;
   - 7.4 Discontinuation criteria, including discontinuation criteria for study participants and criteria for termination of the proposed research;
   - 7.5 Implementation and monitoring procedures, including data collection and analyses;
   - 7.6 Special considerations;
     - If blood samples are required, objective(s), quantity and frequency of blood collection must be specified. Additionally, how many times blood samples will be drawn must be stated clearly;
     - For clinical trials, trade and generic names of the drug, manufacturer's and distributor's names including the registration number of licensed drug (if any) are required;
     - For other non-pharmaceutical products, detailed information of the products and results of relevant research (if any) must be attached;
     - For research that requires an operation or any medical practice, procedure(s) to be conducted must be described.

8. Ethical considerations. The following content should be included:
   - 8.1 Foreseeable risks, including preventive and alleviative measures;
   - 8.2 Compensation, medical care and other services to be provided to the study participants who may be affected by any complication;
   - 8.3 Other related ethical aspects;
   - 8.4 Human subject information sheet in Thai language, in which physician or hospital's name, address and telephone number have been included;
   - 8.5 Informed consent document in the format as recommended by the ERC. An altered format may also be used, if approved by the ERC;
   - 8.6 The investigator may make a request to the ERC for an exemption for the use of information sheet and/or informed consent, if deem appropriate. Rationale(s) for such exemption must be provided.

9. Summary of budget and source of funding(s).

10. References.

11. Curriculum vitae of all investigators (may be provided as an addendum).

12. Letter of approval to conduct the proposed research at the location/institution where the research will take place.

Information Sheet:

There are guidelines set by MOPH ERC to regulate what contents are necessary to be provided to the prospective research participants to ensure fully understanding and to avoid coercion. It is recommended that information sheet be concise, informative and include essential information. It should also be written in Thai language at the level that is understandable by the prospective research participants. Some English words may be used as a supplement for clearer explanation, if needed; they should be written in

parentheses next to Thai words. In addition, if the prospective participants are those who are not capable to understand Thai language, i.e., hill tribes, an information sheet should be translated into their local language. The translated information sheet *must* be attached with the protocol when the proposal and protocol are initially submitted for review. Every effort must be made to avoid discrepancy of these two versions of information sheet. Contents of the Thai information sheet will supercede those in the translated one if there is any discrepancy. As advised by the ERC, a translator who is certified by the court or Ministry of Foreign Affairs may provide the translation service for this purpose. However, according to our experiences, translation may also be done by a *local* researcher who has experience in the areas related to the research. The document may or may not need to be further certified by a certified translator (please check with the ERC's secretary).

Additionally, it is preferable that the information sheet be written in the language understandable by those who have at least a primary school education (grade 6) and be pilot tested before use. For completion and to make it comprehensible, the information sheet should be written in the format recommended by the ERC and include recommended content (see **Appendix 4**).

As advised by the MOPH ERC, the information sheet may be combined into one document with the informed consent document. These two documents may also be used independently. If combined, introduction and consent sections should be clearly delineated. The information sheet and a copy of signed informed consent document should be made available to each research participant. The investigator should hold the original signed informed consent document.

Informed Consent Document, Estimated Expenditure Form and Checklist:

In addition to copies of research proposal and protocol, it is required that the investigator submit informed consent document, estimated expenditure form, and other related documents such as cover letter signed by head of institution where the Principal Investigator is affiliated, questionnaire or script to be used in the interview (if any). To avoid unnecessary delay in the review process, investigator may communicate with the ERC's secretary at telephone numbers: +66-2591-8251 or +66-2590-6172 to ensure that all required documents are properly prepared. Examples of recommended informed consent document, estimated expenditure form and checklist can be found in **Appendixes 3, 5 and 6**.

5. TRAINING OF STUDY PERSONNEL IN HUMAN SUBJECTS PROTECTION

It is important that all field staff members that have contact with study participants have adequate training in human subjects procedures, including an understanding of the informed consent process. For key personnel and senior staff, online training in English is available from NIH at the following website: http://cme.cancer.gov/c01. The certificate of completion should be printed out or saved because it is irretrievable once you leave the website. Some funding agencies (including Fogarty International Center (FIC), NIH, and CDC) and IRBs require that you demonstrate completion of a training program in the protection of human subjects. You may need to hold separate training sessions for non-English-speaking staff members who have contact with study subjects or information collected from study participants. For a list of educational and training materials, please see section 14 of this document. If your study is of a relatively long duration (longer than

a year), it is important to ensure that staff participate in follow-up training on human subjects protection.

6. INVOLVING THE US EMBASSY AND OTHER INSTITUTIONS

Effective partnership and collaboration should be established as early as possible in the protocol development process. There are several international collaborative organizations established in Thailand. AITRP scholar planning Thai-US collaborative project may contact one of the following organizations (list is not comprehensive) for advice and support.

Embassy of the USA, Bangkok
Information Resource Center
95 Wireless Road, Bangkok 10330, Thailand
Tel: +66-2205-4192, +66-2205-4641
Fax: +66-2650-8918
Email: irc@usa.or.th
Home Page: http://bangkok.usembassy.gov/services/irc/irc.htm

Thailand MOPH - US CDC Collaboration
DDC Building, 4th Floor, Ministry of Public Health, Soi 4,
Tiwanon Road, Nonthaburi 11000, Thailand
Tel: +66-2258-0669
Fax: +66-2591-5443
Home Page: http://tuc.or.th

Armed Forces Research Institute of Medical Sciences
U.S. Army Medical Component
315/6 Rajvithi Road, Bangkok 10400, Thailand
Tel: +66-2644-4888
Fax: +66-2247-6030
Home Page: http://www.afrims.org
Home Page: http://bangkok.usembassy.gov/embassy/usamc.htm

Research Institute for Health Sciences
P.O. Box 80 Chiang Mai University, Muang, Chiang Mai 50202, Thailand
Tel: +66-5394-5055 to 8, +66-5394-2508
Fax: +66-5322-1849, +66-5389-2298
Home Page: http://www.rihes.cmu.ac.th

7. TRANSFER OF FUNDS TO THAILAND

AITRP funds cannot be transferred to the Thai institution without a FWA. Once the IRB approvals and FWA are obtained, a system has to be set up for money transfer. This might require a budget, a scope of work/budget justification, and a completed sub-award (sub-contract) form to be submitted to the Sponsored Projects Office (SPO) at UCB. On the basis of this SPO will generate a contract document (3 weeks minimum) which will need to be signed by the authorized signatory at the Thai institution and returned to SPO. Once the signed contract has been received at SPO, the funds can be released to the Thai institution upon submission of an invoice (via fax is okay). This process often takes 2-3 months even with courier delivery to and from Thailand. Although the

assumption with an invoice is that the funds have been spent and that the institution is requesting a reimbursement, there are no restrictions on when an invoice can be submitted which allows UCB to disburse funds prior to undertaking any work in Thailand. The following information will be required for transferring funds to Thailand:

a. Beneficiary (Thai institution's name)
b. Beneficiary's address and email address
c. Beneficiary's bank account number
d. Beneficiary's bank name and address
e. SWIFT code of the Thai bank

In addition, the Thai institution/agency will need to possess a valid Foreign Contribution Regulation Act (FCRA). FCRA Registration means registration under Foreign Contribution (Regulation) Act, 1976. This is necessary, if an NGO wants to receive any funds, material etc. from a 'foreign source'. Any foreign agency (or person) or organization which is not controlled by Thais is a 'foreign source'. Note that once funds have been transferred from the US to an FCRA account, these funds cannot be returned. That is, if funds are under-spent, they cannot be returned to UCB or the US institution. This is why it is usually best to transfer funds as a reimbursement of expenses rather than as an advance. Typically, many Thai institutions will not have sufficient funds of their own to start up a research project. Thus, the first one or two invoices may need to be advanced. Subsequently, it is better to reimburse actual expenses.

8. SPECIAL SITUATIONS: EXPORT OF BIOLOGICAL SPECIMENS FROM THAILAND

Researchers who are planning to send biological specimens from Thailand to the US (or other countries) should be aware of specific guidelines issued by the MOPH, Government of Thailand and the collaborating institution(s), for export of biological specimens. In addition to obtaining approval for export of biological specimens, researchers are also expected to obtain an import license for importation of biomedical material from Thai Food and Drug Administration (Thai FDA).

To set up a system for export of biological specimens out of Thailand might take a long time. A small number of specimens may be sent out of Thailand for quality control purposes in short notice, but if all the tests need to be done outside of Thailand, there are lots of hurdles and time delays to overcome.

9. SPECIAL SITUATIONS: NATIONAL REPOSITORY REGULATION FOR HIV/AIDS RELATED SPECIMENS IN THAILAND

The Thai NIH has established a national repository unit to store, study and distribute biological specimens obtained from different vaccine-related studies in Thailand, including cohorts. The repository will function as a service to all HIV/AIDS vaccine research in the country. This facility will ensure standard specimen collection for re-testing and for future assays. The Thai NIH has been actively working with AIDS Division and the expert panel on laboratory aspects of clinical research network to draft recommendations for standard specimen collection procedures. Currently, more than 26,000 specimens of the volunteers participating in the phase III trials are being kept in this repository. AITRP scholar who will be involved in research related to HIV/AIDS

vaccine trial should be familiar with this regulation. More information may be obtained by contacting AVCU at telephone number: +66-2590-3209 or writing to vipa@aidsthai.org or vipa@health.moph.go.th (see list of contacts for full contact information).

10. SPECIAL SITUATIONS: INDUSTRY FUNDING AND SUPPORT

Researchers who receive assistance or funding from the industry (e.g., drug or device companies) have to follow specific guidelines "Working with industry," per the UCB Sponsored Projects Office (SPO). Please see www.spo.berkeley.edu/industry.html.

All funding and/or material contribution has to be received via the SPO. The SPO will negotiate and sign a legal contract with the industry to protect the rights of the researchers and to ensure that the agreement between the industry and research team conforms to UCB's policies. Individual researchers are not allowed to directly sign any contract or agreement with the industry. Even when drugs or kits are donated, they still need to be received via SPO. The SPO will negotiate and sign a "Material Transfer Agreement" with the industry sponsor for in-kind contribution or donation of drugs/device to the study. Industry funding/support must be disclosed in the CPHS cover sheet and also in the conflict of interest form. The SPO will not sign any agreement with the industry until CPHS review is complete.

11. VISA STATUS AND ENROLLMENT DURING FIELD RESEARCH IN THAILAND

International students at UCB (on J or F visa) are required to be enrolled full-time each semester, in order to maintain their 'status' as legal aliens in the US. Therefore, students who plan to be away from Berkeley for prolonged periods during field work might "fall out of status." It is critical to meet with an international student's advisor from the Services for International Students and Scholars (SISS) at UCB [http://ias.berkeley.edu/siss/] before leaving for Thailand. Students might need new Student and Exchange Visitor Information System (SEVIS) visa documents (DS-2019 or I-20) for re-entering the US after field training. In some cases, students might need to apply for new US visas before re-entry. Since the period of absence will vary from student to student, it is important to get individualized counseling from the SISS adviser early during the planning phase of the field project.

Visa regulations rapidly change and it is important to constantly stay in touch with SISS to get the latest information. The SISS has a listserv which is used to notify through email international students about immigration procedures and travel alerts [http://ias.berkeley.edu/siss/intlstudents/stlistserv.htm]. If you haven't already signed up for this, please do so. It is the best current source of immigration/travel information for international students.

Prolonged absence from school also affects progress towards degree and Graduate Division requirements. It is important to work out the academic registration/enrollment issues with the Epidemiology Graduate Assistant (Ron Jeremicz) or the Dean's office (Rick Love at 19 Warren Hall), and the Graduate Division before leaving for Thailand. A leave of absence can be granted for up to one year but arrangements must be made beforehand.

Foreign (that is, non-Thai) nationals planning to do research in Thailand should contact one of the Thai diplomatic representative offices for advice on visa options. There are

four Thai diplomatic representative offices in the US, including the Royal Thai Embassy in Washington DC, and three Consulates throughout the U.S. - one in Chicago, one in New York City, and the other in Los Angeles. There is also the Permanent Mission of Thailand to the United Nations in New York and there are several Honorary Thai Consulates. Please visit: http://www.thaiembdc.org/index.htm to see the list of states which that particular office serves. AITRP scholars at UCB should contact the Royal Thai Consulate General in Los Angeles by Email at thai-la@mindspring.com or by telephone at 323-962-9574 (Monday through Friday from 9:00 a.m. to noon and 1:00 p.m. to 4:00 p.m.) for advice.

12. KEEPING THE FOGARTY AIDS INTERNATIONAL TRAINING AND RESEARCH PROGRAM INFORMED

Please keep the following people informed about your field training, and make sure they have a folder with copies of all important documents (IRB approvals, FWA, etc.).

Arthur L. Reingold	Director, AITRP and Head, Division of Epidemiology School of Public Health Email: reingold@berkeley.edu Tel: 510-642-0327
Diane Hinkly	Division Manager, Division of Epidemiology School of Public Health Email: dmhinkly@berkeley.edu Tel: 510-643-0380
Juanita Cook	Fogarty Program Coordinator, Division of Epidemiology School of Public Health Email: juanitac@berkeley.edu Tel: 510-643-8154
Ron Jeremicz	Graduate Student Adviser, Division of Epidemiology School of Public Health Email: rtj@berkeley.edu Tel: 510-643-9912
International Student Adviser, SISS	Services for International Students and Scholars Email: siss@berkeley.edu Tel: 510-642-2818

The Epidemiology Division Team
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(Administrative Assistant),
Diane Hinkly
(Division Manager),
Ron Jeremicz
(Graduate Adviser),
Susan Meyer
(Administrative Assistant),
Juanita Cook
(AITRP Program Coordinator)

13. LIST OF CONTACTS

Agency	Contact Detail
AVCU - AIDS Vaccine Coordinating Unit, Thailand	AIDS Vaccine Coordinating Unit Bureau of AIDS, TB and STIs Department of Disease Control Ministry of Public Health, Tiwanon Road Nonthaburi 11000, Thailand
AITRP, Fogarty International Center, USA	Division of International Training and Research Fogarty International Center National Institutes of Health Building 31, Room B2C39 31 Center Drive, MSC 2220 Bethesda, MD 20892-2220 http://www.fic.nih.gov/programs/aitrp/aitrp.html
CHR - Committee on Human Research at UCSF, USA	Committee on Human Research Office of Research 3333 California Street, Suite 315 University of California San Francisco, CA 94118 http://www.research.ucsf.edu/chr/index.asp
CPHS - Committee for the Protection of Human Subjects at UCB, USA	Committee for the Protection of Human Subjects University of California at Berkeley 101 Wheeler Hall Berkeley, CA 94720-1340 http://cphs.berkeley.edu
IRC - Information Resource Center, Embassy of the USA, Thailand	Information Resource Center Embassy of the USA, Thailand 95 Wireless Road Bangkok 10330, Thailand http://bangkok.usembassy.gov/services/irc/irc.htm
MOPH ERC - Ministry of Public Health Ethical Review Committee, Thailand	Office of the Secretary Ethical Review Committee for Research in Human Subjects Department of Medical Services 3rd Floor of Building 4, Ministry of Public Health Tiwanon Road, Nonthaburi 11000, Thailand
NIH - National Institutes of Health, USA	National Institutes of Health 9000 Rockville Pike Bethesda, Maryland 20892 http://www.nih.gov/
OHRP - Office for Human Research Protections, USA	Office for Human Research Protections Department of Health and Human Services The Tower Building 1101 Wootton Parkway, Suite 200 Rockville, MD 20852 http://ohrp.osophs.dhhs.gov/index.html
Royal Thai Consulate - General, Los Angeles, USA	Royal Thai Consulate - General, Los Angeles 611 North Larchmont Boulevard, 2nd Floor Los Angeles, CA 90004 http://www.thai-la.net

Agency	Contact Detail
SISS - Services for International Students and Scholars at UCB, USA	Services for International Students and Scholars 2299 Piedmont Avenue (at International House) University of California, Berkeley Berkeley CA 94720-2321 http://www.ias.berkeley.edu/siss/
SPO - Sponsored Projects Office at UCB, USA	Sponsored Projects Office University of California, Berkeley 336 Sproul Hall Berkeley CA 94720 http://www.spo.berkeley.edu/

14. LIST OF WEBSITES AND RESOURCES

Resource	Website
AFRIMS, US Army Medical Component	http://www.afrims.org
AITRP, Fogarty International Center	http://www.fic.nih.gov/programs/aitrp/aitrp.html
Consular Service, Royal Thai Embassy	http://www.thaiembdc.org/index.htm
CPHS, UCB	http://cphs.berkeley.edu:7006/
CPHS templates for IRB protocol and consent forms	http://cphs.berkeley.edu/content/sample.htm
CHR, UCSF	http://www.research.ucsf.edu/chr/index.asp
Forum for Ethical Review Committees in Thailand	http://www.geocities.com/fercit/index.html
NIH - National Institutes of Health	http://www.nih.gov/
NIH online training course on human subjects protection	http://cme.cancer.gov/c01/
IRC, US embassy, Bangkok	http://bangkok.usembassy.gov/services/irc/irc.htm
OHRP Home page	http://www.hhs.gov/ohrp/
OHRP guidelines for using external IRBs	http://www.hhs.gov/ohrp/assurances/index.html
OHRP educational materials for IRBs	http://www.hhs.gov/ohrp/education/#materials
OHRP online IRB guidebook	http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
OHRP database of institutions with registered IRBs	http://ohrp.cit.nih.gov/search/asearch.asp#ASUR
OHRP database of institutions with assurances	http://ohrp.cit.nih.gov/search/asearch.asp#ASUR
OHRP - IRB registration form	http://www.hhs.gov/ohrp/humansubjects/assurance/regirb.htm
OHRP - IRB registration guidelines	http://www.hhs.gov/ohrp/humansubjects/assurance/regirbi.htm
OHRP - FWA application form	http://www.hhs.gov/ohrp/humansubjects/assurance/ifilasur.htm
OHRP - FWA application guidelines	http://www.hhs.gov/ohrp/humansubjects/assurance/ifilasuri.htm

Resource	Website
OHRP - guidelines on minimal requirements for new IRBs	http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.107
Research Institute for Health Sciences, Chiang Mai University	http://www.rihes.cmu.ac.th
Services for International Students and Scholars, UCB	http://ias.berkeley.edu/siss/
SPO, UCB	http://www.spo.berkeley.edu/
SPO - "Working with industry", guidelines	www.spo.berkeley.edu/industry.html
Thai MOPH Home page	http://eng.moph.go.th/index.asp
TUC, Thailand MOPH - US CDC Collaboration	http://tuc.or.th
University of California, Berkeley	www.berkeley.edu

15. LIST OF ABBREVIATIONS

- AFRIMS — Armed Force Research Institute of Medical Services, Thailand
- AITRP — AIDS International Training and Research Program, USA
- AVCU — AIDS Vaccine Coordinating Unit, Thailand
- CDC — Centers for Disease Control and Prevention, Atlanta, USA
- CHR — Committee on Human Research, UCSF
- CPHS — Committee for the Protection of Human Subjects, UCB
- DHHS — Department of Health and Human Services, USA
- ERC — Ethical Review Committee for Research in Human Subjects
- FCRA — Foreign Contribution Regulation Act
- FDA — Food and Drug Administration
- FIC — Fogarty International Center, USA
- FWA — Federalwide Assurance
- HHS — Department of Health and Human Services, USA
- IEC — Independent Ethics Committee
- IRB — Institutional Review Board
- MOPH — Ministry of Public Health
- MOPH ERC — Ethical Review Committee for Research in Human Subjects, Ministry of Public Health, Thailand
- NAC — National AIDS Committee, Thailand
- NGO — Non-Governmental Organization
- NIH — National Institutes of Health, USA
- OHRP — Office for Human Research Protections, USA
- SEVIS — Student and Exchange Visitor Information System
- SHAVD — Subcommittee on HIV/AIDS Vaccine Development, Thailand

- SISS — Services for International Students and Scholars, UCB
- SPO — Sponsored Projects Office, UCB
- TUC — Thailand MOPH - US CDC Collaboration, Thailand
- UCB — University of California, Berkeley
- UCSF — University of California, San Francisco
- WHO — World Health Organization

16. LIST OF QUICK GUIDES

17. CONTRIBUTORS AND CREDITS

This survival guide has been modified from the documents entitled: “A survival Guide for Conducting International Collaborative Research in India (October 2003)” by Madhukar Pai, Nitika Pai, Purnima Madhivanan, Asheena Khalakdina, and Suneeta Krishnan, and “A survival Guide for Conducting International Collaborative Research in Uganda (May 2004)” by Samuel Malamba and Edward Bitarakwate. The following persons listed below have contributed to this Thai version:

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PICTURE CREDITS

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All others: Madhukar Pai
Nitika Pai
Samuel Malamba

Appendix 1: List of Thai Institutions with IRBs (as of August 2004)

IRB number	Institution	City
IRB00000904	Mahidol U - Faculty Tropical Med IRB#1	BANGKOK
IRB00001189	Khon Kean U Ethics Committee IRB#1	KHONE KAEN
IRB00001439	Royal Thai Army Med Dept IRB#1	BANGKOK
IRB00001607	Chulalongkorn U IRB#1	BANGKOK
IRB00001629	Ministry Public Health, Thailand IRB#1	NONTHABURI
IRB00001734	Mahidol U - Faculty Med Ramathibodi Hosp IRB#1	BANGKOK
IRB00001994	Siriraj Hosp, Mahidol U IRB #1	BANGKOK
IRB00002623	Mahidol U IRB #1	NAKORNPATHOM
IRB00002688	Chiang Mai U, Faculty Associated Med Sci IRB #1	CHIANG MAI
IRB00003039	Faculty Med, Prince Songkla U IRB #1	SONGKHLA
IRB00003396	Bangkok Metropolitan Admin (BMA) IRB #1	BANGKOK
IRB00003605	Chiang Mai U, Rsch Inst Hlth Sci IRB #1	CHIANG MAI
IRB00003938	Assumption U Thailand IRB # 1	BANGKOK
IRB00004184	Faculty Med, Chiang Mai U IRB # 1	CHIANG MAI

Appendix 2: List of Thai Institutions with FWA (as of August 2004)

Assurance	Institution	City	Type*
FWA00000015	Armed Forces Rsch Inst Med Sci (AFRIMS)	BANGKOK	C
FWA00000926	Mahidol University, Faculty Tropical Med	BANGKOK	F
FWA00000943	Chulalongkorn U	BANGKOK	F
FWA00001604	Chonburi Regional Hosp	CHONBURI	F
FWA00001605	Nakornping Hosp	CHIANG MAI	F
FWA00001606	Nakhonpathom Hosp	NAKHONPATHOM	F
FWA00001607	Chiangrai Regional Hosp	CHIANG RAI	F
FWA00001608	Hlth Promotion Ctr Region 10	CHIANG MAI	F
FWA00001608	Mother and Child Hosp	CHIANG MAI	C
FWA00001609	Chiang Kham Hosp	PRAYAO	F
FWA00001610	Banglamung Hosp	CHONBURI	F
FWA00001611	Klaeng Hosp	RAYONG	F
FWA00001612	Khon Kaen Hosp	KHON KAEN	F
FWA00001613	Kalasin Hosp	KALASIN	F
FWA00001614	Hat Yai Hosp	HAT YAI	F
FWA00001615	Kranuan Crown Prince Hosp	KHONKAEN	F
FWA00001616	Mae Sai Hosp	CHIANG RAI	F
FWA00001617	Chacheongsao Hosp	CHACHEONGSAO	F
FWA00001618	Mahasarakam Hosp	MAHASARAKAM	F
FWA00001619	Mae Chan Hosp	CHIANG RAI	F
FWA00001643	Prapokklao Hosp	CHANTABURI	F
FWA00001644	Samutsakorn Hosp	SAMUTSAKORN	F
FWA00001645	Pranangklao Hosp	NONTHABURI	F
FWA00001646	Phayao Provincial Hosp	PHAYAO	F
FWA00001647	Phan Hosp	CHIANG RAI	F
FWA00001648	Phaholpolphayuhasena Hosp	KANCHANABURI	F
FWA00001649	Roi-et Hosp	ROI-ET	F
FWA00001650	Rayong Hosp	RAYONG	F
FWA00001651	Bhumibol Adulyadej Hosp	BANGKOK	F
FWA00001652	Ratchaburi Hosp	RATCHABURI	F
FWA00001653	Somdej Prapinklao Hosp	BANGKOK	F
FWA00001695	Mahidol U, Ramathibodi Hosp	BANGKOK	F
FWA00001719	Mahidol U, Siriraj Hosp	BANGKOK	F
FWA00001813	Royal Thai Army Med Dept	BANGKOK	F
FWA00001813	Anandharmahidol Hosp	LOPBURI	C
FWA00001813	Armed Forces Rsch Inst Med Sci	BANGKOK	C

Assurance	Institution	City	Type*
FWA00001813	Phramongkutklao Hosp	BANGKOK	C
FWA00001813	Phramongkutlao Coll Med	BANGKOK	C
FWA00001813	Royal Thai Army Nursing Coll	BANGKOK	C
FWA00001953	Ministry Public Hlth	NONTHABURI	F
FWA00001953	Ministry Public Hlth	BANGKOK	C
FWA00002126	Institut de Recherche pour le Developpement (IRD)	BANGKOK	F
FWA00002126	IRD 054/PPT 57/2 Faham Road, Soi 3	CHIANG MAI	C
FWA00002126	IRD Lab in Faculty Associated Med Sciences, Chiang Mai U	CHIANG MAI	C
FWA00002127	Khaiprajaksillapakom Hosp	UDONTHANI	F
FWA00002128	Samutprakarn Hosp	SAMUTPRAKARN	F
FWA00002129	Nong Kai Hosp	NONG KAI	F
FWA00002130	Hlth Promotion Centre, Region 6	KHON KAEN	F
FWA00002130	Mother and Child Hosp	KHON KAEN	C
FWA00002131	Buddhachinaraj Hosp	PISANULOK	F
FWA00002132	Somdej Pranangchao Sirikit Hosp	CHONBURI	F
FWA00002133	Hlth Promotion Ctr Region I	BANGKEAN	F
FWA00002133	Mother and Child Hosp	BANGKOK	C
FWA00002134	Nopparat Rajathanee Hosp	BANGKOK	F
FWA00002135	Lamphun Hosp	LAMPHUN	F
FWA00002250	Queen Sirikit Natl Inst Child Hlth	BANGKOK	F
FWA00002882	Mahidol U	NAKHONPATHOM	F
FWA00002882	ASEAN Inst for Hlth Devl	NAKHONPATHOM	C
FWA00002882	Dentistry Hosp	BANGKOK	C
FWA00002882	Faculty Dentistry	BANGKOK	C
FWA00002882	Faculty Engineering	NAKHONPATHOM	C
FWA00002882	Faculty Environment & Resource Studies	NAKHONPATHOM	C
FWA00002882	Faculty Med Tech	BANGKOK	C
FWA00002882	Faculty Medicine, Ramathibodi Hosp	BANGKOK	C
FWA00002882	Faculty Medicine, Siriraj Hosp	BANGKOK	C
FWA00002882	Faculty Nurse	BANGKOK	C
FWA00002882	Faculty Pharmacy	BANGKOK	C
FWA00002882	Faculty Physical Therapy & Applied Movement Sci Proj	BANGKOK	C
FWA00002882	Faculty Public Hlth	BANGKOK	C

Assurance	Institution	City	Type*
FWA00002882	Faculty Sci	BANGKOK	C
FWA00002882	Faculty Social Sci & Humanities	NAKHONPATHOM	C
FWA00002882	Faculty Tropical Med	BANGKOK	C
FWA00002882	Inst Language & Culture for Rural Devl	NAKHONPATHOM	C
FWA00002882	Inst Nutrition	NAKHONPATHOM	C
FWA00002882	Inst Sci & Tech for Rsch & Devl	NAKHONPATHOM	C
FWA00002882	Inst for Population & Social Rsch	NAKHONPATHOM	C
FWA00002882	Mahidol U	NAKHONPATHOM	C
FWA00002882	Natl Inst for Child & Family	NAKHONPATHOM	C
FWA00002882	Natl Lab Animal Ctr	NAKHONPATHOM	C
FWA00002882	Ramathibodi Hosp	BANGKOK	C
FWA00002882	Siriraj Hosp	BANGKOK	C
FWA00002882	Tropical Med Hosp	BANGKOK	C
FWA00003418	Srinagarind Hosp	KHON KAEN	F
FWA00003781	Faculty Associated Med Sci Chiang Mai U	CHIANG MAI	F
FWA00003790	Faculty Med , Prince Songkla U	SONGKLA	F
FWA00005164	Bangkok Metropolitan Admin (BMA)	BANGKOK	F
FWA00005355	Research Institute for Health Sciences, Chiang Mai U	CHIANG MAI	F
FWA00006263	Assumption U	BANGKOK	F
FWA00006391	Suan Prung Psychiatric Hospital	CHIANG MAI	F
FWA00006553	Thanyarak Institute on Drug Abuse	PATHUMTHANI	F
FWA00006553	Thanyarak Hospital	PATHUMTHANI	C
FWA00006703	Pfizer (Thailand) Limited	BANGKOK	C
FWA00006956	Rajavithi Hosp	BANGKOK	F
FWA00006966	InRes Clinical Consultants Co., Ltd.	BANGKOK	F
FWA00007260	Lampang Hospital	LAMPANG	F

* Where: 'F' = FWAs 'C' = Components in this country

Appendix 3: Checklist for Submission of a Research Protocol (Format Recommended by MOPH ERC)

This checklist is to be accompanied with copies of research proposal and protocol.

No.	Content	Yes	No
1	Does the proposed research have a concise and informative Thai title? If accompanied by an English title, are the meanings of both titles exactly the same?		
2	Are the name and address of the Principal Investigator(s) provided?		
3	Is the 2-page summary of proposed research attached?		
4	Does the introductory section include the following?		
	4.1 Background		
	4.2 Rationale and justification		
	4.3 Expected benefit(s)		
5	Is (are) the objective(s) clearly stated?		
6	Is (are) the location(s) where the research will take place and length of the research clearly stated?		
7	Does the methodology section include the following?		
	7.1 Study population (both experimental and control groups) detailing:		
	a. Sex		
	b. Age		
	c. Characteristics		
	d. Disease or specific sign/symptom		
	e. Number of study participants		
	7.2 Inclusion criteria		
	7.3 Exclusion criteria		
	7.4 Discontinuation criteria detailing:		
	a. Discontinuation criteria for study participants		
	b. Criteria for termination of the proposed research		
	7.5 Implementation and monitoring procedures, including data collection and analyses		
	7.6 Special considerations		
	a. If blood sample is required, are the objective(s), quantity and frequency of blood collection as well as the total number of blood collection clearly stated?		
	b. For clinical trial, are the trade and generic names of the drug, manufacturer's and distributor's names, including the registration number of licensed drug (if any), stated? For other non-pharmaceutical products, detailed information of the products and results of relevant research (if any) must be attached.		
	c. For research that requires an operation or any medical practice, is (are) the procedure(s) to be conducted described?		
8	Does the ethical consideration section include the following?		
	8.1 Foreseeable risks, including preventive and alleviative measures		
	8.2 Compensation, medical care and other services to be provided to the study participants who may be affected by any complications		
	8.3 Other related ethical aspects		
	8.4 Information sheet (in the format recommended by the ERC) in the Thai language, in which physicians or hospital's name, address and telephone number have been included		
	8.5 Informed consent document (using format as advised by the ERC or similar format) in the Thai language		

No.	Content	Yes	No
	8.6 Rationale(s) for the exemption of the use of information sheet and/or informed consent, if applicable		
9	Is the summary of budget and source of funding(s) provided?		
10	Is the list of references provided?		
11	Are the curriculum vitae of all investigators provided? (may be provided as an addendum)		
12	Is letter of approval to conduct the proposed research at the location/institution where the research will take place attached?		
13	Is (are) the result(s) of the ethical or human rights review by the ethic committee(s) of the implementing institution(s), if available, provided?		
14	Is the proposed research signed by the Principal Investigator(s) or project team leader and all participating researchers?		
15	Is(are) the questionnaire(s) and/or interview script to be used in the proposed research provided?		
16	Is cover letter signed by the Principal Investigator's supervisor attached?		

Please make sure that name of the ERC is stated correctly in all of submitted documents.
The English name is "The Ethical Review Committee for Research in Human Subjects Ministry of Public Health, Thailand".
The Thai name is "คณะกรรมการพิจารณาการศึกษาวิจัยในคน กระทรวงสาธารณสุข".

Appendix 4: Information Sheet
(Format Recommended by MOPH ERC)

1. Title of proposed research _____

2. Name and title of Principal Investigator _____

3. Contact info of Principal Investigator:
   Address _____
   Office phone number_____
   Home phone number_____
   Cellular phone number_____
   Fax number _____
   Pager number _____

4. Essential information includes:
   - 4.1. Rationale and justification
   - 4.2. Objective(s)
   - 4.3. Methodology
   - 4.4. Length of required participation time
   - 4.5. Foreseeable benefit for participants and others (participants must be informed clearly if there is no direct benefit)
   - 4.6. Foreseeable risk or discomfort to the participants, associated with the participation in the research, both physical and psychosocial risks
   - 4.7. Prevention of anticipated risks and measures prepared to cope with problem
   - 4.8. Any standard or alternative procedures or courses of treatment that may be as advantageous to the participants as the procedure or treatment being tested
   - 4.9. The extent to which confidentiality of records in which the participants are identified will be maintained
   - 4.10. The extent of the investigator's responsibility, if any, to provide medical services to the participants
   - 4.11 Therapy to be provided free of charge for specified type of research related injury
   - 4.12 Compensation, if any, to the participants, including the amount and length of compensation
   - 4.13 Whether the participants or their families or dependents will be compensated for disability or death resulting form participating in the research, the amount and length of compensation must be stated clearly
   - 4.14 That the participants are free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which they would otherwise be entitled
   - 4.15 Name, address, telephone numbers of physicians or investigators to be contacted conveniently both during and out of duty in case of need or emergency

Appendix 5: Informed Consent Document
(Format Recommended by MOPH ERC)

Title of research _____

Consent date (d/m/y) _____

Before consenting to participate in this research, I have been explained by the investigator the objective(s), methodology, foreseeable risks/signs/symptoms and benefits that may occur by participating in this research or by the testing drug; and I clearly understand all of that which that has been explained to me.

I understand that the investigator is obliged to answer all of my inquires to my satisfaction.

I understand that participation in this research is completely voluntary and I have the right to withdraw from this research at anytime. Withdrawal from this research will not have any impact on any treatment and care to which I may be entitled.

The investigator has an obligation to protect my confidentiality. Persons not related to this research will not have access to my confidential information. Reports made available to the public will contain only a summary of the results of the research.

The investigator has an obligation to provide treatment and care free of charge as well as compensation for losing opportunities or disability should adverse events occur. I can contact the person listed below for information regarding treatment and care or compensation.

Name _____

Contact information _____

I have read and fully understood the above statement. My participation in this research is completely voluntary.

Participant _____

Witness 1 _____

Witness 2 _____

I cannot read, but the content in this form has been read to me by the investigator. I clearly understand and my participation in this research is completely voluntary.

Participant _____

Witness 1 _____

Witness 2 _____

For minors, written consent must be obtained from his/her legal guardian.

Legal guardian _____

Witness 1 _____

Witness 2 _____

For a person incapable of making a decision consciously (mentally retarded or unconscious), written consent must be obtained from his/her legal guardian or closet relative.

Legal guardian/closest relative _____

Witness 1 _____

Witness 2 _____

Note: This form may be altered to delete non-relevant content or add related content, if necessary.

Appendix 6: Estimated Expenditure Form
(Format Recommended by MOPH ERC)

Title of proposed research _____

Name of Principal Investigator _____

Name of responsible organization _____

Source of funding (please also specify relationship of the investigators and funding source) _____

Duration of proposed research _____

Budget justification

1. Personnel

    1.1 Number of full time staff ____
    Duration _____ months
    Total salary _____ Thai Baht

    1.2 Number of part time staff ____
    Duration _____ months
    Total salary _____ Thai Baht

2. Honorarium for investigators _____

3. Honorarium for consultants _____

4. Subsidy for participants _____

5. Curative cost (if any) _____

6. Operation cost _____

7. Report preparation cost _____

8. Others _____

Total _____ Thai Baht