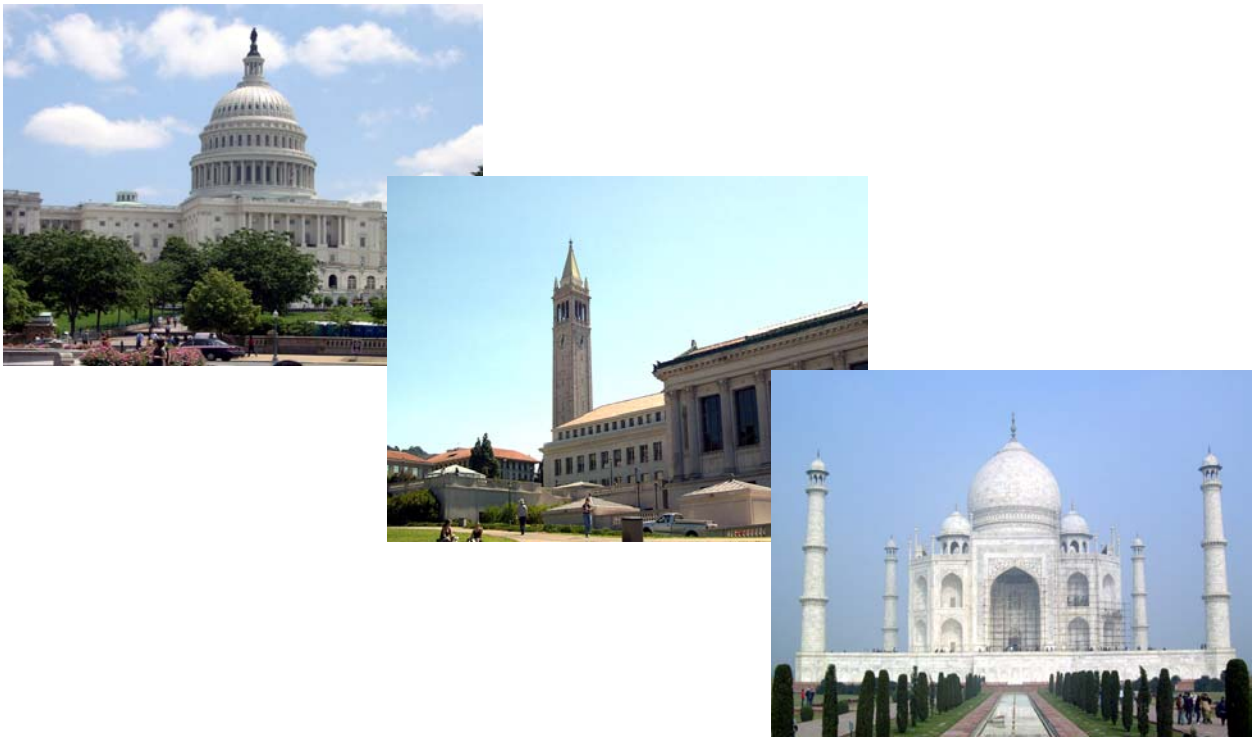
A Survival Guide for Conducting International Collaborative Research in India



October, 2003

Fogarty AIDS International Training Program (AITRP)
University of California, Berkeley & University of California, San Francisco

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 developing country like India. International research may also raise unique ethical issues and dilemmas.

This survival guide, compiled by current and former Fogarty scholars, is intended to assist Fogarty AITRP scholars planning collaborative research projects in India. The guidelines provided are not comprehensive and are, naturally, subject to change. You are advised to check with relevant agencies (such as ICMR and AITRP/NIH), and the AITRP team for any new developments, prior to starting your research project in India.

With best wishes,

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1. APPROVALS REQUIRED BEFORE STUDIES CAN BE INITIATED IN INDIA

CPHS approval from UC Berkeley:

All research involving human subjects requires approval from the Committee for the Protection of Human Subjects (CPHS), UC Berkeley: 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

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.
2. Respond to CPHS requests/calls immediately.
3. 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.
4. Get your faculty adviser to critique your draft protocol. Make sure the CPHS cover sheet is signed by your faculty adviser.
5. 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.
6. 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.
7. 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).
8. 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.
9. If your project has already been approved by the IRB of your Indian 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 Indian institution and attach this to your CPHS protocol. The letter of support should briefly describe the project and state that the Indian institution is willing to collaborate with UCB and support your project.
10. 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.

IRB approval from the collaborating Indian institution(s):

All collaborative research projects require IRB approval from the collaborating Indian institution(s). The first step would be to check if the Indian institute has a functioning IRB in place. Major institutions and research centers usually have IRBs. Check with your Indian collaborators about this and the time they usually take for the review process. Some Indian 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 Indian institution; or, 2) convince the Indian 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 Indian 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://ohrp.osophs.dhhs.gov/humansubjects/assurance/iprotsup.rtf

If the collaborating Indian institution decides to constitute its own IRB, then OHRP guidelines (see box) may be used to decide on IRB composition, role, etc:

http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirbi.htm. In addition, the ICMR has also provided guidelines on IRBs: http://icmr.nic.in/ethics_SOP.pdf

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 Office for Human Research Protections (OHRP) offers educational materials for IRBs (including videos and CDs). Please check their site: http://ohrp.osophs.dhhs.gov/educmat.htm. OHRP also offers an online IRB Guidebook: http://ohrp.osophs.dhhs.gov/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 Suneeta Krishnan, a former Fogarty scholar, currently working in India [please see list of contributors at the end of this document] for assistance/advice regarding IRB establishment and ethics training in India. She has conducted such programs in the past and her team is developing educational materials relevant for India.

After this process is complete, request the Indian IRB to review and approve your protocol. If the IRB does not meet regularly, you will need to request your Indian 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 Indian IRB a sample IRB approval letter—you could use the CPHS letter as a template).

US guidelines on IRB composition and role

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.
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/

IRB approvals from external US or international institution(s):

In addition to UCB and Indian 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 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 Indian 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

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 review.

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 IRB (CPHS and the Indian 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 Indian IRB approvals first, and subsequently apply for external IRB renewals.

2. IRB REGISTRATION AND ASSURANCE FROM OHRP FOR THE INDIAN 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 NIH-funded grants such as AITRP) must obtain an assurance of compliance approved by the Office for Human Research Protections (OHRP: http://ohrp.osophs.dhhs.gov/index.html). Also, as per AITRP regulations, the Indian 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. Indian 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 HHS 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 FWA:

Before applying for a FWA, check if your collaborating Indian institute has already filed an assurance. Check: http://ohrp.cit.nih.gov/search/asearch.asp#ASUR. More than 90 Indian hospitals and medical colleges (including some NGOs) already have FWAs. 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 Indian 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://ohrp.osophs.dhhs.gov/humansubjects/assurance/irbs.htm. The form has to be submitted by the Indian institution (although you can help in completion of the form and following-up with OHRP). If the Indian 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 Indian IRB is assigned a unique ID number. The Indian IRB information also gets posted on the OHRP website http://ohrp.cit.nih.gov/search/asearch.asp#IORG
c. The last step is to submit an application for FWA. This application form needs to be submitted by the Indian institution and signed by the head of the institution. The form [http://ohrp.osophs.dhhs.gov/humansubjects/assurance/fwas.htm] can be submitted via mail or completed online (in which case the page with the Indian 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 Indian 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 Indian institution. The FWA is valid only for a limited period (usually, 3 years); it has to be renewed periodically.

Getting the FWA faster

The FWA application cannot be processed without prior IRB registration. So, apply for the IRB registration early.

It is very important to call/email OHRP and follow-up with the OHRP staff member assigned to handle IRB registrations and FWAs for India. Without follow-up, the process can take several weeks. To find out the name of the staff member assigned to handle submissions from India, check: http://ohrp.osophs.dhhs.gov/daqi-staff.htm#Region%205

One important reason for delay of FWA approval is the time required for the page with the institution head's signature to reach OHRP from India. You could speed up the process by submitting the application electronically, and making sure the signature page is sent to OHRP via courier from India.

3. ICMR GUIDELINES FOR BIOMEDICAL RESEARCH IN INDIA

The Indian Council of Medical Research (ICMR http://www.icmr.nic.in) is India's apex organization for scientific research in medicine and health. In 2000, the ICMR released its report on ethical guidelines for biomedical research. This report forms the basis for conducting ethical research in India. The full report is available at: http://icmr.nic.in/ethical.pdf. This report has a separate section on foreign collaborative projects.

All AITRP scholars planning studies in India should be familiar with the ICMR guidelines. The ICMR guidelines are also listed on the OHRP FWA application form—these guidelines could be used by Indian IRBs instead of guidelines such as 45 CFR 46, CIOMS, etc.

4. TRAINING OF STUDY PERSONNEL IN HUMAN SUBJECTS PROTECTION

It is important that all field staff members that have contact with study subjects 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 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 subjects. 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.

5. CLEARANCES FROM THE ICMR AND GOVERNMENT OF INDIA

All research projects involving foreign assistance and/or collaboration (e.g. NIH-funded grants in India) have to be cleared by the ICMR and Government of India. An Indo-Foreign Cell (IFC) was set up in the Indian Council of Medical Research in the early 1980s to coordinate collaboration in biomedical research between India and other countries. The IFC was upgraded to the Division of International Health (IHD) in 2000. By and large, biomedical research has figured in practically every bilateral agreement in the field of Science and Technology. In addition, there have been a few specific agreements signed by the Ministry of Health and Family Welfare with other countries as well as those signed directly by the ICMR. The purposes of these agreements have been for: (i) exchange of scientific information; (ii) exchange of scientists/technicians and joint execution of scientific projects, including support in the procurement of scientific equipments; and (iii) organization of joint scientific meetings, seminars, workshops, symposia on identified subjects of cooperation.

Applications for research projects involving foreign assistance/collaboration in health research are to be submitted to ICMR for approval of Govt. of India through Health Ministry's Screening Committee (HMSC). The ICMR is the secretariat of HMSC. **This application must be submitted by your collaborating Indian institution. The HMSC will not communicate with the US investigators.** The application process involves submission of the protocol and other materials (such as Indian and US IRB approvals, budget, and consent forms), along with an application form that has 45 questions. 30 copies of this package have to be submitted to ICMR. The forms and instructions are found at: http://icmr.nic.in/guide.htm. The ICMR will screen the application and forward it for technical peer review. This technical review process can take up to 6 months or even longer. HIV-related research protocols will be reviewed by the National AIDS Control Organization (NACO). This can delay the review further. Indian investigators may be requested to respond to queries raised in the technical reviews. Once these queries have been responded to, the application is tabled before the Health Ministry's Screening Committee, which meets once in 3 months. The entire approval process can take up to 1 year or even longer, depending on the issues identified during technical review.

It is very important that the Indian investigators establish a relationship with key personnel at ICMR. They should begin contacting ICMR as soon as they receive an

acknowledgement of their submission. Typically, the acknowledgement letter states the name of the person/office that is handling the application.

Do AITRP students need ICMR and HMSC clearance for their field training/research conducted as part of their graduate studies? There is no clarity regarding this issue. The ICMR guidelines do not specifically mention review of training projects. After informal discussions with ICMR staff, we understand that ICMR needs to clear all foreign collaborative research projects (such as NIH RO1, USAID funded grants, etc.) for which they have bilateral agreements in place. Those planning to work with governmental agencies (such as NACO and the ICMR institutes) might also have to obtain HMSC clearance before starting the study. However, the ICMR does not normally engage with Indian nationals who plan to return to India for field work as part of graduate or doctoral training. The ICMR does not usually review training projects. Fogarty scholars are advised to tackle this issue on a case-by-case basis in consultation with Dr Reingold and their Indian collaborators.

Time delays and other constraints

AITRP scholars who submit their protocols to ICMR and HMSC for review will have to be prepared for very long delays. The approval process could take anywhere from 6 months to 2 years. Protocols have also been denied approval (rarely). It might be a good idea to submit the protocol early during the PHD program and budget for a 1-2 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).

6. INVOLVING THE OFFICE OF THE HEALTH ATTACHE, US EMBASSY, INDIA

The Office of the Health Attaché, US Embassy, New Delhi, coordinates Indo-US collaborations in health and scientific research [http://newdelhi.usembassy.gov]. This office provides advice and support to those planning Indo-US collaborative projects. The contact information: The Health Attaché, Embassy of the USA, Shantipath, Chanakyapuri, New Delhi – 110021 (Tel: 011-2419-8213). The key person to contact for advice and support is Mr. Manmohan Saxena at manmohan_saxena@hotmail.com (Tel: 011-2419-8647). He will assist with preparation of submissions and responses to ICMR and will follow-up with ICMR and HMSC, once the protocol has been submitted for review. Unlike with ICMR and HMSC, both you and your Indian investigators may get in touch with the Office of the Health Attaché. Getting in touch with Mr. Saxena is highly recommended, especially if you need to get HMSC approval. If you have received an NIH RO1 award, the Health Attache's office will automatically contact your Indian collaborator and explain the process of getting ICMR/HMSC approval.

7. TRANSFER OF FUNDS TO INDIA

AITRP funds cannot be transferred to the Indian 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 Indian institution and returned to

SPO. Once the signed contract has been received at SPO, the funds can be released to the Indian institution upon submission of an invoice (via fax is okay). This process often takes 2-3 months even with courier delivery to and from India. 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 India.

The following information will be required for transferring funds to India:

a. Beneficiary (Indian 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 Indian bank

In addition, the Indian institution/agency will need to possess a valid 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 Indians 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 Indian 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 advances. Subsequently, it is better to reimburse actual expenses.

8. SPECIAL SITUATIONS: EXPORT OF BIOLOGICAL SPECIMENS FROM INDIA

Researchers who are planning to send biological specimens from India to the US (or other countries) have be aware of specific guidelines issued by the Ministry of Health and Family Welfare, Government of India, for export of biological specimens. These guidelines entitled "Guidelines for Exchange of Human Biological Material for Biomedical Research Purposes" are available at: http://icmr.nic.in/min.htm. In addition to obtaining GOI approval for export of biological specimens, researchers are also expected to prepare a "Material Transfer Agreement" between the Indian and foreign institutions.

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

9. 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 UC Berkeley'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.

10. VISA STATUS AND ENROLLMENT DURING FIELD RESEARCH IN INDIA

International students at UC Berkeley (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 & Scholars (SISS) at UC Berkeley [http://ias.berkeley.edu/siss/] before leaving for India. Students might need new 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), Rick Love in the Dean's office (19 Warren Hall), and the Graduate Division before leaving for India. A leave of absence can be granted for up to one year but arrangements must be made beforehand.

Foreign (that is, non-Indian) nationals planning to do research in India should contact Mr. Saxena in the Health Attache's office in Delhi for advice on visa options. A research visa may take a lot of time and also may be refused (depending on the type of research you plan to do). A business visa may be a viable option. Persons of Indian Origin (PIO) may get five year multiple entry visas to India or may apply for a long term Person of Indian Origin (PIO) card.

11. KEEPING THE AITRP 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 & Head, Division of Epidemiology School of Public Health Email: reingold@uclink4.berkeley.edu Tel: 510-642-0327
Diane Hinkly	Division Manager, Division of Epidemiology School of Public Health Email: dmhinkly@uclink4.berkeley.edu Tel: 510-643-0380
Juanita Cook	Fogarty Program Coordinator, Division of Epidemiology School of Public Health Email: juanitac@uclink4.berkeley.edu Tel: 510-643-8154
Ron Jeremicz	Graduate Student Adviser, Division of Epidemiology School of Public Health Email: rtj@uclink4.berkeley.edu Tel: 510-643-9912
International Student Adviser, SISS	Services for International Students & Scholars (SISS) Email: siss@uclink.berkeley.edu Tel: 510-642-2818

The Epidemiology Division Team (L to R): Roberta Myers, Diane Hinkly (Division Manager), Ron Jeremicz (Graduate Adviser), Susan Meyer, Juanita Cook (AITRP Program Coordinator)

12. LIST OF ABBREVIATIONS

AITRP	AIDS International Training & Research Program, USA
CDC	Centers for Disease Control, Atlanta, USA
CHR	Committee on Human Research, UCSF
CPHS	Committee for the Protection of Human Subjects, UC Berkeley
DHHS	Department of Health and Human Services, USA
FCRA	Foreign Contribution Regulation Act
FIC	Fogarty International Center, USA
FWA	Federalwide Assurance
GOI	Government of India
HMSC	Health Ministry's Screening Committee, India
ICMR	Indian Council of Medical Research, India
IFC	Indo-Foreign Cell, ICMR, India
IHD	Division of International Health, ICMR, India
IRB	Institutional Review Board
NACO	National AIDS Control Organization, India
NGO	Non-Governmental Organization
NIH	National Institutes of Health, USA
OHRP	Office for Human Research Protections, USA
SISS	Services for International Students & Scholars, UC Berkeley
SPO	Sponsored Projects Office, UC Berkeley
UCB	University of California, Berkeley
UCSF	University of California, San Francisco
WHO	World Health Organization

13. LIST OF CONTACTS

Agency	Contact Details
AITRP, Fogarty International Center	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, UCSF	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	The University of California at Berkeley Committee for the Protection of Human Subjects 101 Wheeler Hall Berkeley, CA 94720-1340 http://cphs.berkeley.edu
Health Attaché Embassy of the USA, India	Health Attaché Embassy of the USA Shantipath, Chanakyapuri New Delhi – 110021 http://usembassy.state.gov/posts/in1/wwwhmain.html
ICMR - Indian Council of Medical Research	Indian Council of Medical Research V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi - 110029, India http://www.icmr.nic.in
NIH - National Institutes of Health	National Institutes of Health (NIH) 9000 Rockville Pike Bethesda, Maryland 20892 http://www.nih.gov/
OHRP - Office for Human Research Protections	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
SISS - Services for International Students & Scholars	Services for International Students and Scholars (SISS) 2299 Piedmont Avenue (at International House) UC Berkeley Berkeley CA 94720-2321 http://www.ias.berkeley.edu/siss/
SPO - Sponsored Projects Office	Sponsored Projects Office University of California, Berkeley 336 Sproul Hall Berkeley CA 94720 http://www.spo.berkeley.edu/

14. LIST OF WEBSITES & RESOURCES

Resource	Website
AITRP, Fogarty International Center	http://www.fic.nih.gov/programs/aitrp/aitrp.html
CPHS, UC Berkeley	http://cphs.berkeley.edu:7006/
CPHS templates for IRB protocol & consent forms	http://cphs.berkeley.edu/content/sample.htm
CHR, UCSF	http://www.research.ucsf.edu/chr/index.asp
ICMR - Indian Council of Medical Research	http://www.icmr.nic.in
ICMR guidelines on international collaborative research	http://icmr.nic.in/guide.htm
ICMR ethical guidelines (full report)	http://icmr.nic.in/ethical.pdf.
ICMR guidelines on IRB composition	http://icmr.nic.in/ethics_SOP.pdf
ICMR/GOI Guidelines for Exchange of Human Biological Material	http://icmr.nic.in/min.htm
NIH - National Institutes of Health	http://www.nih.gov/
NIH online training course on human subjects protection	http://cme.cancer.gov/c01/
OHRP Home page	http://ohrp.osophs.dhhs.gov/index.html
OHRP guidelines for using external IRBs	http://ohrp.osophs.dhhs.gov/humansubjects/assurance/iprotsup.rtf
OHRP educational materials for IRBs	http://ohrp.osophs.dhhs.gov/educmat.htm
OHRP online IRB Guidebook	http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm
OHRP database of institutions with registered IRBs	http://ohrp.cit.nih.gov/search/asearch.asp#IORG
OHRP database of institutions with assurances	http://ohrp.cit.nih.gov/search/asearch.asp#ASUR
OHRP - IRB registration forms and guidelines	http://ohrp.osophs.dhhs.gov/humansubjects/assurance/irbs.htm
OHRP - FWA application forms and guidelines	http://ohrp.osophs.dhhs.gov/humansubjects/assurance/fwas.htm
OHRP – Guidelines on minimal requirements for new IRBs	http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirbi.htm
OHRP staff assigned to handle FWA submissions from India	http://ohrp.osophs.dhhs.gov/daqi-staff.htm#Region%205
Services for International Students & Scholars, UCB	http://ias.berkeley.edu/siss/
SPO, UC Berkeley	http://www.spo.berkeley.edu/
SPO - “Working with industry,” guidelines	www.spo.berkeley.edu/industry.html
University of California, Berkeley	www.berkeley.edu

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