A Survival Guide for Conducting International Collaborative Research in Uganda

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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. International research may also raise unique ethical issues and dilemmas.

This survival guide on conducting research in Uganda, compiled by current and former Fogarty scholars, is the second 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 agencies (such as UNCST and AITRP/NIH), and the AITRP team for any new developments, prior to starting your research project in Uganda.

With best wishes,

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1. APPROVALS REQUIRED BEFORE STUDIES CAN BE INITIATED IN UGANDA

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 is 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 Ugandan 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 Ugandan institution and attach this to your CPHS protocol. The letter of support should briefly describe the project and state that the Ugandan 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 Ugandan institution(s):

All collaborative research projects require IRB approval from the collaborating Ugandan institution(s). The first step would be to check if the Ugandan institute has a functioning IRB in place. Major institutions and research centers usually have IRBs. Check with your Ugandan collaborators about this and the time they usually take for the review process. Some Ugandan 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 Ugandan institution; or, 2) convince the Ugandan 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 Ugandan 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 Ugandan institution decides to constitute its own IRB, then OHRP guidelines **(see text box #1)** may be used to decide on IRB composition, role, etc:

http://ohrp.osophs.dhhs.gov/humansubjects/assurance/regirbi.htm. In addition, the UNCST has also provided guidelines on IRBs: http://www.uncst.go.ug

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. Jonathan Mermin, Director of CDC Program in Uganda, a University of California-Berkeley alumnus, currently working in Uganda. He also chairs the UVRI Science and Ethics committee and his team reviews research proposals on a regular and frequent basis.

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

US guidelines on IRB composition and role **Text box #1**

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 Ugandan 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 Ugandan 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 Ugandan 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 first renew CPHS and the Ugandan IRB approvals, and subsequently apply for external IRB renewals.

2. IRB REGISTRATION AND ASSURANCE FROM OHRP FOR THE UGANDAN 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 Ugandan 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. Ugandan 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 Ugandan institute has already has one. Check: http://ohrp.cit.nih.gov/search/asearch.asp#ASUR. Several Ugandan institutions (including some NGOs) already have FWAs (see table). 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 Ugandan 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 Ugandan institution (although you can help in completion of the form and following-up with OHRP). If the Ugandan IRB conforms to the OHRP requirements, the application is usually approved in 2-3 weeks.

b. Once the IRB registration is complete, the Ugandan IRB is assigned a unique ID number. The Ugandan 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 Ugandan 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 Ugandan 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 Ugandan 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 Ugandan institution. The FWA is valid only for a limited period (usually, 3 years); it has to be renewed periodically.

Table: List of Ugandan institutions with FWA (as of February 2004)

Assurance	Institution	City
FWA00006255	Medical Biotechnology Laboratories	KAMPALA
FWA00001293	AIDS Control Program Ministry Hlth	KAMPALA
FWA00001354	Ctr for Disease Control (CDC)	ENTEBBE
FWA00001354	Ctr for Disease Control (CDC)	TORORO
FWA00001354	Intl AIDS Vacinne Initiative (IAVI)	ENTEBBE
FWA00004119	Jane Goodall Inst	ENTEBBE
FWA00001293	Joint Clinical Rsch Ctr	KAMPALA
FWA00005788	Makerere Inst Social Research(MISR)	KAMPALA
FWA00001293	Makerere Med Sch	KAMPALA
FWA00006255	Med Biotech Laboratories	KAMPALA
FWA00001354	Med Rsch Council	ENTEBBE
FWA00001354	Med Rsch Council	MASAK
FWA00001293	Mulago Hosp	KAMPALA
FWA00001354	Rakai Project	ENTEBBE
FWA00001354	Rakai Project	KALISIZO
FWA00001293	Uganda AIDS Commission	KAMPALA
FWA00001293	Uganda Natl Council Sci Tech	KAMPALA
FWA00001354	Uganda Virus Rsch Inst	ENTEBBE
FWA00005617	Uganda Youth Devl Link	KAMPALA

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 Uganda. Without follow-up, the process can take several weeks. To find out the name of the staff member assigned to handle submissions from Uganda, 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 Uganda. You could speed up the process by submitting the application electronically, and making sure the signature page is sent to OHRP via courier from Uganda.

3. UNCST GUIDELINES FOR BIOMEDICAL RESEARCH IN UGANDA

The Uganda National Council of Science and Technology (UNCST) Telephone +256-41-250499, Fax +256-41-234579, © 2003 UNCST Email: uncst@starcom.co.ug http://www.uncst.co.ug is Uganda's apex organization for scientific research in medicine and health. The UNCST website http://www.uncst.go.ug/research.asp?id=29 has more information on ethical guidelines for biomedical research and these form the basis for conducting ethical research in Uganda.

All AITRP scholars planning studies in Uganda should be familiar with the UNCST general information for researchers intending to conduct research in the country. This information is given below and could be used instead of guidelines such as 45 CFR 46, CIOMS, etc.

GUIDELINES FOR RESEARCHERS

All inquiries concerning clearance of research proposals should be directed to the **UNCST Researchers' Desk**.

Procedure for clearing research proposals

1. Permission to carry out or conduct research or engage in research or experimental development, trials or tests, shall be granted only after the application to do so is cleared by the UNCST and the Office of the President.

2. It is illegal to carry out or conduct research or engage in research or experimental trials and tests without valid research permits.

3. All research applications and clearance forms are obtained from and returned to the UNCST Researchers' Desk.

4. Complete the following forms:

a) **UNCST/RC 1 Form** for "Application for Permission to Conduct Research in Uganda", in duplicate. Attach 2 copies of your research proposal. The research proposal should be well written, fully developed with a title, justification for the project, comprehensive review of literature, objectives, methodology, significance and expected output of the study, estimated duration, a budget and bibliography.

b) **RS 6 form** - for clearance from the Research Secretariat, Office of the President, in 3 copies and attach 4 passport size photographs, 2 on one copy.

c) All research assistants and co-workers will be required to fill form RS 6.

5. You will be advised within 2 weeks from the date of submission of filled forms in 2(a) and 2(b) above whether UNCST has approved your research project.

6. Payment of Research Administration and Clearance Fees: (Currently US $ 200 or its equivalent)

i) Eligible to pay

All researchers are expected to pay research administration and clearance fees.

ii) Current Exemptions

-Ugandan students irrespective of the source of funding for research.

-Researchers whose funding for research is from the Uganda Government Treasury.

iii) Procedure of payment

Administration and clearance fees are paid directly to the bank, by the researcher on special bank slips (obtainable from the UNCST) in triplicate. Return one stamped banking slip to the officer in charge of the Researchers' Desk who will facilitate issuance of final research clearance.

7. Researcher's Identity Card:

i) All researchers, research assistants and co-workers on receipt of final research clearance, will receive a Researcher's Identity Card. The officer in charge of the Researchers' Desk will issue the clearance.

ii) Only researchers who are exempted from payment of research fees, pay a prescribed charge for a Researcher's Identity Card. This is paid to the officer in charge of the Researchers' Desk who will issue a receipt for this charge.

iii) No researcher may proceed to the field without the final research clearance from the UNCST to the Resident District Commissioners.

8. Filing of research reports:

i) All persons granted permission and having a research permit shall submit to UNCST prescribed progress reports and detailed final reports of research findings within six months of expiry of the research permit.

ii) No foreign researcher shall leave the country following expiry of research permit before submitting detailed or at least an acceptable provisional draft report of research findings.

9. Miscellaneous:

A person who fails to register with the UNCST a research or experimental development undertaking or research or experimental trial or test in Uganda shall NOT be exonerated from the legal consequences.

ANNEX I

1. In the case of applicants in Government or academic institutions, applications must be submitted through their Heads of Department.

2. This form is to be submitted to the Executive Secretary, Uganda National Council for Science and Technology in duplicate together with two copies of the research proposal.

3. All research falling under any of the following categories shall require approval:

(i) Research financed from public funds;

(ii) Research to be carried out by non-Ugandans;

(iii) If it entails interviewing members of the public or officers;

(iv) Research involving access to Government archives or other Government documents;

(v) Research involving use of or access to plants, animals, human subjects or any natural resource of the country.

4. Research falling under any of the following categories shall require notification of the Council,

(i) If it does not fall within the categories in 3 above;

(ii) If it is to be carried out by undergraduates.

For undergraduate field research by students registered at an educational institution in Uganda, the Head of Department shall provide the following information to Executive Secretary - UNCST:

(i) Name(s) of student(s).

(ii) Subject of research assignments;

(iii) Area in which research is to be conducted;

(iv) Government documents required to be examined (if any);

(v) Estimated duration of research;

(vi) Sources of funds;

(viii) Name(s) of supervisor(s).

5. A researcher who wishes to export plant or animal specimen for investigations abroad, must seek quidance on the procedure for export from the UNCST.

6. The Uganda National Council for Science and Technology reserves the right to reject any research proposal.

ANNEX II

Guide for the Documentation of Research Proposals:

By following this guide, applicants will greatly help in speeding up the processing and approving or otherwise of requests to carry out research in Uganda.

Documentation:

1. In the first instance, the person wishing to undertake a particular research should provide particular of him/herself on the official application form.

2. The proposed research project should have a title, review of literature on the subject, objectives, methodology, budget and the estimated duration.

3. In the review, take note of the following:

(i)References: Place all references alphabetically BY AUTHOR, IN A NUMBERED LIST AT THE END OF THE review in a section entitled "References" when you refer in the text to a publication in this list, insert its number in brackets including specific page number if necessary, e.g. (12p,126).

(ii) Footnotes: Number footnotes consecutively throughout the paper, and note page by page.

(iii) Tables: Tables should have clear headings and be numbered consecutively throughout the paper.

(iv)Identification of research project: At the end of the paper the applicant should identify areas which require research in order of priorities, and indicate clearly the reasons for selecting a particular area.

4. The proposed research methodology, estimated budget and length of time, should then be provided, indicating sources of finance whether from a grant from Government, or any other institution. A statement as to what progress has been made in securing finances, would be or great help in processing the application.

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 UNCST AND GOVERNMENT OF UGANDA

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

Applications for research projects involving foreign assistance/collaboration in health research are to be submitted to UNCST for approval by the Government of Uganda through the Presidents office. **This application must be submitted by your collaborating Ugandan institution. The local review board will not communicate with the US investigators.** The application process involves submission of the protocol and other materials (such as Ugandan and US IRB approvals, budget, and consent forms), along with an application form that has some 20 questions in five sections (See

Appendix). Originals and 10 copies of this package have to be submitted to UNCST. The forms and instructions are found at: http://www.uncst.co.ug/rc1form.pdf. The UNCST will screen the application and forward it for technical peer review. The time through the technical review process (IRB and UNCST) can vary from topic to topic but should be within a period of 3 months. There are several institutions that can reviews HIV-related research protocols (See list of Ugandan institutions with FWA above). Ugandan investigators may be requested to respond to queries raised in the technical reviews. Once these queries have been responded to, the application is resubmitted before the technical peer review again, which usually meet once a month. The entire approval process can take some time, depending on the issues identified during technical review.

It is very important that the Ugandan investigators establish a relationship with key personnel at UNCST and the technical review boards. They should begin contacting UNCST 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 UNCST clearance for their field training/research conducted as part of their graduate studies? Yes, the UNCST 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 Makerere University, UVRI etc) also have to obtain clearance before starting the study. Ugandan nationals who plan to return to Uganda 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 their Ugandan collaborators and the UNCST. Fogarty scholars should also consult with Dr Reingold.

Time delays and other constraints

AITRP scholars who submit their protocols to UNCST and other external review will have to be prepared for delays. The approval process could take anywhere between 3 months to 1year depending on the follow-up and the quality of the submitted protocol. If suggested revisions are addressed, protocols usually approved without further delay. It might be a good idea to submit the protocol early during the PHD program and budget for a 6 months 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 intellectual property concerns.

6. INVOLVING THE US EMBASSY, UGANDA AND CDC-UGANDA OFFICES

The US Embassy, Kampala http://kampala.usembassy.gov and CDC-Uganda, can provide advice to those planning Uganda-US collaborative projects in health and scientific research. Their contact information is as follows: The Embassy of the USA, Kampala - Plot 1577 Ggaba Road, P.O.box 7007, Kampala Uganda, Tel #: 256 41 233231, 259791/2/3/5, 345422, 259794 and CDC-Uganda office UVRI, P.O.Box 49 Entebbe Tel: 256 41 320776. Once the protocol has been submitted for review, it's highly recommended that both you and your Ugandan investigators get in touch with these two offices. If you have received an NIH RO1 award, the US Embassy can help you contact your Ugandan collaborator and explain the process of getting UNCST/Government of Uganda approval.

7. TRANSFER OF FUNDS TO UGANDA

AITRP funds cannot be transferred to the Ugandan 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 Ugandan institution and returned to SPO. Once the signed contract has been received at SPO, the funds can be released to the Ugandan institution upon submission of an invoice (via fax is okay). This process often takes 2-3 months even with courier delivery to and from Uganda. 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 Uganda.

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

a. Beneficiary (Ugandan 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 Ugandan bank

Any foreign agency (or person) or organization which is not controlled by Ugandans 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 Ugandan 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 UGANDA

Researchers who are planning to send biological specimens from Uganda to the US (or other countries) have to be aware of specific guidelines issued by the UNCST and the collaborating Institution for export of biological specimens. In addition to obtaining UNCST approval for export of biological specimens, US researchers are also expected to obtain an import license for the importation of biological specimens.

To set up a system for export of biological specimens out of Uganda might take a long time. A small number of specimens may be sent out of Uganda for quality control purposes in short notice, but if all the tests need to be done outside of Uganda, 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 UGANDA

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 fieldwork 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 Uganda. 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 Uganda. A leave of absence can be granted for up to one year but arrangements must be made beforehand.

Foreign (that is, non-Ugandan) nationals planning to do research in Uganda should contact UNCST for advice on visa options. A research visa may take some time to secure but very rarely refused (see box below).

Planning to visit Uganda? A few things you should know

First Things First - You'll Need a Visa
Ugandan visas are issued at Uganda Missions/Embassies abroad and also at the Entry/Exit Points e.g. Entebbe, Busia, Malaba etc.

Underlying the Uganda Visa Policy is the principle of reciprocity, that is, all countries that require visas for Ugandans are also visa prone in Uganda.

Visa Fees

Student Visa	US$20
Single Entry	US$30
Multiple Entry 6 months	US$80
Multiple Entry 1 year	US160
Inland Transit	US$15

Countries Exempted from Visa requirements to Uganda

Angola, Antigua, Comoros, Bahamas, Eritrea, Barbados, Belize, Kenya, Fiji, Malawi, Mauritius, Gambia, Madagascar, Grenada, Jamaica, Rwanda, Seychelles, Lesotho, Swaziland, Malta, Tanzania, Sierra Leone, Zambia, Singapore, Zimbabwe, Solomon Islands, St. Vincent, Tonga, Vanuatu, Italy (only Diplomatic Passports), Cyprus

For further information please search the immigration website
http://www.immigration.go.ug

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@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
DIH	Division of International Health, UNCST, Uganda
FCRA	Foreign Contribution Regulation Act
FCU	Foreign Cell, UNCST, Uganda
FIC	Fogarty International Center, USA
FWA	Federalwide Assurance
GOU	Government of Uganda
LM	Line Ministry in Uganda
IRB	Institutional Review Board
NGO	Non-Governmental Organization
NIH	National Institutes of Health, USA
OHRP	Office for Human Research Protections, USA
SEC	Science and ethics committee
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
UNCST	Uganda National Council of Science and Technology
UVRI	Uganda Virus Research Institute
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
The Embassy of the USA, Uganda	Embassy of the USA Plot 1577 Ggaba Road, P.O.box 7007, Kampala Uganda Tel #: 256 41 233231, 259791/2/3/5, 345422, 259794 http://kampala.usembassy.gov
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
UNCST - Ugandan National Council of Science & Technology	http://www.uncst.go.ug
UNCST guidelines on international collaborative research	http://www.uncst.go.ug/rc1form.pdf
UNCST ethical guidelines	http://www.uncst.go.ug/rc1form.pdf
UNCST guidelines on IRB composition	http://www.uncst.go.ug
NCST/GOU Guidelines for Exchange of Human Biological Material	http://www.uncst.go.ug/research.asp?id=29/
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
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

15. CONTRIBUTORS & CREDITS:

This survival guide has been adapted from a document entitled "*A Survival Guide for Conducting International Collaborative Research in India*," by Madhukar Pai, Nitika Pai, Purnima Madhivanan, Asheena Khalakdina, and Suneeta Krishnan (October 2003). The following Fogarty scholars from Uganda have contributed to the Uganda version:

Samuel Malamba	Doctoral Student, Division of Epidemiology malambas@uclink.berkeley.edu
Edward Bitarakwate	Graduate Student (MPH program), Division of Epidemiology eddiebit@uclink.berkeley.edu

We acknowledge the helpful feedback provided by Grant Dorsey, University of California, San Francisco.

PICTURE CREDITS:

Reingold: Office of Public Affairs, UC Berkeley
All others: Malamba Samuel, Nitika Pai & Madhu Pai

APPENDIX

UNCST/RC 1

THE REPUBLIC OF UGANDA

UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

APPLICATION FOR PERMISSION TO CONDUCT RESEARCH

(N.B. Read instructions and guide in Annexes I and II before completing this form)

FOR OFFICIAL USE

APPLICATION No. .....

FIELD OF RESEARCH PROJECT No. .....

.....
.....

SECTION A: PARTICULARS OF APPLICANT

1. Full Name .....

(U nderline Surname)

2. Male [ ] Female [ ] (Please tick (3))

3. Date and Place of Birth .....

4. Marital Status .....

5. Nationality .....

6. (i) Permanent Address .....
.....

Fax: .....Telephone: .....

E-mail: .....

(ii) Address of Institution of affiliation in Uganda .....
.....

Fax:.....Telephone: .....

E-mail: .....

7. Current Immigration Status:* .....

(if already in Uganda)

* Refers only to foreign applicants .

8. Present Occupation Status:
.....
.....
.....

(i) Post .....

(+ Temporary/Contract/Permanent)

(ii) Institution: .....

(iii) If on contract, date of expiration: .....

9. Education

(i)
University.....
Qualification.....

Class.....

Year .....

Field of Speciality .....

(ii) Postgraduate Research experience, with list of publications, if any (use additional paper if necessary).

.....
.....
.....
.....

(iii) Names, qualifications and status of personnel involved in the research:-

Name ……

Qualifications ……

Status* ……..

* STATUS with regard to the project

+ Delete whichever is inapplicable .

SECTION B: MAIN FEATURES OF RESEARCH PROJECT

10. Title of research project: ……
……
……

11. Main objective of research ……
……
……
……
……
……

12. Brief outline of research methodology……
……
……
……
……
……

13. Research type (Please tick (3)):

[ ] Degree Award [ ] Non-degree Award

(If Degree Award, state type of degree e.g BA, MSc or Ph.D etc, and the institution awarding it)……
……

14. Districts of Uganda in which research will be carried out.....
.....
.....

15. (i) Estimated cost of research .....

(ii) Source of funds .....

(iii) Duration .....

16. BREAKDOWN OF EXPENDITURE:

(This table must be filled by all applicants)

ITEM

Year 1

(US $)

Year 2

(US $)

Year 3

(US $)

Total

(US $)

Personnel

Travel*

Materials & Supplies

Administration

Results dissemination

Other

Contingency

*Both local and international.

SECTION C

17. Names and addresses of two referees:

.....
.....
.....
.....
.....

18. (a) I undertake to submit:

(i) Six monthly progress reports of my project

(ii) Final results on completion of the project

(iii) Copies of any published paper/article arising from the project

(b) I hereby certify that to the best of my knowledge and belief, the particulars given in this form are true and complete in all respects.

Date ..... Signature of Applicant .....

SECTION D

TO BE FILLED IN BY HEAD OF DEPARTMENT, INSTITUTION AND/OR SUPERVISOR

19. Comments by Head of Institution/Department .....
.....
.....
.....

Name .....

Signature ..... Date .....

21 Ethical clearance (especially for health research involving human subjects).

.....

Chairman Ethical Committee (Name, Signature & Stamp).

Date .....

SECTION E:

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21.0. Decision of the Uganda National Council for Science and Technology:-

21.1. Research project reviewed:

(i) Internally [ ]

(ii) Externally by:

a) UNCST Specialized Technical Committee [ ]

b) Task Force [ ]

c) Peer reviewer [ ]

21.2 Research project :

(a) Approved [ ]

(b) Not Approved [ ]

Reason for not approving .....
.....
.....

Date .....

.....
Executive Secretary

UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

Summary:

A checklist of things you have to do in order to get your project started in Uganda:

1. Begin by writing the protocol (including informed consent documents) and obtain feedback from Ugandan and AITRP advisors
2. Find out whether separate consent forms are required for collecting biological specimens
3. Translate documents into the relevant local languages – Get help from local collaborators
4. Identify local IRBs relevant for the type of study you plan to do
    a. Makerere University IRB (takes longer),
    b. Uganda Virus Research Institute IRB (rapid and no fee required, but handles specialized topics),
    c. Joint Clinic Research Center IRB (Rapid, but incurs a fee of $500)
5. Seek IRB approval(s) simultaneously at all relevant institutions in order to save time
6. Write the standard operating procedures for your study
7. After obtaining IRB approval(s), apply to get clearance from the UNCST
8. Obtain your CPHS approval
9. Start the process of transferring funds to Uganda
10. Obtain license to import/export biological specimens from Uganda/US
11. Check whether your study has special situations that would need industry funding and support
12. Remember to get a visa that is appropriate for your research schedule (Single/Multiple) and legal status (Student/Researcher)
13. Start enrollment during field research in Uganda
14. Keeping the AITRP program informed