Fellowship in Clinical Research Methods

With an Emphasis on Implementation Science and HIV Care
or
Prevention and Early Detection of HIV-associated Malignancies

Overview

We are pleased to announce the availability of fellowship positions to promote rigorous training in the methods of clinical research. The selected fellows will learn the methods of clinical research through enrollment in the Master's Degree Program in Clinical Research at the University of California, San Francisco (UCSF). Scholars are expected to reside in San Francisco for 17 months of the 22 month-long program that will be completed from August 2015 to May 2017. Scholars will apply the methods they have learned through participation in one or more concurrent research projects. Fellows will be required to focus their research in one or both of the following areas:

- Implementation Science and HIV care; or
- Prevention and early detection of HIV-associated malignancies.

At the end of the two-year fellowship, scholars will be positioned to pursue careers as independent principal investigators in Uganda, contribute to the development of research programs in Uganda, and be competitive at an international level for publication and funding opportunities.

The fellowship is sponsored by the United States National Institutes of Health (Fogarty International Center) and PEPFAR. It is being implemented by partners from Makerere University, the Infectious Diseases Institute, Makerere University Joint AIDS Program, Infectious Diseases Research Collaboration, and the University of California, San Francisco.

Objective

The overall objective of this fellowship is to provide training to emerging Ugandan scientists to equip them with the skills necessary to be independent principal investigators. It is then expected that these emerging scientists will apply their methodologic skills to the study of either a) implementation science and HIV care; or b) the prevention and early detection of HIV-associated malignancies. These objectives will be achieved by:

- Formal didactic training in the general methods of clinical research leading to a Master's Degree in Clinical Research from the University of California, San Francisco in the U.S.; and
- Individualized mentoring and opportunities to perform clinical research related to implementation science and HIV care; or the prevention and early detection of HIV-associated malignancies.

No obstacle to research in Africa is more rate-limiting than the lack of African principal investigators who can accomplish the three key elements of research: identify relevant and feasible research questions; write compelling proposals and attract funding; and conduct, interpret, and disseminate high-quality research. To address this, one of our main objectives of the fellowship is to provide training in the full range of domains required to be a human subjects-oriented principal investigator. This spectrum is extensive and includes observational and experimental study design, epidemiology, biostatistics, data management, scientific writing, good clinical practice, and responsible conduct of research. Scholars selected for the implementation science component will also enroll in the implementation science curricular track.

The overall philosophy of the fellowship is that there are no short cuts to achieving comprehensive training to become an independent principal investigator. The leaders of this fellowship have observed the outcomes of a variety of approaches to clinical research training including, for example, “short” courses in study design, grant writing or statistics, and have concluded that there is no substitute for in-depth instruction taken over a sufficient amount of time to allow for contemplation and discourse with experienced faculty. The UCSF Master's Degree Program in Clinical Research exemplifies this latter approach.
Prerequisites

- Formal education in clinical medicine or public health.
  - For those with clinical backgrounds, we expect that these will be from internal medicine, pediatrics, obstetrics/gynecology, oncology, dermatology, HIV/AIDS or infectious diseases. Candidates will be expected to have finished medical school and have at least one year of post-graduate research experience. A Master's Degree in a health-related discipline is preferred.
  - For those with public health backgrounds, we expect that these will be, for example, from epidemiology, biostatistics, community health, health education, or health promotion. Candidates will be expected to have completed their doctoral training and have at least one year of post-graduate experience in research or public health practice.

- Commitment to perform research related to either:
  - Implementation science and HIV care; and/or
  - Prevention and early detection of HIV-related malignancies

The fundamental goal of this fellowship is to develop principal investigators who will perform Uganda-oriented research both during and after the fellowship in one or both of these two areas.

- Commitment to return to Uganda after training in the U.S. and participate in research. The scarcity of well-trained principal investigators in clinical research in Uganda is a major impetus for this fellowship. It is therefore expected that candidates will have a long term objective of contributing to the development of a research program in Uganda, either in implementation science or in the prevention and early detection of HIV-related malignancies.

Program of Study

The principal training platform for this fellowship is the Master's Degree Program in Clinical Research at University of California in San Francisco. This is a 22 month course of study beginning in August 2015 and ending in May 2017. Conducted over 7 academic quarters (Summer, Fall, Winter, and Spring of the 1st year and Fall, Winter, and Spring of the 2nd year), the program purposefully features a heavy concentration of coursework in the first six months in order for students to build independent skills that they will use to perform their research during the rest of the program. Scholars will have the opportunity to return to Uganda during this training to initiate and continue research projects. The formal breaks in coursework occur in late December, late March, and in June/July.

The program website describes all required coursework, research, and instructional experience. In brief, the program includes:

- Coursework. A total of 36 quarter units are needed, divided into required and elective courses. While most scholars find these offerings sufficient, they may also choose from a wealth of other courses offered at UCSF and UC, Berkeley. Students may also elect to be enrolled in the Implementation Science track, which features coursework in the principles of bringing evidence-based practices to use in public health and clinical medicine. This track will be required for those fellows selected for the Implementation Science and HIV care area of research focus.

- Research. There are three research requirements that must be completed in order for a scholar to complete the program. The first is a comprehensive review of the literature pertinent to the scholar's research question. The second is a first-authored abstract submission and presentation at an international conference. The third and most substantial requirement is a first-authored manuscript which is submitted to a biomedical journal. (The manuscript may be an extension of the work submitted in abstract form to a conference). Finding relevant independent research projects which can be completed within two years can sometimes be a challenge for trainees, but fortunately the emerging scientists in this fellowship will have at their disposal a multitude of existing data and biological specimens related to HIV care and HIV-associated
malignancies. Achievement of all research requirements is assessed by a Master’s Committee, consisting of three faculty members.

- **Instructional experience.** All scholars in the Master’s Program are required to serve as instructional assistants in their second year in one course at UCSF related to clinical research. This involves leading a weekly small-group discussion section, holding office hours, and grading. We view the ability of our trainees to teach the methods of clinical research upon their return to Uganda as an important long-term objective of this fellowship.

- **Other activities.** In addition to the degree program activities above, the emerging scientists will have the opportunity to attend an extensive variety of conferences and seminars throughout UCSF. Depending upon interests, they will also be able to observe clinical practice, for example, in HIV/AIDS, oncology, obstetrics/gynecology, or dermatology.

In addition to tuition, books, supplies and software, all scholars will receive a stipend to cover rent and daily living expenses while in San Francisco. All travel costs will also be covered.

**Areas of Research Focus**

Two areas of research are being featured in this fellowship, meaning that fellows will be required to conduct their research in one (or both) of these two fields. Applicants to this fellowship will be asked to identify which area of research they are interested at the time of their application. The two areas are:

*Implementation science and HIV care.* With over 25 million infected individuals, sub-Saharan Africa has borne the greatest burden of HIV disease in the world. The high morbidity and mortality associated with untreated HIV in Africa has formed what is the arguably the single largest public health problem of our generation. The past decade, however, has witnessed a remarkable reversal in the battle against HIV in Africa with the availability of potent antiretroviral therapy (ART). Indeed, ART is effective in both treating HIV-infected individuals and preventing the spread of HIV to others. Yet, getting ART to those who need it, ensuring compliance, monitoring the effectiveness, and preventing the complications of therapy is a considerable challenge in any setting, let alone a resource-limited one such as Uganda. With documented “leaks” at each step in the cascade of HIV care, research is needed to identify solutions to fulfill the promise of ART in affected populations. The field of implementation science formalizes the research process that identifies the optimal approaches that promote adoption of evidence-based interventions (i.e., behaviors, drugs, tests, or devices) into public health or clinical practice. Specifically, the field includes research within one or more of the targets in the health care system for implementation of evidence-based practices, namely individual patients or people in the community, health care providers, health care systems and funders, and health care policymakers. The goal of implementation science is to develop generalizable approaches which enhance the uptake of one or more evidence-based healthcare practices in one or more target populations. As it relates to HIV care, this means the development of strategies that enhance access to ART, compliance with ART, and optimization of the benefits of ART while minimizing the risks. The ultimate goal is to increase survival and quality of life of HIV-infected persons and reduce HIV transmission in the community.

*Prevention and early detection of HIV-associated malignancies.* Two HIV-associated malignancies — Kaposi’s sarcoma (KS) and cervical cancer — are amongst the most common cancers in all of sub-Saharan Africa. In the most current data from Uganda, cervical cancer is the most common cancer and KS is the second most common. This is, of course, owing both to the high incidence of these cancers amongst HIV-infected individuals and the high prevalence of HIV in the general population. Not only are these malignancies common, but they are also lethal. Accurate data on survival after diagnosis of these malignancies is hard to find in Uganda, but one-year mortality following diagnosis of KS is estimated to be at least 20% and 5-year mortality following cervical cancer diagnosis is 80% to 85%. In fact, cervical cancer holds the distinction of the top ranked cancer in terms of “years of life lost” in Uganda. Thus, by any definition, both KS and cervical cancer are not just niche conditions relevant to a small population; they are significant public health problems. While elimination of HIV is one ultimate solution that would have
an enormous impact on the occurrence of KS and cervical cancer, this is not in the foreseeable future and thus other more immediate interventions are needed. In considering all of the elements in the clinical course of KS and cervical cancer in Africa and where success could be achieved, one aspect is very clear: most diagnoses of these cancers are currently made in advanced/late stages of the disease, well past when available treatment is successful. Accordingly, it is hypothesized that the fastest and most feasible route to the greatest public health impact on KS and cervical cancer in Africa is by either prevention of these cancers or detection of the cancers in their earliest stages, at which time effective interventions are available. For this fellowship, scholars are sought who are interested in investigating various aspects of the prevention and early detection of these two HIV-associated malignancies. This includes epidemiologic research in the contemporary incidence and causal determinants of the cancers, implementation science research to increase awareness of KS and cervical cancer amongst community residents and health care providers, development of point-of-care diagnostic tests, and health care services research to facilitate more rapid access to treatment amongst recently diagnosed patients.

**Application**

Interested scholars are requested to send the following materials by **a deadline of February 24, 2015**:

- a cover letter summarizing their background, why they are interested in and well-suited for this program, and their intended area of research focus (Implementation science and HIV care; or Prevention and early detection of HIV-associated malignancies)
- a detailed curriculum vitae (CV)
- two letters of recommendation from authorities who can speak to their background and potential for success in research.

All materials should be sent by email to amukhwana@idi.co.ug or delivered in person to

Senior Research Administrator  
Research Department  
Infectious Diseases Institute – Mulago Kampala  
Research Room 1 (155)  
P. O. Box 22418, Kampala

Letters of Recommendation should also be sent via email or in person, via a sealed envelope.

For questions regarding:
- General application procedures: call Dr. Philippa Makanga at 0751 541 693
- Implementation and HIV Care research component: call Dr. Fred C Semitala at 0755 553 004
- Prevention and Early Detection of HIV-associated Malignancies research component: call Dr. Aggrey Semeere at 0772 621 181