Introducing the Florida Consortium for HIV/AIDS Research

The Scientific Arm of The AIDS Institute

In 2009 and 2010, Florida led the nation in the number and rate of new HIV diagnoses.\textsuperscript{1,2} This report is to summarize information about a statewide research consortium in Florida, which applies novel strategies to the investigation and control of HIV.

Overview

The Florida Consortium for HIV/AIDS Research (FCHAR) is the scientific arm of The AIDS Institute, a nonprofit organization founded in Florida in 1985, with a focus on policy, research, advocacy and education. FCHAR currently comprises 110 members who account for more than 400 recent and ongoing HIV-related studies. The researchers represent seven universities, the Florida Department of Health, and 11 other research entities across the state, including those from the private sector.

Conceived in 2010, and first convened at a symposium in February 2011, FCHAR conducted its second annual summit in Orlando on January 9, 2012. Sixty prominent researchers from around the state gathered to advance a collaborative HIV/AIDS research agenda. Eighteen experts participated in didactic presentations and audience-interactive panels covering ethics, institutional review boards (IRBs) and three types of HIV/AIDS studies: clinical trials, epidemiologic/behavioral investigations, and basic science research.

FCHAR functions as a coordinating body that facilitates communication, policy development and establishment of best practices among cooperating member organizations. It serves as a vital conduit of information on how best to partner on research studies. The expectation is that inter-organizational collaboration, rather than self-interest, will help attract greater HIV/AIDS research resources to the state and avoid duplication.

Specific aims of FCHAR include leveraging these collaborations into the development of highly effective prevention interventions, new diagnostics and novel antiretrovirals and immunotherapies. Ultimate goals include the translation of cutting-edge research into prevention of onward transmission, provision of uninterrupted care and treatment, and the discovery of therapeutic and preventive vaccines, as well as a cure.

During the past year and a half, an FCHAR Executive Advisory Committee and four working subcommittees have been lowering barriers to research collaboration, both natural (e.g., geography) and manmade (e.g., multiple IRBs and legal counsels). A current, specific initiative that emerged from the committee meetings and the second annual FCHAR summit is to streamline the IRB process, while preserving essential local and ethical perspectives. Also,


several innovative, multi-organizational study protocols are currently in development. FCHAR has compiled a statewide HIV/AIDS Research Inventory, which is evolving into a more comprehensive, web-based database to facilitate and expedite recruitment of participants into research studies. A recent member survey on hard-to-reach populations (e.g., MSM who do not identify as gay or bisexual) and hard-to-obtain biological specimens (e.g., those from acutely infected individuals) has identified a number of common challenges and unique solutions for sharing among the organizations.

**A Pilot Study and a Clinical Trial**

On July 23, 2012, during the XIX International AIDS Conference, FCHAR conducted a strategic planning meeting of 14 conference delegates who are also FCHAR members. The subject was the development of a protocol for identifying individuals with acute HIV infection (AHI), recent infection, and chronic/established infection, and recruiting them into an innovative clinical trial. The primary hypothesis of the clinical trial is that the timeliness of a new drug regimen will significantly decrease viremia and onward transmission, especially during the critical AHI period. Treatment-naive patients in each of the three categories would be offered a novel combination of antiretroviral drugs to evaluate viral load, immune response, and other outcome parameters. It was determined that we would seek funding first for a pilot study in a high-prevalence Florida county to demonstrate our ability to ascertain sufficient numbers of AHI cases for one arm of the trial. These cases have been extremely hard to identify, but part of our protocol is to apply unique outreach and seek-test-treat-retain (STTR) strategies for enhanced case-finding and study-enrollment.

A workgroup has been formed to further develop these strategies, advance the protocol development, and identify and seek funding support for the pilot study. A successful pilot would then lead to a funding request for the clinical trial to the National Institutes of Health (NIH) (most likely the National Institute of Allergy and Infectious Diseases).

The proposed pilot study to be conducted in the short term (and ultimately, our full clinical trial protocol to be submitted to NIH) will be headed up by university-based medical researchers and epidemiologists from several institutions. Staff from local Department of Health (DOH) county health departments and community-based organizations (CBOs) across counties will be an integral part of the clinical trial to conduct outreach, partner notification, and referral into care.

As of mid-August 2012, the principal investigator has yet to be identified. However, a prominent and experienced investigator, Margaret Fischl, MD, a co-founder of FCHAR who is affiliated with the University of Miami, will be playing a key role in protocol development and project implementation. For the clinical trial, study participants will be quickly recruited, and a novel combination of antiretroviral (ARV) drugs (mega-HAART) will be offered immediately to those who are in any one of three stages of infection: AHI, recent infection, and chronic/established infection. The protocol for both the pilot study and full clinical trial will be innovative in several respects.

Local educational campaigns would be conducted, to lay the study groundwork and facilitate study participation. There will be a three-pronged approach designed to educate 1) the community, (2) local pharmacists, and 3) local providers about the personal and public health benefits of taking enhanced ARVs during the AHI phase.
The nature and extent of the inter-institutional collaboration is unique and consistent with FCHAR’s goals and objectives. This kind of collaboration will make the project even more attractive to potential funders, given their anticipated emphasis on projects involving multiple organizations.

FCHAR will play the coordinating role, and its parent 501(c)(3) organization, The AIDS Institute, will be the applicant for funding, given that the indirect costs that this organization requires is far less than that which a university requires. FCHAR will also ensure that the institutional review board process is streamlined across institutions by establishing inter-organizational reciprocity for an IRB submission.

Although we have also not yet identified the pilot study county, Broward County is a top candidate. Within the county, there will first be an analysis of reported HIV diagnoses by ZIP code to help distinguish “hot spots” from “cold spots”. DOH is about to provide these HIV diagnosis data by ZIP code for several counties. The full clinical trial will be conducted in multiple high-incidence counties.

We will obviously focus our most intense outreach efforts on areas where the epidemic is most intense, to find those with acute HIV infection (AHI). Project staff will investigate and reach out with HIV testing to persons in sexual and social networks, as well as partners of individuals with AHI. And exposed partners will be identified by staff in the STD Program and CBOs. This would be the “seek” part of a comprehensive new strategy for (seek-test-treat-retain) STTR and study recruitment.

A bio-repository of specimens collected in the course of the study will be established at the Vaccine and Gene Therapy Institute (VGTI), located in St. Lucie County, for shared utilization. This will include the design and conduct of another study that will help develop a functional cure for HIV. The Scientific Director of VGTI is the renowned Rafik-Pierre Sekaly, PhD, who is also a prime mover of FCHAR.

**Preparation of Funding Applications**

A workgroup will be formed to 1) select locale(s) for the pilot study, 2) refine AHI case-finding strategies, 3) finalize the design of the pilot study protocol, and 4) apply for funding to support the pilot study. The chief aim of the pilot study is to demonstrate our ability to ascertain sufficient numbers of AHI cases for one arm of the clinical trial. A successful pilot would then lead to a funding request for a multi-county clinical trial, to be submitted to the National Institutes of Health (NIH) (most likely the National Institute of Allergy and Infectious Diseases). The nature and extent of the proposed inter-institutional collaboration is unique and consistent with FCHAR’s goals and objectives. This will make the project even more attractive to potential funders, given their anticipated emphasis on projects involving coordination and broadening of research scope and generalizability among multiple organizations.

FCHAR will play the coordinating role, and its parent 501(c)(3) organization, The AIDS Institute, will be the applicant for funding, given that the indirect costs that this organization requires are far less than those of a university. FCHAR will obtain and help analyze the DOH incidence surveillance estimates (if available) and the reported HIV diagnoses data. FCHAR will coordinate the development of a single consent form to ensure that the institutional review board
process is streamlined across institutions. FCHAR will seek reciprocal approval of using the single consent form from legal counsel of collaborating organizations.

A comprehensive literature search will be conducted. In the process, AHI researchers from other states will be consulted to advise us about case-finding strategies. A specific timeline for developing, implementing, and completing the pilot and the clinical trial will be developed. A budget and funding request for the pilot – mostly for personnel and testing – remains to be detailed. For the clinical trial, Pharma’s interest in providing ARVs should result in the provision of free drugs.

**Patient-Centered Educational Material**

FCHAR has developed patient-focused brochures to inform prospective study participants, case managers and other providers about the nature, benefits and risks of clinical trials. The brochures focus on 1) clinical trials, 2) observational/behavioral studies, and 3) HIV-related laboratory tests. An educational program about how to interpret basic epidemiologic data has been developed for widespread, web-based publication to benefit health professionals and the media, as well as vulnerable populations and study participants. Another web-based program is being developed to provide information to those in care on the interpretation of complicated lab reports.

**Comment**

In today’s economic environment, it makes sense for Florida’s HIV research community to work together toward common goals, and to share data and resources. FCHAR has the momentum and talent to lay a solid research foundation for the achievement of ambitious goals like reducing HIV incidence, morbidity, and mortality. The successful completion of our proposed research will help provide evidence of scalable ways to bring about these reductions.

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