

## **A PLAN FOR HOUSING THE FLORIDA CONSORTIUM FOR HIV/AIDS RESEARCH AT THE AIDS INSTITUTE**

### **Background**

An estimated 1.1 million individuals are living with HIV infection in the U.S.,<sup>1</sup> with 135,000 in Florida. The number of living persons reported with a diagnosis of HIV or AIDS was 95,335 in Florida through 2010. During most of the course of the HIV epidemic, Florida has consistently ranked third behind New York and California in morbidity and mortality. The most recent national data, however, indicate that Florida has surpassed New York in the annual number of HIV diagnoses, and leads the country in the number of late diagnoses of HIV,<sup>2</sup> an indicator of progress of testing efforts to identify infected persons.

As in most areas of the country, the Florida epidemic is disproportionately impacting minorities, who account for 70% of living HIV/AIDS cases, but 40% of the state's population. Through 2010, the HIV/AIDS prevalence rate among black women is 19.8 times that of white women in the state. Estimates indicate that gay/bisexual men and men who have sex with men (MSM) but are not gay-identified account for only 7.8% of the adult male population,<sup>3</sup> but 60% of all incident HIV infections.<sup>4</sup> Research has shown the estimated HIV/AIDS prevalence rate among all Florida MSM is 66 times that of adult males who are not MSM; and marked racial/ethnic disparities persist in HIV incidence, prevalence, and mortality among the MSM.<sup>5</sup>

In Florida, deaths due to HIV/AIDS as the underlying cause peaked at 4,336 in 1995, but decreased 29% in 1996, the first year of protease inhibitors. Declines of 39% in 1997 and 18% in 1998 were followed by a flattening of the mortality trend during 1999-2006, with annual deaths hovering around 1,700. Apparently, the initial beneficial effects of advanced antiretroviral therapy began to stabilize. Then, deaths decreased by 29% during 2007-2009, most likely the result of increased access and adherence to simpler antiretroviral therapy regimens. Florida HIV/AIDS mortality data for 2010 will not be available until September 2011, but will be watched closely in view of a recent funding crisis and concomitant increasing demand for HIV services. These factors were responsible for an unprecedented patient waiting list for drug treatment. As of June 30, 2011, the number of Florida patients waiting for AIDS Drug Assistance Program (ADAP) services had grown to 3,562, the longest waiting list in the U.S.

Statewide HIV incidence surveillance system estimates for 2006-2009, scheduled to be released in the summer of 2011, will be carefully analyzed. A relevant question is whether recent increases in the numbers of reported HIV diagnoses and late HIV diagnoses are indicative, respectively, of rising incidence and decreasing linkage to effective HIV care and treatment.

### **Rationale for Housing the Research Consortium at The AIDS Institute**

The epidemic in Florida is particularly intense. There is urgent need to develop and implement a comprehensive set of vigorous HIV prevention and treatment strategies. To gain an understanding of which interventions can best be translated into strategic action, specific studies need to be designed and conducted. The epidemic also calls for the advancement of basic science research into finding microbicides, a cure, and a vaccine.

Currently, HIV/AIDS-related research in Florida and elsewhere is mostly conducted in isolated “silos”. Integrated functions with statewide leadership are needed to maximize research. New strategies are needed to enroll certain hard-to-reach populations into HIV-related studies. Strategies are needed to collect hard-to-obtain biologic specimens. There is a timely opportunity to advance inter-institutional collaboration on HIV studies, especially since a combination of research resources has become a priority of funding agencies.

To address structural and specific prevention and treatment research challenges like these, an innovative statewide HIV research organization was formed in Florida in 2011 – the Florida Consortium for HIV/AIDS Research (FCHAR). A well-established, non-profit HIV organization – The AIDS Institute (TAI) – offered to become the administrative and programmatic support home for the research group. This report presents a plan for housing FCHAR at TAI, and discusses the resultant benefits for the promotion of collaborative HIV research in the state.

### **The Organizations**

The Florida Consortium for HIV/AIDS Research was conceived in the spring of 2010. After months of planning, FCHAR became fully operational in February 2011, with an inaugural meeting of 65 Florida HIV researchers in Orlando. At the meeting, it was agreed that FCHAR should ultimately be housed independently of the Florida Department of Health, Bureau of HIV/AIDS, out of which the Consortium has been operating.

*FCHAR Vision:* The Consortium will lead research efforts in Florida in the prevention and treatment of HIV and AIDS, resulting in decreased incidence, morbidity, and mortality.

*FCHAR Goals:* To design and conduct studies that will translate to the development of highly effective, wide-scale HIV prevention and treatment interventions; and to make significant gains in finding microbicides, a vaccine, and a cure for HIV.

*FCHAR Objectives:*

**Cooperation:** Find common HIV research interest areas and network to bring new resources/studies to Florida

**Share** and inventory HIV clinical trials, prevention studies, and basic science research to develop a central source for research study compilation within Florida

**Educate** clinicians, HIV support teams, and consumers to promote appropriate referral and entry of patients into clinical trials

**Collaborate:** Partner on proposed and future unique studies that address primary and secondary HIV prevention, improve patient outcomes, and advance an understanding of microbicides, a cure, and a vaccine

**Resolve** challenges and discuss solutions to recruitment of participants for prevention studies, behavioral studies, and clinical trials; address challenges in collecting biologic specimens for virologic and other basic science studies

**Identify** active or future protocols accessible to our patients for the prevention and treatment of HIV infection.

Thus far, FCHAR's accomplishments have included the following:

1. Recruitment of Florida HIV researchers interested in promoting collaboration on grants and studies. Members currently include 110 researchers from seven universities; from the Bureau of HIV/AIDS, county health departments (CHDs), the state laboratory, and the private sector. Staff from The AIDS Institute (TAI) also belong to FCHAR.
2. Development of a comprehensive inventory of HIV research recently or currently conducted in the state. HIV-related studies include clinical trials, prevention trials, behavioral/epidemiologic studies, and basic science/virology. The current Inventory catalogues more than 400 studies, and is available at [www.floridaaids.org](http://www.floridaaids.org). An FCHAR website will be created for future posting of the Inventory.
3. Formation of a Steering Committee of approximately 35 Consortium members. The Committee was formed to provide academic and programmatic advice and direction. In April 2011, the first Steering Committee conference call was held, to initiate and begin to operate FCHAR.
4. On the call in April, four Subcommittees were formed to address specific research challenges, and in May, a separate conference call was conducted with each of them:
  - I. *Regional Networks Subcommittee*: Establish regional networks to position FCHAR for future funding; seek and obtain funding for research on networks or collaborative projects
  - II. *Hard-to-Reach Populations Subcommittee*: Develop strategies for identifying, accessing, and recruiting hard-to-reach populations needed for all types of research studies; and strategies to obtain hard-to-find biologic specimens for virologic study
  - III. *Therapeutics and Basic Science Research Subcommittee*: Propose study protocols focused on answering research questions utilizing FDA approved antiretroviral therapy, thus providing an alternative to ADAP waiting-list enrollment that would also benefit science. Provide opportunities to share challenges and solutions to basic science problems
  - IV. *Research Education Subcommittee*: Formulate a statewide strategic plan for educating clinicians, case managers, and patients of research options
5. In early June, a proposal was drafted, describing the relationship and benefits of an alliance between FCHAR and TAI.
6. The draft proposal to house the Consortium at The AIDS Institute was distributed to the full FCHAR membership on June 20.
7. The proposal was discussed and accepted on a conference call with the FCHAR membership, conducted on June 29.
8. Developed a survey to determine successes and failures in reaching and enrolling hard-to-reach participants in research studies. The survey also collects data for studies that have

an unmet need of obtaining biological specimens. The survey was discussed on the June 29<sup>th</sup> conference call, and then distributed to the full FCHAR membership. FCHAR will act as a clearinghouse for the information, and will put researchers in touch with each other to share lessons learned.

The AIDS Institute was established 25 years ago as a non-profit agency. The Institute conducts public policy research, but not scientific research. Their mission is to promote action for social change through research, advocacy, and education. They partner with numerous Florida and national HIV/AIDS organizations to accomplish their goals and objectives.

TAI has offices in Tampa and Washington, DC, overseen by an Executive Director. It has four full-time staff in each office. A major benefit of locating the Consortium at the Institute is that there is less perception of a potential conflict of interest than if it were housed at an entity that conducts scientific research. Nonetheless, TAI's organizational experience and relationships with NASTAD, NIH, NIAID, HRSA, and CDC will help advance scientific HIV-related research in Florida. TAI also has much experience convening and facilitating meetings and conference calls.

The AIDS Institute brings a national perspective to issues that FCHAR will be facing. The Institute has a long history as a trusted source of information for state leaders, members of Congress, the administration, and departments. This access to individuals and government programs will be useful for the administration of and grant solicitation by the Consortium. If the Consortium were totally free-standing, separated from TAI, it would need to go through a lengthy process of applying for non-profit status and would lack the infrastructure to carry out its operations effectively and efficiently. TAI already is a non-profit agency. It has the infrastructure necessary to immediately provide support for FCHAR in the areas of staffing, program budget monitoring, and communications.

### **Proposed Structure of the Research Consortium within The AIDS Institute**

An FCHAR Executive Advisory Board (EAB) will oversee the work of four Subcommittees. Members of the Board will be nominated by each participating organization. The EAB will provide scientific and programmatic advice and recommendations to a Project Coordinator and the general FCHAR membership, as well as to TAI. Day-to-day supervision of the Coordinator's position will be provided by the TAI Executive Director. Additional Subcommittees may be formed by the Board to meet newly identified scientific or organizational challenges, as needed. Each Subcommittee will consist of volunteers from the general membership, which has been the method of recruitment thus far.

The EAB will consist of 15 Consortium members, including one from each of the seven participating universities (Florida State University, University of Florida, University of Central Florida, University of South Florida, NOVA Southeastern University, Florida International University, and University of Miami), the Vaccine and Gene Therapy Institute, the Florida-Caribbean AIDS Education and Training Center, the private sector, county health departments, the State Laboratory, and the Bureau of HIV/AIDS. A consumer will be appointed to the EAB. A representative from an historically black college or university (HBCU) will be appointed.

Each EAB member will designate a backup who would attend conference calls in their absence. The Project Coordinator and a member of The AIDS Institute's organizational Board of Directors will sit *ex officio* on the FCHAR EAB as non-voting members.

Consensus among Board members will always be sought. Where there is lack of consensus on a specific decision, recommendation, or set of recommendations, a two-thirds majority vote will suffice.

The FCHAR Executive Advisory Board will also be responsible for the development of systems of innovation. This involves long-term support to build both management capacity and linkages between researchers through a series of knowledge-sharing opportunities. The Consortium as a whole, under the leadership of the EAB, will work to build bridges among universities, science parks, technology transfer centers, consultants, and grantors. Long-term relationships among institutions with different scientific skill sets, even different aims, can help researchers and Consortium members build on their strengths and identify strategic needs over time.

### **Capacity Building**

TAI and the Executive Advisory Board will be responsible for funding and providing capacity building in science and technology, and will work with policymakers and foundations to determine the best means of channeling those funds. There are many opportunities to support the Consortium and find new and innovative approaches to capacity building.

TAI has years of experience providing and administering capacity building assistance. Currently TAI provides a national capacity building program for the CDC under a 5-year cooperative agreement. There are three key issues that need to be addressed to develop successful and meaningful capacity-building within the Consortium: 1) understand the local/regional context; 2) find the correct mix of short, medium, and long-term research studies; and 3) encourage the development of systems of innovation.

However capacity building is part of a continuous process and cannot be completed through project-funding alone. Although short-term funding may produce some long-term capacities, it may not necessarily be cost-effective or appropriate. Long-term support for research alone does not guarantee that immediate development goals will be met. The FCHAR EAB, along with project staff, will be responsible for overseeing capacity building needs and ensuring appropriate use of funding.

### **Project Coordinator**

A full-time Project Coordinator position will be funded and recruited by TAI's Executive Director to provide continuity to FCHAR and to sustain the momentum already gathered, advancing the vision, goals, and objectives of the Consortium. TAI would provide in-kind intern support for the position. *A proposed organizational chart is shown on the last page of this proposal.*

Functions and responsibilities of the Coordinator include the following:

- Maintain a comprehensive, Internet-based inventory of all HIV-related studies conducted in Florida
- Serve as a conduit to FCHAR member-researchers of solutions to participant recruitment and enrollment problems, as well as other common and uncommon challenges, identifying and sharing successes
- Promote and facilitate inter-institutional collaborative research
- Continue to recruit university-based, CHD-based, and private sector researchers to join the FCHAR
- Serve as liaison with the Bureau of HIV/AIDS, as well as with other external organizations
- Compose and disseminate correspondence to keep the FCHAR membership abreast of plans and developments
- Help identify new funding opportunities and procure new funding for inter-institutional, collaborative research studies
- Contribute to selected grant applications, including helping to draft the HIV/AIDS epidemiology sections within statements of statewide or local need, as required by grant guidances; developing a template that could be re-used for several different grants
- Review and comment on specific, overall grant applications, as requested by the researchers
- Participate in the design and conduct of selected studies as requested by the researchers
- Assist researchers during the Institutional Review Board process
- Prepare press releases
- Prepare periodic monitoring and progress reports
- Produce a newsletter
- With assistance from TAI, plan and convene an annual face-to-face meeting of all FCHAR members and prospective members
- Conduct periodic conference calls or audio/visual conferencing with the Executive Advisory Board, and calls with each of the four Subcommittees; conduct at least one such conference call per year with the general FCHAR membership
- Assume other responsibilities and perform other functions, as necessary, to advance the vision, goals, and objectives of the Consortium.

### **Funding**

Funding for the FCHAR operations will be sought from various private and/or public sources in the short and long term.

### **Timeline**

#### **July:**

Distribute Hard-to-Reach Populations survey to the general FCHAR membership

Distribute a press release announcing the housing of the Consortium at The AIDS Institute

Structural, formal integration of FCHAR with TAI

Begin implementation of other key Subcommittee recommendations, as identified by the Project Coordinator in consultation with TAI's Executive Director

Schedule the next conference calls with the Subcommittees within 4-6 weeks

Seek and obtain short- and long-term funding to support staff and operations

**August:**

Distribute analysis of survey findings, including specific opportunities to share lessons learned

Continuation of short- and/or long-term funding for the project

Conduct conference calls with the four Subcommittees

**September:**

Recruitment of the Project Coordinator

Appointment of FCHAR members to the Executive Advisory Board, selected by TAI's Executive Director in consultation with the Project Coordinator from a pool of nominees from each participating institution, the private sector, and the community of consumers.

**References**

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  4. White S, Grigg BL. Florida 2006 HIV incidence estimates. Unpublished data. Florida Department of Health. Available at [www.floridaaids.org](http://www.floridaaids.org).
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# The AIDS Institute - Proposed Organizational Chart

