AIDS and Cancer Specimen Resource (ACSR)/AIDS Malignancy Consortium (AMC)
Latin American Regional Biospecimen Repository RFA

The AIDS Cancer Specimen Resource (ACSR), (https://acsr1.com) and the AIDS Malignancy Consortium (AMC), (www.AIDSCancer.org) are pleased to announce the establishment of an AIDS cancer specimen regional biospecimen repository site in Latin America. This site will process Latin American AMC clinical trial associated biospecimens and become an ACSR regional biospecimen repository (RBR) with functions that mirror those of the other ACSR RBRs, concordant with the current ACSR structure.

A biorepository is an entity that receives, stores, processes and disseminates specimens as needed for research. Biorepositories ensure that quality biospecimens are available for basic/clinical research including for drug discovery and enrichment of personalized medicine. Biorepositories may perform some or all of the following activities: acquisition/documentation of participant consent, specimen collection, processing, storage, quality control, distribution and tracking; collection of data pertaining to specimens and participants; scientific analysis of specimens and data; and use of information technology to support these activities. Biorepositories may be independent biobanks or part of academic medical centers, community hospitals, or other biostorage facilities.

The biorepository will have two major goals. The first goal is to acquire process, store and equitably distribute tissue, bodily fluids, and other biological samples from individuals diagnosed with HIV and cancer as a fully integrated regional biospecimen repository of the ACSR and as the central biorepository for AMC trials in Latin America. The second goal is to actively develop well-annotated tissue and bodily fluid collections that will help the scientific community to better understand the biological basis of genetic and non-genetic factors that contribute to ethnic and geographical differences in HIV and cancer incidence and prognosis. For each patient and sample, the biorepository will be required to obtain demographic, clinical and other data to be included in the ACSR's database and that can be de-identified for distribution to approved investigators.

This initiative is designed to provide support for the specimen and data collection, storage, processing, and distribution activities of the biorepository. After formal review through established ACSR protocols, specimens and their associated data are to be made available to investigators working in, but not limited to, the following fields of HIV/AIDS research: cancer, virology,

immunology, pathology, epidemiology, and assay/technology development. It is hoped that this broad distribution will encourage interdisciplinary HIV-related studies.

The successful applicant organization is required to work closely with the ACSR and AMC to establish the biorepository in accordance with the National Cancer Institute's (NCI) Best Practices (https://biospecimens.cancer.gov/bestpractices). Additionally, the applicant organization is expected to contribute to the scientific agendas of the ACSR and the AMC in Latin America.

Background

The HIV/AIDS epidemic continues to be a global issue. There is and will be a continuing need for annotated biospecimens for HIV research until we find a "cure" and can prevent HIV transmission. Scientific discoveries arising from research using human biospecimens and the translation of these discoveries to patient care have been instrumental in decreasing the morbidity and mortality of persons living with HIV/AIDS. However, these positive effects have not been uniformly distributed globally. In Latin America, the incidence rate of new HIV infections has changed little over the past 15 years.

Prospective and longitudinal clinical samples collected across the time-line of the HIV/AIDS crisis are critical to understanding the epidemic and its impact on cancer incidence and prognosis. Availability of such specimens facilitates efforts to identify therapeutic targets and to gain further insight into the pathogenesis and treatment of cancer in the HIV-infected population.

Developing countries face an increasing burden of cancer among people living with HIV/AIDS. Morbidity and mortality with non-AIDS defining cancers (NADC) are becoming more common in Latin America, similar to the trend seen in the U.S. and some other countries.

The ACSR, established in 1994 by the National Cancer Institute (NCI), is funded through a cooperative agreement to acquire, store and equitably distribute tissues and biological fluids with associated clinical, pathological, diagnostic, and demographic data from people with cancer in the context of HIV. The ACSR currently is composed of four Regional Biospecimen Repositories (RBRs) and a Technical Core. The primary purpose of the ACSR is to support translational research of malignancies in HIV (http://acsr1.com).

The AMC is an NCI-supported clinical trials group founded in 1995 to support innovative trials for HIV-associated malignancies. The AMC is composed of more than 35 clinical trials sites worldwide, scientific working groups, a Statistical Center, an administrative office, and an Operations and Data Management Center. Collectively, these components develop and oversee the scientific agenda, manage the group's portfolio of clinical trials and other scientific-based studies, and help to develop new protocols. In September 2010, the AMC Executive Committee decided to utilize the ACSR's proficiency in biobanking by having them assume their biospecimen repository functions. This collaboration strengthens and harmonizes both programs by allowing each to focus on their areas of expertise.

The Office of HIV and AIDS Malignancy (OHAM), an Office in the Office of the Director, National Cancer Institute (NCI), has increased its research efforts in HIV-associated malignancies in Latin America supporting the AMC in four clinical trials sites in Mexico, Brazil and Argentina. To support this work and to assure that blood and tumor specimens from participants in these trials are properly collected, processed, stored and maintained using NCI best practices, the ACSR proposes the establishment of an AIDS and Cancer Specimen Regional Biospecimen Repository (RBR) site in Latin America. This biospecimen repository is envisioned to be led by a local Latin

American investigator with expertise in HIV and/or cancer (anatomical pathology) and overseen by the ACSR and the AMC Laboratory Resources Committee. The biorepository will accept biospecimens donated from people living with HIV/AIDS (PLWHA) who have been diagnosed with cancer and consented to have their samples used for research. Such specimens will only be given to researchers after a defined review process and with proof of institutional IRB/ethical approval of the research. This site will also serve as a central repository for specimens collected by the AMC sites in Latin America as part of AMC-sponsored studies.

Funding Available

The National Cancer Institute's (NCI) Office of HIV and AIDS Malignancy (OHAM) has allocated funds for investment in the development of a regional biospecimen repository for the ACSR to collect, process, store and equitably distribute biospecimens to approved investigators for use in HIV-related research projects and also to serve as a central specimen biorepository site in Latin America supporting regional AMC clinical trial sites.

The total budget should not exceed $300,000 per year for the three year project period. Funding proposals should include site personnel costs, supplies, shipping costs and requests for purchase of equipment (e.g. freezers, computers and software, supplies, minor space renovations, etc.).

It is expected that the chosen site will be integrated with the ACSR immediately.

Timeline

During the first year, after development of the physical space, it is anticipated that most prospectively obtained specimens will be AMC study-related from the current AMC core clinical trial sites in Latin America. Subsequently, the RBR may, with appropriate regulatory clearance, begin accepting donated specimens from both AMC and other contributing Latin American sites for the ACSR. In addition, site investigators will work with the ACSR to identify local sources of existing cancer tissues of high value for entry into the RBR.

In the subsequent two years, funds will be used primarily for maintaining and expanding the operations of the repository, its contributions to the ACSR and AMC scientific agendas, and to increase its outreach and ability to acquire, process, and ship specimens for HIV/AIDS-associated malignancy research. The ACSR will work with the site to set up mechanisms and establish procedures for investigators to apply to the biorepository for specimens to be utilized for their funded research studies.

The ACSR has established procedures and protocols for receiving and reviewing of investigator requests for samples, shipping/distributing samples and associated data, and establishing mechanisms for specimen tracking specimens.

Successful projects will have the following required components

- Key investigators who have appropriate experience in biorepository functions, managing clinical data under ethics committee approval, and biorepository quality management including the ability to establish mechanisms that adhere to National Cancer Institute's Best Practices and the ACSR's Manual of Operations and Standard Operating Procedures. Scientists with infectious disease and or cancer as research areas of expertise would be important contributors to the overall ACSR function.

- Infrastructure (physical and resources including IT, IRB and other Core services,) in place to support a human biorepository (collection, processing, storage, and distribution of specimens and associated clinical data as well as patient consenting)
- Clinical laboratory and pathology components (with secured access to appropriate pathology expertise- anatomic pathology, hematopathology) capable of validating diagnoses of all tissues entered into the RBR inventory system.
- Oncology expertise - pediatrics and adult. Access to cancer registries and ability to cross-reference with HIV registries if they exist.
- Qualified personnel to function as biorepository technicians.
- Data manager/program analyst with experience in clinical trials, medical record abstraction/terminology/coding, inventory management systems, data entry/export and various database management systems/software. Capability to link electronic medical record data with specimens entered into the RBR inventory system.

Proposals with the following additional qualities will be given highest priority

- Level 2-biosafety laboratory with biosafety cabinet
- Emergency back-up power supply that could be maintained for at least 48 hours
- Established laboratory supply chain for processing and storage of specimens
- Access to liquid nitrogen delivery, LN2 shipping containers, and access to dry ice for shipping
- Access to or established electronic surveillance of room air and freezer temperatures
- 24/7 contact coverage for personnel to respond in case of electronic surveillance monitor alarms
- Secured area for equipment and storage for information sensitive paperwork
- High speed internet connections and IT infrastructure to support and secure web and cloud-based applications
- Secured storage area to accommodate initially, one -80C freezer and one LN2 freezer with adequate ventilation and space to grow
- A temperature-controlled room/area for slides and blocks

Eligibility

In order to be eligible for this initiative, applicants must demonstrate:

- Institutional commitment and resources to support the missions of the ACSR and AMC.
- The willingness, ability, and institutional and governmental approval to accept and ship specimens from other Latin American and international sites.
- The ability to distribute samples to investigators from other countries (domestically and/or internationally).
- The knowledge and understanding of the regulatory aspects of all processes and policies related to biorepository functions and biospecimen science.

Application and Selection Process

The ACSR will host a Webinar on November 20, 2020 at 2 PM EST to introduce the ACSR and answer questions. Registration is required by contacting ssilver@gwu.edu.

Applications will be solicited from sites with proven strong pathology, infrastructure capacity and prior experience in HIV research in both clinical trials and laboratory studies. These sites will be asked to submit an application describing their interests, experience, and facilities for conducting this work. A site visit team comprised of members from the ACSR, AMC, and OHAM/NCI will visit each of the competing sites for evaluation.

Successful applications must include the following:

- Defined reliable mechanisms to create, implement, and assess adherence of the applicant institution to the ACSR's Manual of Operations and Standard Operating Procedures and NCI Best Practices for Biospecimen Resources, and quality control/quality assurance (QC/QA) tests
- Defined procedures by which the applicant institution will work with the ACSR, AMC Clinical Trials sites, other NCI-funded projects, and other sites willing to contribute in obtaining specimens that fit the needs of the research community.
- Projected number of tumor samples (both fresh frozen and FFPE), associated body fluids, and associated clinical data that could be acquired each year that reflects the HIV epidemic locally (*e.g.,* KS, non-Hodgkin lymphoma, cervical cancer, Hodgkin lymphoma, lung, liver)
- Current or previous participation in HIV/AIDS-related clinical trials research and/or biobanking activities
- Confirmed ability to collect fresh frozen tumor tissues for research purposes
- Investigators should include a pathologist for tissue diagnosis validation and doctoral level scientists with research interests in infectious disease or cancer

Once selected, the ACSR and AMC will evaluate the resources of the approved site and determine the need for the purchase of required equipment to establish and maintain the biorepository, conduct training of the local investigators and staff, assist in the development of administrative policies and technical SOPs, introduce and help facilitate interactions and transfer of specimens from AMC sites to the biorepository, assure that all necessary IRB and other regulatory requirements are met, and assure that proper procedures for handling of specimens and data are in place prior to their receiving specimens from the AMC trial sites. The ACSR and AMC will also assist the site to establish connectivity and an electronic inventory system and database for specimen annotation and tracking, receive training in the ACSR and AMC standardized data capture systems to assure proper specimen tracking and entry of required data.

The biorepository site will be required to adhere to all ACSR and AMC required specifications and SOPs, which will be subject to regular auditing by the ACSR and AMC.

The biorepository PI will be required to attend selected ACSR Executive Committee and AMC Steering Committee meetings and other HIV-related meetings (scientific and/or biorepository conferences).

Submission Process

Proposals will be submitted and assessed through the ACSR.

- Letter of Intent required by December 30, 2020
- Proposals must be submitted via e-mail in PDF or MSWord format no later than ***Friday, January 29, 20201 by 5 PM EST to ssilver@gwu.edu***.

Applicants should submit their **six-page maximum narrative**, plus a three-year budget using the PHS398 budget forms and budget justification. Also, include biosketches for key personnel (using NIH biosketch) and resources.

Finalists will be informed to prepare for a site visit conducted by members of the ACSR, AMC and OHAM to assess their site's infrastructure and capacity to perform biorepository functions. The assessment will involve reviewing the site institution's commitment, proposed key personnel, present pathology support and laboratory infrastructure, data management operations and understanding of local, state and government regulatory policies and procedures.

Award will be announced in July/August 2021

If you are interested in submitting a proposal, or for more information and additional details on how to participate, please e-contact Dr. Sylvia Silver at ssilver@gwu.edu or 202-994-2945.