

## **Self-Sustaining Infectious Disease (ID) Clinical Specimen Repository**

### **What is a Clinical Specimen Repository?**

A clinical specimen repository is a facility that collects, catalogs, and stores samples of biological material, such as urine, blood, tissue, cells, DNA, RNA, and protein, from humans for laboratory research. Medical information also may be stored along with a written consent to use the samples in laboratory studies. Clinical specimens already frequently are collected during clinical trials. Preserving these specimens for future use would strengthen infectious diseases research and critically needed diagnostics development by reducing redundancies (i.e. eliminate the need for multiple players to collect the same types of specimens numerous times), assuring quality specimens are collected, and saving valuable time and resources. A clinical specimen repository could house clinical specimens obtained, for example, from phase II or phase III clinical trials of drugs or devices.

### **How would an ID Clinical Specimen Repository Work?**

Initially, federal funds would be needed to establish and house the repository. The National Institute for Allergy and Infectious Disease (NIAID) is best situated to take the lead. To ensure usability in multiple instances, samples would be collected prospectively through clinical trials, etc. (including through the new NIAID supported clinical trial infrastructure focused on antibiotic resistant bacterial infections), with defined protocols and linked to all available patient clinical data. The repository could allow researchers — both government-funded and industry-based — to access samples without having to conduct new clinical trials to obtain specimens.

Companies, including those developing diagnostics, that wish to access the repository would pay a fee to do so. NIAID would collect the fees and, ultimately, the fees would entirely sustain the maintenance of the repository.

A central repository would represent a significant advance over current sample collection where each facility or company exclusively collects and owns all samples and no cross-validation is possible.

A similar Cancer Human Bio-Bank (ca-HUB) is being established by the National Cancer Institute (NCI). On the concept of the cancer specimen repositories, IOM has opined that, “The broader use of high-quality, standardized repositories would speed the pace of scientific and clinical advances at a much lower expense than would be required if new clinical samples had to be collected to study each new concept.” We propose the same is true for infectious disease research.

### **How Could an ID Clinical Specimen Repository be Useful in Combatting Antimicrobial Resistance and Infectious Disease?**

Prospectively archived infectious disease (ID) specimens would be highly valuable for the development of rapid point-of-care molecular diagnostic devices capable of detecting pathogenic organisms from patient samples. Rapid diagnostic tests improve physicians’ ability to prescribe antibiotics in a manner consistent with antibiotic stewardship. Better diagnostics reduce the costs of new antibiotic development by increasing the number of microbiologically evaluable patients in the clinical trial population. There are currently serious challenges to enrolling eligible patients in clinical trials for new antimicrobials, including a lack of rapid diagnostics to identify patients with particular resistant infectious.

The existing rapid influenza point-of-care tests have only limited clinical utility, especially for detection of novel influenza A viruses. Additional investments are needed to facilitate the development of

advanced diagnostics for influenza. Inexpensive, accurate diagnostic tests that can provide results in a timely manner can guide laboratory, clinical and public health responses.

Unfortunately, numerous disincentives exist that hamper the development of new diagnostic tests, including the expense of collecting clinical specimens against which to validate diagnostics, difficulty in obtaining FDA approval for diagnostic tests and challenges in securing Medicare and private insurance coverage of new diagnostics. A repository could serve as an essential component of clinical validation for new diagnostics and could reduce overall diagnostic development time. Efforts must be made to encourage research and development of new diagnostics, and a repository that would allow access to high quality clinical infectious disease specimens would be an important tool to ease research burdens.

### **Has a Clinical Specimen Repository Been Useful in Other Areas of Medical Research?**

Yes. A 2010 Institute of Medicine (IOM) report titled “A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program,” found that “The Cooperative Groups have a history of collecting biospecimens from the diverse populations of patients who participate in their clinical trials and maintaining them in repositories with detailed information about patient characteristics, treatment, and outcome. These resources have proven immensely valuable in the development of molecular-based classification schemes and diagnostic tests that now guide decisions on the most appropriate therapy for numerous types of cancer.”

ca-HUB aims to modernize the field of cancer specimen biobanking by developing an infrastructure for collaborative biospecimen collection and research including through the production of evidence-based biospecimen standard operating procedures. NCI currently is developing ca-HUB which is expected to be implemented in 2012-2014. ca-HUB will make the resulting data, analysis, policy documents, and scientific tools publicly available to enable the community to collect biospecimens fit for specific scientific purposes. The primary operating components of caHUB will consist of medical research and health care institutions for biospecimen collection, a pathology reference center, core biospecimen processing and analysis operation, a comprehensive and highly integrated informatics platform (e.g. , including patient clinical data, patient consent, biospecimen handling data, and molecular analysis), and a research and development program integrating the efforts underway within NCI's Biospecimen Research Network and NCI's Innovative Molecular Analysis Technologies Program.

The caHUB network will make biospecimens available to a larger scientific community and assure quality control of biospecimens. Such assurance will come through the adoption of national standard operating procedures for collecting, processing, and storing biospecimens and better guidance and educational opportunities for biobank personnel and managers.

CA-HUB also will serve a critical role in coordinating a systematic approach to biospecimen science. CA-HUB will work to facilitate communication and coordination across sectors through an extensive network of partners which includes government agencies, private industry, and non-profit and advocacy organizations. NCI has allocated \$23.5 million that the institute received from the American Recovery and Reinvestment Act (ARRA) of 2009 for development of caHUB.