Testimony
Before the Subcommittee on Investigations and Oversight
Committee on Science and Technology
United States House of Representatives

Biorepository Policies and Practices at the National Cancer Institute

Statement of
Jim Vaught, Ph.D.
Deputy Director
Office of Biorepositories and Biospecimen Research
National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 AM
Tuesday, September 9, 2008

Good morning Mr. Chairman, Mr. Sensenbrenner and members of the Subcommittee. I am Dr. Jim Vaught, the Deputy Director of the Office of Biorepositories and Biospecimen Research (OBBR[1]) at the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). I have been engaged in the area of biospecimen research and biorepository management for over 15 years, and I have participated in the development of a number of practices and policies relevant to today's discussion. This testimony will highlight four specific activities relevant to the hearing topic.

In 2007, NCI published its Best Practices for Biospecimen Resources, which provide guiding principles that define state-of-the-science biospecimen resource practices, promote high standards of biospecimen and data quality, and facilitate compliance with ethical standards and legal requirements. NCI has also been involved in a trans-NIH effort to develop a policy framework on legal and ethical issues that would apply to all NIH-supported human specimen collections. Additionally, I have been an active participant in the NIH Scientific Directors Subcommittee on Biorepository Practices and Guidelines within the Intramural Research Program, formed in 2006 to address biospecimen storage and tracking practices and policies at laboratories at NIH facilities. The recommendations of this group are currently being implemented.[2] In 2005, I was appointed to a Federal-wide Interagency Working Group on Scientific Collections

[1] NCI Office of Biorepositories and Biospecimen Research (OBBR) web site: http://biospecimens.cancer.gov/

[2] NIH Intramural Research Program Biospecimen Guidelines: http://www1.od.nih.gov/oir/sourcebook/oversight/Biospecimen%20Storage%20and%20Tracking%20Guidelines%2020080717.pdf

(IWGSC). This working group is a subcommittee of the Committee on Science (COS), within the National Science and Technology Council (NSTC), managed by the Office of Science and Technology Policy (OSTP). Our charge has been to identify resources and requirements, including research and development needs, for long-term stewardship of these collections, and to foster coordination of collections-related activities across the Federal government.

These aforementioned activities - the development of the NCI biospecimen best practices document, the NIH guidelines for the intramural program, the trans-NIH policy framework on legal and ethical issues and the Federal-wide Working Group - were triggered in part by the acknowledgment that the value of biospecimens and other scientific research collections is not always recognized and that these collections need to be managed in an optimal way. Substandard practices can have a negative impact on research studies as well as the practice of medicine. In a September 2007 report on Personalized Health Care,[3] HHS also recognized the critical importance of biospecimens to the research infrastructure that will support personalized medicine. The vision of personalized medicine is one in which the standard of medical care is improved by adding an individual's genetic and molecular profile to the decision-making process.

Scientists can now study cancer at the most fundamental level, identifying genes and their functions in the body, called genomics, and studying the corresponding set of proteins programmed by the genetic code, called proteomics. At NCI we recognize the critical

[3] *Personalized Health Care: Opportunities, Pathways, Resources*. U.S. Department of Health and Human Services, http://www.hhs.gov/myhealthcare/

role that biospecimens play in these endeavors. OBBR's mission is to ensure that human specimens are available for cancer research and that they are of the highest quality. The OBBR is responsible for developing a common biorepository infrastructure that promotes resource sharing and team science, in order to facilitate multi-institutional, high throughput genomic and proteomic studies. These types of studies will lay the groundwork that will lead us to personalized medicine.

With the support of NCI senior leadership, our office worked in a highly collaborative manner with many NIH and external experts to develop the NCI Best Practices for Biospecimen Resources. Following a careful analysis of NCI's biological specimen practices, NCI sponsored two workshops in 2005 that resulted in a series of recommendations that, along with existing guidelines, regulations and best practices from other organizations, became the NCI Best Practices. The Best Practices include recommendations from technical and ethical/legal standpoints. I have provided the full document to the Committee, but for the purpose of today's discussion, the recommendations in Section C.1 of the Best Practices, concerning custodianship of specimen collections, are the most relevant. We consider the custodianship issue to be so important that we sponsored a workshop on Ownership and Custodianship Issues in Biospecimen Research in October 2007, which resulted in a series of more specific recommendations[4] that we are considering for incorporation into the next version of the NCI Best Practices.

[4] NCI OBBR Ownership and Custodianship in Biospecimen Research Workshop summary: http://biospecimens.cancer.gov/global/pdfs/CaOSumm.pdf

The NIH Scientific Directors Subcommittee was formed to make recommendations to the Scientific Directors concerning biorepository practices and policies within the NIH Intramural Research Program. As a result of the work of this subcommittee during 2006 and 2007, NIH published Guidelines for Human Biospecimen Storage and Tracking within the NIH Intramural Research Program. These Guidelines make specific recommendations regarding: 1) the transfer of specimen custodianship and informed consent information when the responsible investigator leaves NIH or when the custodianship needs to be changed for other reasons; and 2) reporting requirements for the specimen inventory and tracking systems being used. In addition, NIH intramural investigators were directed in a June 2006 memorandum to include in their Institutional Review Board (IRB) packages the manner that specimens are stored, tracked, and what will happen to the specimens at the completion of the protocol.[5] As a result, any decision to destroy or transfer specimens out of NIH is carefully monitored by Scientific Directors as well as IRBs. At NIH, the specimens obtained belong to the Government, not the researcher. Plans to move materials outside NIH must include appropriate material transfer agreements and must be approved. NIH policy does not permit a scientist leaving the NIH to disperse his/her materials without review.

The Federal-wide IWGSC was formed in response to a call from the White House Office of Science and Technology Policy (OSTP) and the White House Office of Management and Budget (OMB) for Federal agencies to address the scientific, environmental, societal, and national security needs for collections. The Working Group's main activity to date

[5] June 12, 2006 memorandum from Dr. Michael Gottesman: Research Use of Stored Human Samples, Specimens or Data: http://www.nihtraining.com/ohsrsite/info/DDIR.html

has been to conduct a survey to examine the current state of Federal scientific collections and to assess general thematic issues regarding collections management and stewardship. These collections are highly variable, from NIH's human biological specimens to NASA moon rock collections and Smithsonian museum artifacts (for example, from the Lewis and Clark Expedition). A report is being prepared to outline the Working Group's findings. As we had found in our assessment of the NCI and NIH collections, the IWGSC survey found that Federal agencies often do not have standardized, comprehensive approaches to the long-term management and use of their scientific collections. The IWGSC is evaluating recommendations that are consistent with NIH long-term management principles.

In conclusion, there is broad agreement that collections of biological specimens, as well as other collections of materials of scientific value, are critical to the research enterprises that support, among other important endeavors, advances in the medical and technological fields. As such, standardized, high quality management practices and long-term plans for custodianship of these collections are needed. Since many such collections are priceless and irreplaceable, adoption of practices such as those developed by NCI and other groups that I noted will be critical if we are to preserve them in the condition necessary to make the scientific discoveries and medical advances for which they were collected. We are mindful that when patients and other study participants agree to provide blood or other samples for a research study, they generally do so with an expectation that their tissue will be used to provide insight into the causes and/or cures of their disease, or to advance medical research in general.

Based on these considerations, the NCI Best Practices reflect the following themes with respect to custodianship of biospecimens:

1. At the beginning of a study or program that will include biospecimen or other research collections, a custodian, either a person or a governance committee, should be appointed by the institution to develop a plan for addressing long-term management of specimen collections.
2. Responsible custodianship requires appropriate management of financial or scientific conflicts of interest that may interfere with appropriate judgment concerning the proper disposition of the collection, and the most appropriate scientific and/or medical use of the specimens.
3. All applicable regulations and policies concerning, for example, privacy, informed consent, and material transfer must be followed in decisions concerning the disposition of specimens and data.
4. Custodianship plans should state in detail how specimen collections will be managed or dispersed when funding is lost, custodial management changes, or protocols are completed, including careful consideration of the future scientific value of the collection. The plan should recognize that specimens that are no longer valuable or necessary for their original purpose may be useful for other purposes, consistent with the requirements of informed consent and other applicable rules and policies.

These are extremely important issues concerning critical resources that are central to our biomedical research infrastructure.

We appreciate the opportunity to provide our views, Mr. Chairman. Thank you, and I would be pleased to answer any questions.