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June 30, 2006

Dr. John E. Niederhuber  
Acting Director  
National Cancer Institute  
9000 Rockville Pike  
Building 31, Room 11A48  
Bethesda, Maryland 20892

Re: First-Generation Guidelines Comment

Dear Dr. Niederhuber:

The American Society of Clinical Oncology (ASCO), representing more than 20,000 oncologists worldwide, appreciates the opportunity to comment on the First-Generation Guidelines for NCI-Supported Biorepositories. The availability of high-quality biospecimens is critical to research related to the prevention, diagnosis, and treatment of cancer, and we applaud the National Cancer Institute (NCI) for developing solid guidelines for the establishment and maintenance of biorepositories. The comments below address several specific issues, but emphasize the need for additional planning related to the implementation of the guidelines and development of a process for revision of the guidelines.

**Compliance with First-Generation Guidelines**

The guidelines state that managers of all NCI-supported intramural and extramural biorepositories will initially be asked to conform to the new standards on a voluntary basis. We agree that voluntary compliance is appropriate at this time, but we note that a significant obstacle to compliance will be cost. The cost of adhering to the new requirements will be felt by all but may be most burdensome for smaller tissue banks. These costs include state-of-the-art alarm and backup systems, process-oriented informatics, personnel with a higher level of skill than at present, and stringent software engineering standards. We recommend that NCI cooperate with the biorepositories it supports in assessing the resources that will be required to implement these first-generation standards.

Based on such an analysis, NCI should seek to make available additional funding to encourage rapid implementation of the guidelines by biorepositories. Without such resources, we are concerned that existing biorepositories, or so-called "legacy" biorepositories, will not embrace the new standards and that new biorepositories will find the burden of implementation to be prohibitive. We are aware that overall

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funding for NCI is unlikely to be increased substantially this year or for the foreseeable future and new commitments of funding are difficult. However, because of the critical importance of biorepositories, we encourage appropriate funding for implementation of the first-generation standards.

### **Access to Biospecimens and Data**

The first-generation guidelines require NCI-funded repositories to establish clear guidelines for sample distribution. They also state that NCI intends to "... have a substantial role in developing the best practices on which these guidelines will be based." The best practices are intended to delineate the responsibilities of funded biorepositories. ASCO recommends that the process of developing best practices and guidelines for sample distribution be a cooperative one between NCI, the funded repositories, and those organizations responsible for development and oversight of research studies that utilize the biospecimens. The experience and expertise of current repositories in developing standards for access to samples should be fully utilized in describing best practices and drafting comprehensive standards for NCI-funded biorepositories.

### **Collection Protocols**

The guidelines recommend that collection protocols be based on solid research data. For some specific specimen types, data are unavailable or are conflicting. Collection of those specimens should not be delayed while collection protocols are being developed or revised, nor should specimen collection protocols include burdensome requirements not supported by evidence. Biorepository representatives should be included in initiatives to develop such protocols.

### **Definition of Guideline Requirements**

In several instances, the guidelines are not specific regarding the requirements that biorepositories must meet, and we recommend a greater level of detail to ensure more complete compliance.

- The guidelines recommend that biorepositories employ "state-of-the-art sample tracking procedures and supporting informatics." We suggest that NCI define the necessary and appropriate features of such a system.
- NCI recommends that biorepositories improve their inventory management applications and suggests that it is developing the infrastructure to support implementation of the guidelines. Some of our members have reviewed the caTISSUE component of the NCI infrastructure support and have found it of limited functionality. We suggest that NCI and NCI-funded biorepositories cooperate on the development of NCI infrastructure support to ensure that NCI systems are useful to biorepositories.
- The guidelines lack specificity regarding the required reporting functions in the software applications that NCI will consider acceptable for use in repositories. We recommend



that the guidelines specify a minimum standard reporting capability for inventory systems that are approved by NCI. The reporting standards should reflect the annual reporting requirements for NCI-supported biorepositories.

### **Review and Revision of the Guidelines**

The agency has indicated that comments will be accepted during the first year of implementation of the guidelines and that the guidelines will be revised iteratively, with "... input from researchers, biorepository managers, advocates, policymakers, and related stakeholders." Due to the ambitious scope of the guidelines, it is not unexpected that revisions will be necessary. ASCO recommends that NCI define with greater detail the process that it will undertake for soliciting input from the cancer research community regarding the evolving standards for biorepositories.

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We appreciate the opportunity to comment on the First-Generation Guidelines for NCI-Supported Biorepositories and look forward to continued collaboration with the agency on this important issue.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, flowing style.

Joseph S. Bailes, MD  
Interim Executive Vice President and CEO

cc: Office of Biorepositories and Biospecimen Research  
Office of the Deputy Director for Advanced Technologies  
and Strategic Partnerships  
National Cancer Institute  
National Institutes of Health  
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Bethesda, MD 20892