



**Association of
American Medical Colleges**
2450 N Street, N.W., Washington, D.C. 20037-1127
T 202 828 0400 **F** 202 828 1125
www.aamc.org

June 29, 2006

BY ELECTONRIC MAIL: biospecimens@mail.nih.gov

First-Generation Guidelines
Office of Biorepositories and Biospecimen Research
Office of the Deputy Director for Advanced Technologies
and Strategic Partnerships
National Cancer Institute
National Institutes of Health
31 Center Drive, Room 10A03
Bethesda, MD 20892

RE: First-Generation Guidelines Comment

The Association of American Medical Colleges (AAMC) is a nonprofit association that seeks to improve the nation's health by enhancing the effectiveness of academic medicine. It represents all 125 U.S. and 17 Canadian accredited allopathic medical schools, 400 teaching hospitals, 96 academic societies, and the nation's 67,000 medical students and 104,000 residents. It is increasingly important that biospecimens meet uniform standards of the highest quality to facilitate meaningful interpretation of data obtained with ever more powerful and sensitive technologies. The AAMC is especially concerned about this crucial issue because academic institutions house a significant proportion of the nation's biospecimens. We commend NCI's effort to overcome the heterogeneity that exists across biorepositories by standardizing methodologies for quality assurance/quality control (QA/QC); for collecting, annotating, processing, storing, retrieving, and distributing biospecimens; and for formatting, storing, transferring, and accessing associated data.

In facilitating the standardization of policies and procedures, the guidelines consequently facilitate integration, resource sharing, and team science. Other strengths that the guidelines possess include their flexibility, degree of universality, and potential not only to enable higher quality research, but also to ensure ethical integrity and foster public trust. We applaud the plan iteratively to revise the guidelines according to feedback from researchers, patients, biorepository directors, policymakers, and associated stakeholders. This built-in ability to evolve is necessary to accommodate changing needs that arise with technological advances, as well as to accommodate the fine-tuning of best practices.

We also applaud the requirement for biorepository personnel to disclose financial conflicts of interest according to institutional policies and procedures. We believe this requirement is both sensible and necessary due to the extraordinary value of high-grade biospecimens and the need to ensure that they are distributed fairly on the basis of scientific merit and importance.

Page 2

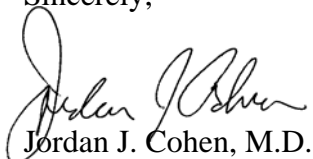
Lastly, we agree with the format of the NCI sample consent form and the accompanying informative brochure, especially the text addressing the scope of future research. The text is non-specific (e.g. "may be used in research to learn more about cancer and other diseases"), allowing a wide-range of future research possibilities without the need for obtaining additional consent. Consequently, the sample informed consent form not only sufficiently informs the research participant, but also allows the biospecimen to be as useful as possible for future research by avoiding gratuitous encumbrances. We would like to note that future research use may also be facilitated by FDA and OHRP guidance (<http://www.fda.gov/cdrh/oivd/guidance/1588.pdf> and <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>.) describing situations in which the use of de-identified samples does not require informed consent.

Although we believe the guidelines successfully achieve NCI's goals on many levels, we have some concerns. First, Section IV ("Implementation") states that "NCI may consider making these guidelines terms and conditions of awards." Furthermore, it states that the "guidelines will eventually apply to all applicants of NCI-supported biomedical research involving biorepositories of human biospecimens." It is unclear what NCI means by this statement. Does it mean the guidelines will eventually apply to *all* NCI grants that may use human tissue specimens or that support the storage of even a small number of biospecimens, or only to grants specifically supporting large-scale biorepositories? Although the guidelines are suitable for large-scale biorepositories, we believe they are inappropriate for smaller facilities or individual laboratories because the guidelines impose administrative, regulatory, and financial burdens too great for smaller biorepositories to bear. A sensible approach would be to pilot the guidelines with large-scale biorepositories, develop best practices, and then determine which aspects could be applied to smaller biorepositories or individual laboratories without undue burden. If NCI eventually decides to require all biorepositories to adhere to the guidelines, then the Institute needs to develop a financial plan to support such an undertaking.

Our second concern relates to text that is more suggestive of regulation than guidance. In accordance with the [Good Guidance Practices](#) issued by the Office of Management and Budget in 2005, guidelines "should not include mandatory language such as 'shall,' 'must,' 'required' or 'requirement,' unless the agency is using these words to describe a statutory or regulatory requirement." The guidelines' language should be modified to adhere to Good Guidance Practices.

In closing, we commend the NCI for its diligent data collection and analyses involving queries to private industry, clinical oncologists, patient advocacy groups, bioethicists, and the broader oncology research community. These efforts have culminated in a set of guidelines that go to great lengths to standardize policies and procedures, and thereby, facilitate integration, resource sharing, team science, and the reliable application of powerful new technologies in human tissue research. Spanning technical, operational, ethical, legal, and policy issues, these guidelines have the potential to set a high standard for biorepositories more broadly.

Sincerely,



Jordan J. Cohen, M.D.
President