MASSACHUSETTS INSTITUTE OF TECHNOLOGY

**Claude R. Canizares**
*Vice President for Research and Associate Provost*
*Bruno Rossi Professor of Physics*

77 Massachusetts Avenue, Building 3-234
Cambridge, Massachusetts 02139–4307
Phone 617–253-3206
Fax 617–253-3193

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Jerry Menikoff
Department of Heath and Human Services
Office of Human Research Protections
1101 Wootton Parkway
Suite 200
Rockville, MD 20852
*Submitted through http://www.regulations.gov*

Subject: Docket HHS-OPHS-2011-0005 - Enhancing Protections for Subjects and Reducing Burden, Delay and Ambiguity for Investigators

Dear Dr. Menikoff:

Thank you for the opportunity to comment on the proposed changes to the Common Rule (codified at Subpart A, 45CFR46) from 1991. While we agree that the Rule is worth reviewing and modernizing, in some places, we would like to note that the Office of Human Research Protections (OHRP) has issued numerous guidance memos over the last several years, which have added significantly to the Rule, increasing the level of regulation.

We support the purpose of the ANPRM, which was meant to improve the efficiency of IRBs and enhance the protection of human research subjects. However, in many cases, we believe that the proposed changes actually take power away from the IRBs at the local level and centralize certain functions elsewhere. In doing so additional new layers of bureaucracy are added and the burdens on investigators and institutions increased. The letter from the Council on Governmental Relations (COGR) and the joint letter from the Association of American Universities (AAU) and Association of Public and Land-grant Universities (APLU) detail many examples of this. MIT supports most of these positions with a few exceptions where we have chosen to implement stricter controls that we believe were necessary and appropriate to protect human subjects. For example:

1. The proposed change from the current "exempt" research category (which requires no IRB action), to "excused" research would now require the researcher to file an informational sheet with the IRB and for the institution to audit these

periodically. Under longstanding MIT policy our IRB (COUHES) has reviewed all types of human subject research whether reviewable under the existing regulations or exempt from review under those regulations, in order to protect human subjects.

2. The ANPRM proposes data protection standards, and MIT agrees. We implemented data security and information protection requirements several years ago. But while we agree that this is necessary, the HIPAA standard for this kind of information is excessive. MIT's data protections requirements include password protected files and computers, locking carrying-cases, awareness training on data for researchers and so forth. We believe these standards are adequate for protecting non-medical related human subject research data.
3. Regarding informed consent for the future use of biospecimens, we believe that DNA sequencing technologies allow for the generation of very powerful data that could have profound consequences for the original donor of a biospecimen (or for his/her family), and therefore, some regulation governing review of their use is necessary. Due to the nature of work at MIT and its partners and affiliates, our IRB has been reviewing this sort of research for quite some time, even though under existing regulations biospecimens do not constitute "human subjects". Consent is an important component of this research. This is particularly true because the results of this kind of research often lead to the potential to identify a sample, especially, as is increasingly the case, when the results are then deposited in a public data bank. Additionally we have found that the researchers themselves want this sort of research reviewed for many reasons, including the fact that publications will not accept their work unless it has been sanctioned by an IRB.

   Any new standards developed in this area should be based on the principle that all biospecimens, whether or not they include identifiers, and whether or not they were initially collected for research purposes or as part of clinical care, should require consent from the original donor, or the follow-on secondary use research should not be allowed. This consent may be open-ended or contain explicit limitations delineated at the time the biospecimen is donated.

We welcome the opportunity to discuss these comments with you further.

Sincerely yours,

Claude R. Canizares