CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

October 26, 2011

Jerry Menikoff, M.D., J.D.
Office for Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway
Suite 200
Rockville, MD 20852

RE: HHS-OPHS -2011-0005, Advance notice of proposed rulemaking, Human Subjects Research Protections

Filed electronically at http://www.regulations.gov

Dear Dr. Menikoff:

The undersigned organizations of the Cancer Leadership Council (CLC), representing cancer patients, physicians, and researchers, are pleased to offer comments on the advance notice of proposed rulemaking on human subjects research protections regulations (the Common Rule). We commend the Department of Health and Human Services (HHS) for announcing its intention to review the current regulations governing human subjects research and soliciting early advice about the review and revision of the research rules. We provide our initial reactions to the review process and will participate in the formal rulemaking process as it proceeds.

We support the principles underlying the revision of the research rules, including the fundamental principles of directing oversight resources to higher-risk studies and modernizing the oversight system to keep pace with the volume of research and movement toward more multi-site research studies. Cancer researchers, research participants, and patients and families hoping for therapeutic advances have long expressed concerns about duplicative institutional review board (IRB) oversight of multi-institutional studies that has significantly slowed the initiation of cancer clinical trials, and we are pleased that this is one of the issues that the Department seeks to address.

Streamlining IRB Review of Multi-Site Studies

The general trend noted by HHS – the movement toward multi-institutional research studies – is the norm in cancer clinical research, and this research trend has been accompanied by delays in review that are also described in the advance notice of proposed rulemaking (ANPRM). The initiation of cancer clinical trials may be significantly slowed as the IRB at institution after institution reviews and revises the trial

protocol or modifies the informed consent form for the trial. These actions offer no additional protections to research subjects but do postpone the initiation – and as a result the completion – of important research trials.

We support the revision of the Common Rule to require the designation of a single IRB – whether a central IRB operating outside a research institution or the IRB at one of the participating research sites – as the IRB of record for the multi-institutional study. A central IRB designated as the IRB of record should be capable of undertaking review of the study's social value, scientific validity, risks and benefits, and adequacy of the informed consent process. The revision of the Common Rule should make clear that the IRB of record will be held responsible for regulatory noncompliance and that such responsibility will not be borne by the IRBs of other participating institutions. Such clarification would not relieve local institutions of the responsibility for protecting research participants, but it would address their concerns related to their legal exposure for the actions of an IRB of record that is located outside the institution.

We are aware of the efforts of the National Cancer Institute (NCI) to establish central IRBs for certain adult research studies and pediatric cancer studies, actions which are important in improving research initiation and oversight but inadequate to prevent duplicative IRB review. Revision of the Common Rule to require, rather than just to permit, central review for multi-institutional studies is necessary to realize the potential of central IRBs that are already established and to discourage institutions from undertaking duplicative protocol and informed consent review even when there is central IRB review.

Consent for Biospecimens and Information

We appreciate the ANPRM analysis suggesting that: 1) de-identification of biospecimens and individual health information is no longer possible in light of information technology advances and 2) individual consent for future research uses of biospecimens and information is necessary and appropriate in view of the inability to de-identify with certainty. We anticipate that many – but certainly not all – individuals will consent to future research uses of their health information and biospecimens.

The decision to apply the consent requirement prospectively is a wise one. However, that determination does not address many issues that will arise from the requirement to obtain consent for future research uses. The ANPRM anticipates that consent for biospecimens would be obtained through a "standard, brief general consent form allowing for broad, future research." The proposed rule must set firm and specific standards for the future research consent form and prohibit researchers and IRBs from modifying the brief general consent form. Only by setting such standards can the efficiencies of a future research consent form be realized.

Modifications to the future research consent would complicate the informed consent process and the ability of institutions to track, manage, and permit the future research uses of biospecimens and information they maintain. Such changes to consent forms

would also have the effect of undermining the potential of future research using biospecimens. These problems should be anticipated and addressed in the proposed rule.

We also anticipate that institutions will confront significant responsibilities for tracking biospecimens and information for which they obtain future research consent (and those for which consent is not granted), as well as those specimens that were collected prior to the imposition of the consent requirement. Such systems for monitoring and tracking will be necessary in order to honor the preferences of individuals about the use of their biospecimens, including the limits that some may place on future research use. It is our hope that enhancements in technology, including information technology, will ease these burdens. Even if institutions can take advantage of technology, however, there will be some transitional and ongoing responsibilities related to tracking of consent for future research use that will require the commitment of financial resources.

We also note that the benefits of a general consent for future research uses – the possibility of undertaking important research studies with biospecimens in future years – may not be realized unless the Health Insurance Portability and Accountability Act (HIPAA) requirements related to authorization for future research uses are revised in a manner consistent with the anticipated revisions of the Common Rule.

*****

The CLC appreciates the opportunity to offer comments at an early stage in the process of revising the Common Rule. We will continue to monitor this process and will offer comments on the proposed rule when it is published.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
Cancer Support Community
Coalition of Cancer Cooperative Groups
Fight Colorectal Cancer
International Myeloma Foundation
The Leukemia & Lymphoma Society
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Susan G. Komen for the Cure Advocacy Alliance
Us TOO International Prostate Cancer Education and Support Network