

October 26, 2011

Jerry Menikoff, M.D., J.D.  
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Member Organizations

*American Association  
for Cancer Research*

*American Cancer Society  
Cancer Action Network*

*American Childhood  
Cancer Organization*

*American College  
of Radiation*

*American Society for  
Therapeutic Radiology  
and Oncology*

*American Society of  
Clinical Oncology*

*American Society  
of Hematology*

*Association of American  
Cancer Institutes*

*Cancer Research and  
Prevention Foundation*

*Cancer Treatment  
Research Foundation*

*Coalition of Cancer  
Cooperative Groups*

*CureSearch National  
Childhood Cancer Foundation*

*International Cancer  
Advocacy Network*

*International Myeloma Foundation*

*Kidney Cancer Association*

*The Leukemia and  
Lymphoma Society*

*The Lustgarten Foundation for  
Pancreatic Cancer Research*

*Melanoma Research Alliance*

*Oncology Nursing Society*

*Pancreatic Cancer Action Network  
PanCAN*

*Prostate Cancer Foundation*

*Society of Nuclear Medicine*

*The Society of  
Gynecologic Oncologists*

*The V Foundation for  
Cancer Research*

**RE: Docket ID Number HHS-OPHS-2011-0005**

Dear Dr. Menikoff,

The National Coalition for Cancer Research (NCCR) is pleased to submit the following comments in response to the Department of Health and Human Services (HHS) Advance Notice of Proposed Rulemaking (ANPRM), "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators." We commend the Department for its efforts to solicit the views of stakeholders on this important matter prior to advancing the rulemaking process. Continued communication and involvement of the research, provider, patient and other impacted entities is imperative as the process moves forward, and we welcome the opportunity to continue this dialogue with HHS.

The NCCR is a coalition of cancer research, cancer care and lay groups, and foundations representing cancer survivors, adults and children with cancer and their families, cancer researchers, nurses and physicians, and cancer hospitals, centers, clinics and specialized research institutions. The NCCR directs its efforts at educating public policy makers and legislators about the impact of specific legislation on cancer research. Specifically, the NCCR advocates for Federal legislation and regulations that will enhance and expand basic, translational and clinical research and ensure that the infrastructure and reimbursement mechanisms are in place to support the translation of research from the laboratory to the bedside. The NCCR supports these goals in their broadest terms, emphasizing national priorities essential to progress in cancer research, treatment, early detection and prevention of cancer.

NCCR recognizes and appreciates the need to update the Common Rule, in large part due to the manner in which cancer research has changed through advancements in basic, clinical and translational research. We believe the ANPRM identifies key areas that represent meaningful reform that will provide greater protections for human subjects participating in research studies and will assist in expediting these important studies.

NCCR appreciates the opportunity to provide comments on the following areas identified in the ANPRM:

- Streamlining IRB Review of Multi-Site Studies;
- Improving Informed Consent;
- Data Security and Protections; and
- Clarifying and Harmonizing Regulatory Requirements and Agency Requirements.

### **Streamlining IRB Review of Multi-Site Studies**

Current regulations regarding Institutional Review Boards (IRBs) need to be revised to take into account the fact that the regulations were implemented at a time when the overwhelming majority of clinical cancer research studies were taking place at single institutions. As noted by HHS, multi-site research studies are growing both in terms of volume and importance.

We note the National Cancer Institute's Central IRB has been a valuable tool to investigators and institutions alike for research studies involving adult and pediatric clinical research participants. We encourage the Department to develop a model that, to the greatest degree practicable, builds upon the NCI Central IRB experience.

A central IRB model will improve the efficiency of clinical trials, increase collaboration between trial sites and investigators, reduce or negate the need for multiple IRB reviews at the local institution level, provide consistency across clinical trial sites, help achieve potential cost savings and accelerate the translation of biomedical discoveries to new cancer therapeutics. The revision of the Common Rule should provide specific guidance on the selection and requirements of the IRB of record for multi-site trials, including scientific validity, the identification of risks and benefits of the study and the adequacy of the informed consent process. A central IRB of record should be held solely accountable for regulatory noncompliance specifically related to the IRB review, and such accountability should not be borne by participating institutions.

We believe the use of a central IRB should be a requirement for NCI Cooperative Group studies, and its use should be strongly encouraged for other federally-sponsored trials. We believe, however, there should be some degree of clearly-defined, limited flexibility for certain studies in order to address local sensitivities, such as geographic variation and diverse racial and ethnic patient populations, which could merit a local IRB review. If HHS ultimately does not *mandate* the use of a central or single IRB, then we believe the Department should clearly express that it is the *preferred* method.

We believe these recommendations will result in an IRB system by which multi-site trials can be performed with greater efficiency, effectiveness and will allow investigators more time to review research data.

## **Improving Informed Consent**

NCCR strongly supports initiatives to simplify, streamline, consolidate and standardize informed consent documents while also maintaining rigorous patient protections. Current informed consent documents have become too complex and legalistic in nature, in part to provide protection to researchers and research institutions from future liability.

Informed consent documents should be clear about the risks and benefits of the investigative cancer therapy. Because most cancer clinical trials test new agents either against, or in combination with, the standard of care, the risks and benefits of the standard of care should be distinguished from the potential risks and benefits of the agent being investigated. Doing so will greatly assist patients when making a better informed decision regarding clinical trial participation.

Furthermore, we believe informed consent documents must be designed to accommodate the educational level of potential clinical trial participants. Such documents should exclude technical, legal and scientific language that cannot be understood by the average layperson. We encourage the Department to utilize the expertise of individuals who have crafted informed consent documents to reflect educational and cultural variances among potential clinical trial participants. The NCI and the Clinical Trials Cooperative Groups are developing an important model template and we urge the Office for Human Research Protections to utilize and expand upon these efforts. We also encourage the use of video presentations to include important information, in layperson language, including the purpose and process of the trial, the risks and benefits of participating in a clinical trial, how their information will and will not be used, and the valuable contributions clinical trial participants make in helping to expand our understanding of many forms of cancer. Finally, we believe any new rules regarding improved informed consent should be applied prospectively.

## **Data Security and Protections**

Strengthening Data Protections to Minimize Information Risks – NCCR believes the current HIPAA standards for security of data for health information would be preferable. Many institutions are already in compliance with such standards, and a new set of standards does not appear to be warranted at this time. We note the Institute of Medicine has provided additional recommendations on this topic, and we encourage HHS to carefully consider these recommendations.

Data Collection to Enhance System Oversight – NCCR supports changes that will result in an improved, more systematic approach for a strengthened system for the reporting and analysis of adverse events data that, as HHS notes, are already required to be promptly reported by an investigator and not intended to expand the information reported. The proposed changes would help to eliminate duplicative and different reporting mechanisms. Furthermore, it will strengthen communication and information sharing across federal agencies, thereby allowing a more rapid identification and responses to risks from experimental agents as well as increasing the safety and efficiency of reporting.

## **Clarifying and Harmonizing Regulatory Requirements and Agency Guidance**

NCCR commends the efforts to harmonize regulations and guidance documents that protect participants in research studies. Investigators must currently comply with differing and complex regulations among various agencies that are frequently inconsistent and burdensome, especially for multi-center trials. We believe the Common Rule should harmonize regulations across all federal agencies in order to protect the privacy and confidentiality of cancer patients' identifiable information.

### **Conclusion**

The National Coalition for Cancer Research appreciates the opportunity to comment on these important issues. We generally agree that these proposed changes will "enhance the effectiveness of the research oversight system by improving protections for human subjects while also reducing burdens, delays, and ambiguity for investigators and research subjects." We look forward to working with the Department and would be pleased to provide any assistance and expertise that would benefit this process.

If you have questions, or if we may provide you with additional information, please feel free to contact us at any time.

Sincerely,

American Association for Cancer Research  
American Cancer Society Cancer Action Network  
American Childhood Cancer Organization  
American College of Radiology  
American Society of Clinical Oncology  
American Society of Hematology  
American Society for Radiation Oncology  
Association of American Cancer Institutes  
Gateway for Cancer Research  
Coalition of Cancer Cooperative Groups  
CureSearch Childhood Cancer Foundation  
Friends of Cancer Research  
International Cancer Advocacy Network  
International Myeloma Foundation  
Kidney Cancer Association  
Leukemia and Lymphoma Society  
The Lustgarten Foundation  
Melanoma Research Alliance  
Oncology Nursing Society  
Pancreatic Cancer Action Network  
Prevent Cancer Foundation  
Prostate Cancer Foundation  
Society of Gynecologic Oncologists  
V Foundation for Cancer Research