THE NATIONAL COALITION FOR CANCER RESEARCH

Member Organizations

American Association for Cancer Research

American Cance Society Cancer Action Netwrk

American Childhood Cancer Organization

American College of Radiology

American Society of Clinical Oncology

American Society of Hematology

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International Cancer Advocacy Network

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The Society of Gynecologic Oncology

The V Foundation for Cancer Research

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January 6, 2016

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

Re: Docket No. HHS-OHPS-2015-0008: Federal Policy for the Protection of Human Subjects; Notice of Proposed Rulemaking

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) Notice of Proposed Rulemaking (NPRM), "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. Continued communication with the research, provider, patient and other impacted entities is imperative, and we appreciate this opportunity to continue our 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 commend the Common Rule Agencies for their efforts to develop an NPRM designed to more effectively safeguard human subjects and reduce excessive regulatory burdens on researchers and their institutions. We believe the proposal to create an "excluded" category of research studies that would not be subject to all

aspects of the Common Rule, including the designation for exclusion of "low-risk" research studies, will help expedite these studies and bring their findings forward to the scientific community for the benefit of the public more quickly. We commend the recommendation to institute mandatory data security and information protection, which could assist with clinical trial accrual by helping to alleviate privacy concerns among potential participants related to their protected medical information. NCCR has long supported the proposed requirement that a single Institutional Review Board (IRB) be utilized for most multi-site research studies. A central IRB model will improve the efficiency of clinical trials, increase collaboration among 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 ultimately accelerate the translation of biomedical discoveries to new cancer therapeutics. We also believe it is proper to apply the Common Rule be to all clinical research studies receiving grant funding from Agencies that utilize the Common Rule, and we commend the efforts to harmonize guidance among those Agencies.

We do, however, have concerns with several of the proposals contained within the NPRM. While these are no doubt well intentioned, we do not believe they will achieve the over-arching goal of enhancing protections for research subjects and reducing burden, delay and ambiguity for investigators. Specifically:

1. **The proposed classification of all biospecimens as "human subjects," regardless of whether the biospecimens contain identifiable information.**

Cancer researchers have raised concerns with proposed modification of the definition of human subjects to include all biospecimens. Specifically, there is concern that the regulation of secondary research uses of non-identified biospecimens is not appropriate, when measured against the very low level of risk of re-identification of de-identified biospecimens. We are equally concerned that secondary research utilizing non-identified biospecimens would be subjected to broad consent, documentation and IRB review requirements. We believe the proposal contained in the NPRM could have a negative impact on the use of non-identified tissue samples, especially tissue samples obtained prior to the implementation of the Common Rule, as well as samples collected during routine clinical and surgical care. Requiring broad consent from every surgical patient from whom a biospecimen is collected is unduly burdensome and would add to the already significant administrative costs for storage and future research utilizing such tissue samples. These additional costs could have a disproportionate impact on hospitals and providers in underserved communities, which are already struggling to meet their current financial obligations. Equally important, this requirement could have the unintended impact of delaying the development of innovative and life-saving therapies and thereby potentially delaying their availability to patients.

We believe the proposed requirement to modify the definition of human subjects to include non-identified biospecimens is premature at this time. The potential future use of non-identified biospecimens in basic, clinical and translational cancer research is essential. At this time, we recommend that the proposed change in definition be set aside. Rather, we believe this matter should be carefully monitored for potential future modifications in the event that scientific advances threaten the re-identification of biospecimens.

Cancer researchers have also recommended the removal of broad consent requirements for secondary research use of biospecimens, and we concur with this recommendation. We also appreciate their concern about the 10-year limit on collection under broad consent, and the need to obtain a new consent form every 10 years if additional biospecimens are collected. The process of locating and re-consenting these subsets of patients would be time-consuming and would provide limited safeguards for patients. We also note that many research institutions have policies and procedures in place to obtain consent for subsets of biospecimens, and these approaches may be beneficial if further regulatory actions become necessary.

2. Clear and consistent privacy standards are necessary, including guidance as to the types of research subject to the Common Rule and the HIPAA Privacy Rule.

In order to expand and enhance cancer research, we believe concerns regarding privacy of protected health information should be addressed by a single, uniform set of criteria. We note this was also recommended by the Institute of Medicine in order to address the secure use of research information. This could be best achieved through guidance as to what types of research are subject to the Common Rule, and those that are subject to HIPAA privacy regulations. If the Agency agrees with this recommendation, we strongly recommend the inclusion of scientific and patient organizations in the development of such guidance to identify specific clarifications and examples in order to avoid confusion and ensure compatibility among all stakeholders.

3. A harmonized electronic database is needed to report unanticipated problems and adverse events.

The use of standardized data elements to streamline and consolidate the reporting of information that is currently required will likely provide improved safety for research participants, harmonize reporting requirements and potentially reduce costs associated with many forms of biomedical research. Comments to the 2011 Advanced Notice of Proposed Rulemaking noted the lack of a uniform definition of "unanticipated problem" or "adverse event" as well as the need for clarity about oversight authority. This could be rectified through further guidance and examination. We believe the 2011 ANPRM proposal addresses the need for Common Rule Agencies to resolve the inconsistencies in reporting requirements. Furthermore, the development of a harmonized set of terminologies and the creation of a uniform set of databases would enable regulators and manufacturers to more easily compare safety data across research studies. We strongly urge the Common Rule Agencies to ensure that regulations outlining plans for a harmonized database are promulgated in an expedited manner.

Conclusion

The National Coalition for Cancer Research appreciates the opportunity to comment on these important issues. 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,

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