ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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January 6, 2016

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

RE: Docket ID Number HHS-OPHS-2015-0008

Dear Dr. Menikoff:

On behalf of the American Society of Nephrology (ASN), I appreciate the opportunity to provide comments on the proposed revisions to the Protection of Human Subjects promulgated as a Common Rule in 1991. The society represents nearly 16,000 health professionals and scientists who are dedicated to treating and studying kidney diseases and to improving the lives of the millions of patients they affect. ASN particularly supports efforts that bolster the ability of federal agencies and the American research and development enterprise to solve scientific challenges at every level from basic science through care delivery.

Kidney diseases affect more than 20 million Americans. There are many unique causes of kidney diseases, but when any type of kidney disease progresses to kidney failure, patients require either dialysis or transplantation to stay alive. Currently, 600,000 Americans have complete kidney failure, called end-stage renal disease (ESRD). Kidney diseases disproportionately affect racial and ethnic minority populations, is associated with multiple co-morbidities including heart disease and diabetes, and is one of the most costly chronic conditions in the United States.

While America's scientific leadership has yielded important treatments for some patients, others still wait because the state of biomedical research and innovation in certain diseases is not as advanced; kidney diseases are among the conditions for which we must accelerate the pace of innovation.

Although patients with kidney failure on dialysis comprise less than 1 percent of Medicare beneficiaries, they account for nearly 7 percent of Medicare's budget: the Medicare ESRD Program is unique in that it covers every American with kidney failure regardless of age or income. Yet despite these staggering costs, the fundamental principles of dialysis have not changed and patients with kidney failure have seen only incremental improvements in their therapy in decades.

The society appreciates the efforts to modernize current regulations for protecting human subjects involved in research, and applauds the goal of decreasing administrative burden, delay, and ambiguity for investigators, institutions, and institutional review boards, as well as strengthening, modernizing, and making the regulations more effective in protecting research subjects. Reflecting the commitment of ASN's members to advance kidney research and innovation, ASN submits the following comments in response the questions posed that are of greatest pertinence to the society's members.

Maintaining appropriate investigator access to existing data and biospecimens—whether originally collected for research or non-research purposes—is an important goal for the research community. ASN agrees with current rules that if data and biospecimens were originally collected for non-research purposes, then written consent should only be required if the researcher obtains information that identifies the subjects. As the risks to research subjects would be similar, ASN feels that it would be preferable that the same rules regarding reuse be used for data that was collected for research and for non-research purposes. Similarly, written general consent should not be required for use of biospecimens under conditions where the researcher does not possess information that would allow him or her to identify whose biospecimen is being studied.

ASN believes that the rules for waiving consent should be uniform regardless of whether information or biospecimens were originally collected for research or non-research purposes.

Regulations should not prohibit de-identified data or biospecimens or publically available data and biospecimens with identifiers from being used for a new purpose if they were originally collected for non-research purposes. In this instance, a waiver of informed consent would be reasonable and pose essentially minimal confidentiality risks to patients. Regulations should also allow under waivers, the use of limited datasets (i.e., not fully de-identified as they contain dates), whether or not the data were originally collected for research purposes.

Whether or not informed consent should be required to be obtained when collecting data for non-research purposes depends on whether or not the samples collected (either biological specimens or data) are going to include patient identifiers. If the sample collected does not contain information that could be used to identify patients, there is no need to obtain informed consent. However, if the research involves collection of patient identifiers, it is likely necessary to obtain informed consent—though the regulations should not preclude the ability for researchers to get a waiver of informed consent. ASN also suggests that it would be reasonable to require obtaining informed consent when it is known that some or all of the data collected will be used for proprietary purposes. Overall, ASN recommends that if data are de-identified there is no reason to require obtaining consent for future research use of data initially collected for non-research purposes.

ASN suggests that use of data for purposes other than those described in the original consent require a new consent, unless the original consent grants blanket consent that covers the new data analyses.

ASN agrees that it would be desirable to implement the use of a standardized, general consent form to permit future research on biospecimens and data. It would be helpful for conducting research in multiple sites if a uniform consent form existed, and would minimize the paperwork burden. The society envisions this as language within a research consent form. ASN feels that a general consent form for the future use of specimens that is administered prior to clinical care does not lend itself to informed consent. It raises issues of who would administer the informed consent and if that person is adequately trained to administer consent.

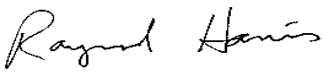
ASN agrees that the new consent rules be applied only prospectively. Previously existing biospecimens and data sets should be grandfathered. The new rules should only be applied going forward, not retrospectively. The society's concerns that informed consent for prospective use of biospecimens may be difficult to obtain in the context of registration for clinical care have already been articulated in this letter. ASN does not perceive any operational issues with maintaining current consent rules for established collections of biospecimens.

ASN recognizes that DNA sequences contain patient information that would be potentially identifiable. At this time, the risk of identification is minimal, but this risk level should be reevaluated as DNA repository access is expanded in the coming years.

Thank you for your willingness to consider these comments. Regulations facilitating biomedical research and innovation are a vital necessity. ASN appreciates efforts to standardize these processes, and streamlining and ensuring safety throughout the research process.

Again, thank you for your time and consideration. To discuss ASN's comments, please contact ASN Associate Director of Policy and Government Affairs Rachel N. Meyer at (202) 640-4659 or rmeyer@asn-online.org.

Sincerely,



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