January 6, 2016

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 -2015-0008, Federal Policy for the Protection of Human Subjects

Dear Dr. Menikoff:

The Cystic Fibrosis Foundation is a national research and patient organization that supports research and development of new cystic fibrosis (CF) therapies, funds CF clinical centers, engages in CF care quality improvement efforts, and provides a wide range of educational and support services to individuals with CF and their families and caregivers. We are pleased to comment on the proposed revision of the Common Rule, the federal policy for the protection of human subjects.

Calibrating Oversight According to Research Risks and the Definition of Excluded and Exempt Activities

The Cystic Fibrosis Foundation commends the federal effort to improve the system for oversight of human subjects research by advancing two core goals: 1) enhancing respect and protections for research participants and 2) increasing research efficiency by reducing unnecessary burdens and matching oversight to risk.

By defining categories of research that are excluded or exempt from oversight, the proposed rule attempts to more appropriately calibrate the oversight of research and reduce regulatory burdens. We support the general intent in defining excluded and exempt activities, including the inclusion of quality improvement programs as "excluded" activities.

The proposed rule also indicates that an online tool will be developed to aid investigators in determining that an activity is exempt from oversight. We urge that this tool be released as it would assist all parties in understanding how exempt activities will be defined and thus the full impact of the proposed rule.

National Office
6931 Arlington Road Bethesda, Maryland 20814
(301) 951-4422 (800) FIGHT CF Fax: (301) 951-6378 Internet: www.cff.org E-mail: info@cff.org

Broad Consent for Storage and Use of Biospecimens

The CF community of researchers and participants has already embraced the standard of obtaining consent for storage and future research use of biospecimens, whether identified or nonidentified. The collaboration between CF patients and CF researchers is critical to efforts to improve the quality of CF care and to foster the development of new treatments. That collaboration must be based on respect for the research participant. We consider consent for biospecimen storage and use to reflect that respect.

Individuals with CF are typically enthusiastic participants in research studies and have been generous in their willingness to share biospecimens and information used in clinical research and in quality improvement activities and research. Their generosity has been a critical part of the success of the CF research enterprise, and it is only fitting that they be asked for consent for storage and use of their biospecimens. That is the standard CF researchers have honored, and it is one that we believe other researchers should and can honor as well.

The broad consent that is described in the proposed rule would provide researchers considerable flexibility in the future use of biospecimens. It is the experience of the CF community that this flexibility will be acceptable to individuals who permit use of their biospecimens.

We are aware that many researchers and research institutions are concerned about the administrative burdens that may result from the biospecimen consent requirement despite the fact that the consent is "broad." We believe these burdens can be managed. However, we urge the agencies to develop and publish a sample broad consent form as publication of a form might reassure investigators regarding their ability to meet the consent standard. We note that the elements of the broad consent listed in the proposed rule do not necessarily describe a simple form, which is another issue that the departments and agencies should address in publication of a sample form. We urge communication about the broad consent form without delay, through a guidance document or otherwise.

Improving the Informed Consent Process

Simplification of the consent form is necessary to ensure that research participants are truly informed of research participation risks and benefits. Despite the best efforts of CF researchers to utilize consent forms that are understandable to participants, many state that the forms have become overly technical, filled with legal language, too long, and difficult to understand. The need for simplification is clear.

We note that the effort to streamline the language of the consent form is accompanied by the requirement that some new elements be incorporated in the consent form. The consent form, according to the proposed rule, would be required to include a statement that the subject's biospecimens "may be used for commercial profit and whether the subject will or will not share in this commercial profit," a statement of whether subject will be informed of clinically relevant findings, and an inquiry about willingness to be re-contacted for additional research.

Consent forms for CF protocols typically inform patients about commercialization and the potential for research participants to share in profits. CF researchers have already gone in this direction in their consent forms as they have already addressed the issue of consent for biospecimens, as discussed above. We believe that these standards for consent honor the commitment of research participants.

We understand that some have articulated concerns that these additional new elements will in fact complicate the consent form, when the overall aim of the proposed rule is to streamline the consent form and process. We believe that these elements can be incorporated in the consent form without unreasonable burden to researchers and their institutions.

Requiring the Use of a Central IRB for Multi-Site Studies

As the preamble to the proposed rule explains, the nature of clinical trials has changed significantly since the initial development of the Common Rule. The multi-site clinical trial has largely replaced trials that are undertaken in a single institution. With those changes have arisen challenges associated with institutional review board (IRB) oversight. The preamble describes the situation where changes to a research protocol or consent form or any other element of a trial by one IRB can trigger additional reviews by all other IRBs and a cycle of delay and inefficiency that is detrimental to researchers and participants alike.

We support the efforts of the agencies to address the inefficiencies of IRB review and agree that requiring single IRB review is critical to improving the review and oversight process. We believe there could be some clarification regarding requirements for local or community representation on IRBs and how these requirements will be addressed in the case of utilization of a single IRB for a multi-site study. More guidance to investigators, institutions, and IRBs on this topic would assist in smooth implementation of revised IRB requirements.

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We support the efforts of the Department of Health and Human Services and other departments and agencies to improve the Common Rule and to assure a balance of protecting participants in research and facilitating research. We urge attention to the issues we have identified above.

Sincerely,

Preston W. Campbell, III, MD
President and Chief Executive Officer