Via Electronic Submission

November 28, 2022

Robert Califf, MD
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Subject: Protection of Human Subjects and Institutional Review Boards (Docket No. FDA-2021-N-0286)

Dear Dr. Califf,

The Association for Clinical Oncology (ASCO) appreciates the opportunity to respond to the U.S. Food and Drug Administration's (FDA) proposed rule to amend its current regulations to modernize, simplify, and enhance oversight of FDA-regulated human subject research. This proposed rule seeks to harmonize with the revised Federal Policy for the Protection of Human Subjects (i.e. the revised Common Rule), in accordance with the 21st Century Cures Act, by adding provisions to potentially reduce the burden on IRBs by allowing more of a focus on higher risk research, revising the informed consent process, and also enhancing human subject protection.

ASCO is a national organization representing nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality, equitable patient care, our members are committed to ensuring access to evidence-based care for the prevention, diagnosis, and treatment for all Americans. ASCO supports robust quality initiatives that enhance performance measurement and improvement, clinical practice guidelines, big data analytics, and the value of cancer care.

Overall, ASCO is supportive of this FDA proposed rule, understanding this proposed rule is limited in scope and does not address all the provisions contained in the revised Common Rule. However, we are pleased to see the FDA begin their efforts to harmonize with the revised Common Rule and look forward to the Agency's additional steps to address other sections of the FDA's-regulated human subject research.

The purpose of the Common Rule is to promote uniformity, understanding, and compliance with human subject protections and to create a uniform body of regulations across all Federal Departments and Agencies. Additionally, the revised Common Rule is intended to better protect human subjects participating in research, while also facilitating valuable research and reducing burden, delay, and ambiguity for the regulated community. By releasing these proposed rules, the FDA is attempting to harmonize with other Agencies' Guidance. The revised Common Rule included several important changes:

- New and Revised Definitions
- New Exemption Categories Regarding Secondary Research
- Elimination of Continuing Review
- Revised Informed Consent Requirements
- Harmonization with Other Agency Guidance
- Guidance on Application to Clinical Data Registries
- Cooperative Research Studies (single IRB)

We applaud the FDA for addressing in this proposed rule the new and revised definitions to reflect the changing research landscape including the use of biospecimens, the elimination of continuing review, and the revised informed consent requirements under the sections of Protections of Human Subjects and Institutional Review Boards.

Protections of Human Subjects

ASCO strongly supports the FDA's proposal to require that the informed consent document "begin with a concise, focused presentation of key information." Placing this information at the beginning of the form has great potential to help facilitate a patient's decision to participate in research by better understanding the language and facilitating the enrollment process.
We also understand the additional considerations for the Agency in remaining flexible in its informed consent process, including consenting for future use with patient identifiers removed and when used for commercial profits. We support the FDA's decision to consider activities preparatory to research not part of a clinical investigation that requires IRB oversight and informed consent. All of these provisions to update current regulations to harmonize with other Agencies polices aligning with the revised Common Rule are important to reduce confusion and burden for the oversight of studies that are subject to both the revised Common Rule and FDA regulations.

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Institutional Review Boards

We believe it is important for the FDA to harmonize with the revised Common Rule by waiving documentation of informed consent for a study with no more than minimal risk of harm to subjects. This focus of resources on high-risk research proposals reduces the burden on IRBs. We also applaud the Agency for proposing to eliminate continuing reviews unless the IRB determines otherwise. We agree that requiring continuing review generally would not provide added protection to human subjects. We also believe that in consistency with the Common Rule exception for the requirement of informed consent if the only risk is breach of confidentially, then the FDA should include this in their proposed rule. If this is not true for FDA-regulated research, the Agency should clarify the other potential risks. However, we agree with the Agency's proposed plan to not harmonize with the revised Common Rule for research eligible for expedited review, due to the nature of FDA-regulated research and the use of investigational therapies and devices where adverse events can occur during the study and then exceed the more than minimal risk requirement. We applaud the FDA's thoughtfulness in harmonizing with the revised Common Rule to the extent practicable and consistent with the Agency's unique statutory responsibilities, as well as the plan to take additional steps to harmonize at a later time, if appropriate. Finally, we also support the Agency's proposal to broaden the diversity of IRB membership to reflect a diversity of professional qualifications and other factors, such as race, gender identity, and cultural backgrounds.

Thank you again for the opportunity to comment on the FDA's proposed rule to harmonize with the revised Common Rule to project human subjects and reduce regulatory burden. We agree with the Agency's plan to minimize disruption by proposing that research proposals initially approved by an IRB before the proposed effective date would not be subject to compliance with the changes. We look forward to additional proposals as the FDA continues its efforts to harmonize with other Agencies' and Departments' policies aligning with the revised Common Rule. Please contact Shimere Williams Sherwood at Shimere.Sherwood@asco.org with any questions and for further discussions.

Sincerely,

Lori J. Pierce, MD, FASTRO, FASCO

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