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: Institutional Review Boards; Cooperative Research (Docket No. FDA-2019-N-2175)

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 participation in research. ASCO agrees with the FDA that these changes will "streamline the IRB review process and decrease administrative burdens and inefficiencies for investigators and institutional review boards (IRBs) without compromising human participants' protections." More importantly, the changes will **expand access to clinical trials for patients** by addressing repeated reviews of multicenter studies that have little added value. We appreciate that this proposed rule is executing administrative changes included in the 21st Century Cures Act, adopting a single IRB approach for review and approval of research conducted in the United States.

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 participation in research.

The purpose of the Common Rule is to promote safety of research participants through uniformity, understanding, and compliance with human participants' protections and to create a uniform body of regulations across all Federal Departments and Agencies. Additionally, the revised Common Rule is intended to both better protect humans participating in research, and reduce burden, delay, and ambiguity for the research and clinical care communities. 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 proposing that any U.S. institution participating in multi-site FDA-regulated cooperative research must rely on review and approval by a single IRB for the portion of the research conducted in the U.S. – when appropriate for the context of the study. We agree with the proposed rule's summary and reference to the National Institutes of Health single IRB policy that enables streamlined IRB review and has potential to enhance protections for trial participants. We would like to continue to work with the Agency on the decision to determine a specific number of investigational sites needed for the exception for a single IRB for cooperative research.

We believe the additional requirement for IRB recordkeeping in the proposed rule is appropriately harmonized with the revised Common Rule to the extent practicable. This recordkeeping requirement for research overseen by an IRB not operated by the institution where the study is conducted will aid in compliance and the FDA's oversight. We agree that single IRB reviews for multi-institutional clinical investigations would streamline the review process, help eliminate administrative burdens that delay access to research, and increase

efficiencies of oversight. More importantly, ASCO believes that single IRBs, like the National Cancer Institute's four central IRBs, help infuse ethical review at the point of greatest impact – i.e., *prior to national launch* – and through involvement of nationally recognized patient partners and ethical experts to facilitate faster initiation of clinical studies. With large, multicenter clinical trials, local IRBs rarely have influence to change a national study.

Thank you again for the opportunity to respond to the FDA's proposed rule to harmonize with the revised Common Rule to protect human participants in research and reduce regulatory burden. We look forward to additional proposals as the FDA continues its efforts to harmonize with other agency and department 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
Chair of the Board, ASCO Association for Clinical Oncology