ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

November 23, 2022

Lauren K. Roth
Associate Commissioner for Policy
Food and Drug Administration, Dockets Management Staff
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: ACRO comment submission on:
***Protection of Human Subjects and Institutional Review Boards – Proposed Rule***
21 CFR Parts 50, 56, and 812 [Docket No. FDA–2021–N–0286] RIN 0910–AI07

Dear Ms. Roth,

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and technology organizations. Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. ACRO member companies manage or otherwise support a majority of all FDA-regulated clinical investigations worldwide. The member companies of ACRO advance clinical outsourcing to improve the quality, efficiency, and safety of biomedical research.

ACRO thanks the Agency for the opportunity to provide feedback on this proposed rule, which offers clear and helpful information to enhance the protection of human subjects. We are pleased to provide the following comments.

**50.25(a)(9) – Table 1, Page 4 of Federal Register Notice**

The proposal discusses adding a basic element of informed consent that would require a description of how information or biospecimens may be used for future research or distributed for future research.

50.25 (9) includes a requirement that the informed consent information provided to subjects include a *"description of how information or biospecimens may be used for future research or distributed to another investigator for future research."* However, it is difficult to describe this adequately when it is far from clear at the time of the initial study what future use may be made of the data and biospecimens.

We encourage FDA to consider modifying this language to recognize the challenges of anticipating future use and, thereby, avoid negative impact to future research.

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**Section 5 "Documentation of Informed Consent" (Page 7 of Federal Register Notice)**

The proposed rule asks for feedback on whether FDA's current policy adequately addresses screening, recruiting, or determining eligibility for an FDA-regulated clinical investigation:

> *FDA's longstanding policy on preparatory activities to a clinical investigation is that some specific activities are not considered to fall within the definition of a clinical investigation, and therefore do not require IRB review or informed consent under FDA's regulations. For example, we generally have not considered performing a survey of patient records at a site to determine whether the site has a sufficient number of patients with the condition of interest for the clinical investigation to be feasible to require informed consent and IRB review.*
> *However, IRB review and informed consent would need to be obtained prior to initiation of any clinical screening procedure that is performed solely for the purpose of determining eligibility for a clinical investigation. We request comment on whether FDA's current policy adequately addresses screening, recruiting, or determining eligibility for an FDA-regulated clinical investigation, or if including the revised Common Rule provision at 45 CFR 46.116(g) would be useful for FDA-regulated clinical investigations.*

ACRO believes the current policy is adequate. Therefore, no changes should be made.
In the US, HIPAA clearly allows for study screening by covered entities (CEs) or BAs operating on their behalf, as well as by anyone with de-identified data that contains a code for re-identification, and so a separate IRB review would be unnecessary, and at best redundant.

Thank you for this opportunity to provide feedback. Please do not hesitate to contact ACRO (knoonan@acrohealth.org) if we can provide additional details or answer any questions.

Respectfully submitted,

Karen A. Noonan, Senior Vice President, Global Regulatory Policy