STANFORD UNIVERSITY

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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted via Regulations.gov
Docket ID # FDA-2018-N-2727

Re: Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations

To whom it may concern:

Thank you for this opportunity to comment on the Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations proposed rule.

We support the proposed rule to add § 50.22 to part 50 (21 CFR part 50) to allow institutional review boards (IRBs) to "approve an informed consent procedure that waives or alters certain informed consent elements or that waives the requirement to obtain informed consent for certain minimal risk clinical investigations" consistent with the Common Rule, recommendations from the Secretary's Advisory Committee for Human Research Protections, and section 3024 of the 21st Century Cures Act. As indicated in the Federal Register notice, current FDA regulations "allow exception from the general requirements of informed consent only in life-threatening situations when certain conditions are met (§ 50.23) or when the requirements for emergency research are met (§ 50.24)." The proposed change would reduce administrative work for investigators and the IRBs while maintaining appropriate human subjects protections. We believe with appropriate safeguards in place this expansion would not compromise the rights, safety, or welfare of human subjects.

We strongly recommend that FDA harmonize with the new Common Rule 2018 requirements in 45CFR46. Currently, the FDA proposal only includes the four pre-2018 Common Rule elements needed to waive or alter informed consent:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waivers or alterations; and
4. Whenever appropriate, the subjects will be provided with additional patient information after participation.

The new 2018 Common Rule 45CFR46.116(f)(3)(i-v.) has introduced an additional element when determining whether a waiver or alteration is permissible. This new element requires the

IRB to assess the identifiability of the information or biospecimen,

> "If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format."

This addition would streamline and harmonize the two sets of regulations without the need to differentiate and distinguish protections provided by FDA-regulated research from other federally funded research.

Promulgation of this regulation to replace the IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects guidance, will greatly reduce the burden on investigators conducting studies that may contribute to the development of products to diagnose or treat diseases. We see this to be most impactful on clinical investigations that involve In Vitro Diagnostics or medical records review. With the additional safeguards listed above, we strongly believe that the IRB will ensure adequate protections to the respective participants.

Stanford encourages the FDA to approve the proposed rule while harmonizing with the 2018 Common Rule requirements. This new rule would reduce administrative burden between the two sets of regulations governing human subjects research, ensure appropriate human subjects protections provided by the 2018 Common Rule, and facilitate minimal risk FDA regulated research.

Respectfully submitted,

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