COGR
Council On Governmental Relations

January 14, 2019

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

RE: Docket No. FDA-2018-N-2727 for "Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations."

To Whom It Concerns,

The Council on Governmental Relations (COGR) is an association of 188 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

We write in support of the proposed rule to add § 50.22 to part 50 (21 CFR part 50) to allow institutional review boards 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 IRBs while maintaining appropriate human subject protections.

We appreciate the opportunity to comment on the FDA's proposed rule. Please contact Lisa Nichols (lnichols@cogr.edu) in our office with any questions.

Sincerely,

Wendy Streitz
President
Council on Governmental Relations