July 8, 2022

Sent Via Email to: diek@uw.edu **and** Jerry.Menikoff@hhs.gov

Douglas S. Diekema, M.D., MPH
Chair, Secretary's Advisory Committee on Human Research Protections (SACHRP)
Professor, Department of Pediatrics
Adjunct Professor, Departments of Bioethics and Emergency Medicine
University of Washington School of Medicine

Jerry Menikoff, M.D., J.D.
Director, Office for Human Research Protections (OHRP)
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

RE: Letter of Support for SACHRP's Efforts to Redefine "Engaged in Research"

Dear Drs. Diekema and Menikoff:

COGR is an association of nearly 200 public and private U.S. 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. One area of expertise among COGR members is the regulatory framework for human subjects research and the promotion of participant protections accomplished in a manner that does not place unnecessary administrative burdens on researchers, institutional review boards (IRBs), or institutions. In this regard, we appreciate SACHRP's consideration at its March 2022 meeting of how to "reimagine" engagement in human subject research, and we write to encourage SACHRP and OHRP to continue with these efforts.

The filing of a federal wide assurance ("FWA") as a condition of receiving federal funds to engage in human subject research, carries the obligation of certifying IRB review and approval. Historically, this meant that institutions would form and run their own IRB, as institutions rarely would rely on an outside IRB, and the FWA commitments focused on the institutional IRB's review standards and training. Today, the landscape has changed: institutions have developed comprehensive human subject protection programs, the 2018 Common Rule standardized the use of single IRBs, and independent IRBs have evolved and are routinely used. Thus, the time is right for OHRP to reconsider its standard for activities that require an FWA filing and when research activities constitute engagement that requires IRB review. With institutions' current broad reliance on single IRBs and their implementation of standard subrecipient monitoring practices, OHRP should consider

tightening the focus of the "engagement" standard to cases in which a subrecipient's filing of an FWA is truly necessary for protection of human subjects.

The lack of a formal definition for the term "engaged in research," as used in 45 C.F.R. Section 46.101, presents on-going challenges for institutions and IRBs. Presently, entities must rely upon a series of non-harmonized OHRP guidance documents[1] that consist, in part, of a handful of examples of particular circumstances for which OHRP has determined that an individual/entity is not engaged in research. The guidance documents are difficult to apply to the myriad of research scenarios that IRBs and institutions routinely confront. These challenges were particularly evident in studies conducted during the height of the COVID-19 pandemic, when lifesaving research had to be conducted in non-traditional research settings and involved partnerships with community-based individuals and organizations and other non-traditional partners (e.g., home health care, community health centers, commercial pharmacies). Many such non-traditional research partners ("Partners") are reluctant to enter into the FWA required of those "engaged in research" because they consider their "engagement" to be the performance of their routine business activities. As a result, efforts to conduct research in more diverse settings and to reach underserved populations that do not have access to traditional research venues (e.g., research universities and hospitals) are hampered. To be clear, COGR is not suggesting that IRBs could not determine who should be added to a protocol, and Partners are often willing to be named in the protocol and comply with protocol specified training and requirements, as they would routinely do in studies subject to FDA regulations. Rather, we believe that IRB oversight and contractual terms for subrecipient monitoring and management provide appropriate oversight for Partners, including the identification/remediation of any noncompliance.

COGR appreciates SACHRP's discussion at its March 2022 meeting aimed at unifying the current OHRP guidance documents on this topic. In particular, we support SACHRP's discussions concerning an exception to "engagement" for parties' who do not play a "key role" in designing/conducting the research or analyzing its results and whose "participation in the research is so substantively similar to its regular activities, or otherwise of such a nature, that [the participation] presents no significantly heightened risks to subjects."[2] We encourage SACHRP to continue its work in framing such an exception, or, more ideally, to develop a definition of the term "engaged in research" that encompasses this concept, that institutions and IRBs can apply.

We believe that continuing efforts to develop a clear definition of when a party is "engaged in research" along the lines of SACHRP's discussion will increase institutions' ability to conduct research in diverse settings with reduced administrative burden and reach historically underrepresented populations at no increased risk to research participants. Since the implementation of the 2018 revisions to the Common Rule, the use of a single IRB

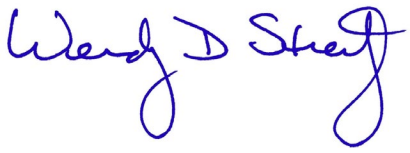
[1] *See, e.g.,* OHRP, "Engagement of Institutions in Human Subjects Research" (2008); "Determining When Institutions are Engaged in Research" (Jan. 13, 2009); "Correspondence on 'Non-Engaged' Scenarios" (Sept. 22, 2011).

[2] Barnes, M., Re-Imagining "Engagement" in Human Subjects Research, SACHRP Meeting (Mar. 11, 2022).

providing oversight for federally supported cooperative research has become the norm, and agreements for reliance on a single IRB cover many of the same elements that are found in an FWA. Indeed, in the scenarios discussed during the March 2022 SACHRP meeting, an FWA would do little to mitigate actual risk to research participants. Instead, the FWA adds extra layers of administrative and contracting complexity, and in many cases, serves as a barrier to entry that entities are unable or unwilling to surmount.

We applaud OHRP and SACHRP's recognition of this critical issue and fully support continuing discussions on this topic at future SACHRP meetings.

Sincerely,



Wendy D. Streitz
President

cc: Mark Barnes, J.D.