PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

August 30, 2022

Jerry Menikoff, MD
Director
Office for Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

RE: Docket No. HHS–OASH-2022–0011 (Use of Single Institutional Review Board for Cooperative Research Draft Guidance)

Submitted electronically at https://www.regulations.gov

Dear Dr. Menikoff,

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to comment on the Office for Human Research Protections (OHRP) "Use of Single Institutional Review Board for Cooperative Research Draft Guidance," published in the *Federal Register* on July 1, 2022.

PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science.

PRIM&R appreciates OHRP's efforts to assist the regulated community in developing institutional policies and procedures to meet the requirements of the revised Common Rule. The current effort to guide the community on the use of a designated or single institutional review board (sIRB) for the review of multisite or cooperative research studies, however, falls short of its stated intent.

Below are PRIM&R recommendations for how OHRP can provide clearer guidance on how to comply with the regulatory requirements for sIRB oversight of cooperative research in the US effectively and efficiently.

When must an institution rely on a single IRB for approval of cooperative research?

PRIM&R notes that the guidance merely restates the regulations, rather than listing criteria that could inform when an institution or researcher might request an exception. Thus, we recommend that OHRP provide examples of instances when it would be appropriate for a researcher or institution to

seek an exception to the sIRB requirement. Furthermore, to ensure a smoother and more efficient process, PRIM&R recommends that departments and agencies that are signatories to the Common Rule collaborate on developing a single a streamlined process for granting sIRB exceptions. Lastly, we note that the statement in the draft guidance that "research that is not supported or conducted by any Common Rule agency is not subject to the single IRB requirement even if one (or more) of the institutions engaged in the research has 'checked the box' on its Federalwide Assurance (FWA)" is confusing. "Checking the box" on the FWA has typically been interpreted as the institution's intent to apply the regulatory requirements to all research conducted at the institution, regardless of the source of funding. The statement is even more confusing given that, in conjunction with the issuance of the revised Common Rule in 2017, OHRP had announced a modification to the assurance process involving elimination of the option to "check the box." PRIM&R requests that OHRP provide clarification and share with the community the rationale for this interpretation.

Who decides which IRB will be the single IRB for the purposes of regulatory compliance?

Regardless of whether the IRB of record is identified by the funding department or agency, or by the lead institution and approved by the supporting department or agency—both of which the regulations, we understand, allow—it is important to ensure that the selected IRB has the experience and resources to adequately oversee the research. PRIM&R endorses the recommendation by Harvard Catalyst that the IRB of record be required to document explicit agreement to serve as the sIRB for the research, attesting to the fact that it is qualified to serve in this capacity.

Can an institution involved in cooperative research choose to conduct its own IRB review of the research even though review is required by a single IRB that is located elsewhere?

PRIM&R strongly recommends that OHRP explicitly discourage institutions from conducting their own reviews when such local reviews are not required under the sIRB requirement for cooperative research. Sanctioning such duplicative review is not only confusing, inefficient, and counterproductive to the stated intent of reducing regulatory burden, but might be potentially harmful to the research enterprise by creating potential for conflicts between local IRBs and the sIRB and unnecessarily delaying research. The regulatory requirement states that if the funding department or agency does not grant an exception from sIRB review, all participating institutions must rely on the sIRB. PRIM&R notes that this requirement does not preclude other types of local review that maybe necessary, beyond IRB review, such as reviews by other units of the institution's human research protection program.

Are there documentation requirements for use of a single IRB in cooperative research?

PRIM&R appreciates OHRP's intent to provide institutions and researchers with greater flexibility in matters related to documentation, and the examples provided in the draft guidance are useful. However, we believe that it would be ideal for OHRP to develop a checklist for what documentation ought to address, that would assist institutions and

researchers to clearly define and allocate responsibilities, thereby ensuring that relevant documentation is not omitted inadvertently.

What are the responsibilities of the single IRB with respect to information pertaining to community attitudes and the local context for proposed research?

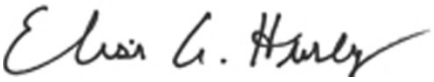
PRIM&R believes that the discussion in the draft guidance about local context is inadequate, especially as the questions of what constitutes local context and how it should factor into sIRB review remain challenging for institutions who rely on a sIRB and those that serve as the designated sIRB. We therefore endorse several of Harvard Catalyst's recommendations in this area, including:

- That OHRP provide a definition of local context to clarify the scope and type of information that should routinely be provided by sites to the sIRB.
- That further guidance is needed on how the sIRB should manage any differences between local institutional policies and those of the sIRB.
- That further guidance is needed on how ancillary reviews are conducted and coordinated between local sites and the sIRB.
- That the guidance include a statement that the sIRB has final authority on what to accept or not accept with regard to local context.
- That OHRP compile, review, and regularly update a list of state and local laws related to human subject research, to assist the IRB of record in its consideration of local contexts.

Additionally, PRIM&R recommends that OHRP consult with and benefit from experience and expertise of members of the research community involved in creating models for single IRB review, such as the NCATS-funded SMART IRB developed and led by the Harvard Catalyst.

Thank you again for the opportunity to comment on the draft guidance. We hope our comments will be useful to the OHRP in its efforts to develop guidance for implementing the Common Rule requirements for sIRB oversight of cooperative research. PRIM&R stands ready to provide any further assistance or input that might be of use. Please feel free to contact me at 617.303.1872 or ehurley@primr.org.

Sincerely,



Elisa A. Hurley, PhD
Executive Director

cc: PRIM&R Public Policy Committee, PRIM&R Board of Directors