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End of the COVID–19 Single Institutional Review Board Exception: Considerations for Academic Medical Centers and Other Research Institutions

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On January 30, 2023, the Biden administration announced it will allow the public health emergency for COVID-19 (PHE), initially declared by the Secretary of the U.S. Department of Health and Human Services (HHS) on January 31, 2020, to expire on May 11, 2023. Just as the PHE declaration spurred many changes to the health care enterprise, the end of the PHE will bring about unique challenges. In particular, over the course of the PHE many federal departments and agencies used authority given to them by the PHE to create certain exceptions to regulatory requirements. Those departments and agencies must now determine whether and how to retract these exceptions.

One such exception concerns institutional review board (IRB) review of research involving human subjects. Specifically, on October 8, 2020, the Office for Human Research Protections (OHRP) within HHS issued an exception to the requirement in the Federal Policy for the Protection of Human Subjects, generally referred to as the "Common Rule," that cooperative research undergo review by a single institutional review board (sIRB), with limited exceptions.[1] OHRP determined that "due to concerns regarding the application of the single IRB requirement to cooperative research subject to the 2018 Requirements when this research is initially reviewed or ongoing during the COVID-19 public health emergency" certain categories of cooperative research that are conducted or supported by HHS do not need to comply with the sIRB mandate.[2] OHRP announced:

> [A]n exception to the requirement to use a single IRB is appropriate for . . . [c]ooperative research:
> 1. that is ongoing or initially reviewed by the IRB during the Coronavirus Disease 2019 (COVID-19) public health emergency, as declared by the Secretary of Health and Human Services at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx;
> 2. where reliance on a single IRB would not be practical; and
> 3. for which the HHS division supporting or conducting the research approves of the use of this exception.[3]

OHRP announced in February 2023 that this exception would expire at the end of the PHE. OHRP clarified on its website that while this exception is applicable to research ongoing or reviewed during the PHE, the "exception applies for the duration of the research study," even if the research extends beyond the PHE.[4] As such, the end of

the PHE will not affect any ongoing research that relies upon this exception. However, after May 11, 2023, all new cooperative research subject to the Common Rule will be required to undergo review by an sIRB unless the research meets another regulatory exception to the sIRB requirement.[5] This means that institutions engaged in such research will need to ensure that they have an appropriate reliance agreement in place with the sIRB before the research commences.[6]

The end of the PHE-exception to the sIRB review requirements comes at a significant juncture for all cooperative research, as the U.S. Food and Drug Administration (FDA) is also considering mandating that cooperative research that is subject to the FDA's regulations on human subjects research (the FDA Regulations) be reviewed by an sIRB, with certain exceptions (notably, different exceptions than those required by the Common Rule).[7] FDA published this proposal on September 28, 2022 in a Notice of Proposed Rule Making intended to harmonize the FDA Regulations pertaining to the review of cooperative research by an sIRB with those of the Common Rule.[8]

FDA instituted this rulemaking in response to a requirement in the 21st Century Cures Act to "revise the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable populations rules to (1) reduce regulatory duplication and unnecessary delays; (2) modernize the provisions; and (3) protect vulnerable populations, incorporate local considerations, and support community engagement."[9] If finalized in its current form, the FDA's sIRB requirement would become effective one year after the final rule is published and would apply only to FDA-regulated cooperative research initially approved by an IRB on or after the proposed effective date.[10]

Given both the removal of the PHE exception to the Common Rule's mandate of review by an sIRB for cooperative research and the FDA's proposal similarly to require review by an sIRB for cooperative research, academic medical centers and other institutions conducting research should evaluate their policies and procedures regarding reliance agreements to ensure they have the infrastructure in place to support sIRB review for research beginning after the expiration of the PHE on May 11, 2023. Moreover, these institutions should ensure that any ongoing cooperative research for which HHS approved an exception to sIRB review under the PHE exception is documented as such, so that it is clear upon an audit that the research is exempt from sIRB requirements due to the PHE exception in place at the time the research was initiated.

We note that in addition to the changes to sIRB requirements, institutions should expect to face increased scrutiny of IRBs in general, as the U.S. Government Accountability Office released to the public on February 16, 2023 a report titled *Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness.*[11] The report encourages OHRP and FDA to, among other things, engage in an annual risk assessment to determine whether they are conducting an adequate number of routine IRB inspections and to optimize the use of IRB inspections in the oversight of IRBs. It also encourages OHRP and FDA to undertake efforts to improve the tracking and monitoring of IRB data being submitted to federal agencies so that the agencies, in turn, can make better decisions about which IRBs to inspect and when. Institutions should be prepared for the possibility that these recommendations will result in an increase in the frequency of governmental audits and an expansion of the types of information that must be reported to OHRP and FDA on a regular basis.[12]

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[1] *See* 45 C.F.R. § 46.114 (Common Rule cooperative research requirements). The Common Rule, which was first promulgated in 1991, applies to human subjects research that is conducted, supported, or otherwise subject to regulation by a federal department or agency that has, through administrative action, made the policy applicable to such research, including HHS. In January 2017, HHS published a final rule revising the Common Rule, which made substantial revisions seeking to modernize

and strengthen human subjects protections, including requiring that, effective January 20, 2020, all U.S. sites participating in "cooperative research" (that is, research projects that involve multiple institutions) be reviewed by an sIRB.

[2] *See October 8, 2020: Exception to the Single IRB Review Requirements for Certain HHS-Conducted or -Supported Cooperative Research Activities Subject to the 2018 Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*, OFFICE OF HUMAN RESEARCH PROTECTIONS (Oct. 8, 2020), https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/october-2020-exception-determination/index.html.

[3] *Id.*

[4] *Id.*

[5] Cooperative research that is (i) "cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe)," or (ii) "research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context" is exempt from the sIRB requirement. 45 C.F.R. § 46.114(b).

[6] A reliance agreement, also referred to as an IRB Authorization Agreement (IAA), is a written agreement between two or more institutions that allows an institution engaged in non-exempt human research to delegate IRB review to another IRB, either that affiliated with another institution or an independent IRB.

[7] The FDA Regulations are codified at 21 C.F.R. pts. 50 & 56.

[8] Institutional Review Boards; Cooperative Research, 87 Fed. Reg. 58752 (Sept. 28, 2022) (to be codified at 21 C.F.R. pt. 56).

[9] 21st Century Cures Act, § 3023.

[10] To read more about the FDA's proposed rule, see Ropes & Gray Client Alert, *Harmonizing the Common Rule and U.S. Food and Drug Administration Human Subjects Research Regulations* (Sep. 30, 2022), https://www.ropesgray.com/en/newsroom/alerts/2022/september/harmonizing-the-common-rule-and-us-food-and-drug-administration-human-subjects-research-regulations.

[11] U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-104721, INSTITUTIONAL REVIEW BOARDS: ACTIONS NEEDED TO IMPROVE FEDERAL OVERSIGHT AND EXAMINE EFFECTIVENESS (Jan. 17, 2023), https://www.gao.gov/products/gao-23-104721.

[12] To read more about the report, see Ropes & Gray Client Alert, *The U.S. Government Accountability Office Recommends Actions to Improve Federal Oversight of Institutional Review Boards for Human Research* (Feb. 17, 2023), https://www.ropesgray.com/en/newsroom/alerts/2023/02/the-us-government-accountability-office-recommends-actions-to-improve-federal-oversight.

