From: Klein, Natalie (HHS/OPHS) <Natalie.Klein@hhs.gov>
Sent: Wednesday, October 20, 2021 12:04 PM
To: MHilliard@ncbcenter.org
Subject: Re: Public Comment - Document Identifier: OS–0990–New: Process, for proposed research involving: (1) Pregnant women, human fetuses and neonates; (2) prisoners; or, (3) children, as subjects that are not otherwise approval by an IRB.

Dear Dr. Hilliard,

Thank you for your letter dated September 27, 2021 in response to a Department of Health and Human Service (HHS) notice published in the July 29, 2021 issue of the Federal Register (FRN) proposing an information collection request entitled "Institutional Review Board (IRB) Records for HHS/OASH Consultation Process." I am writing to respond to your letter.

As stated in the referenced notice, the Office of the Assistant Secretary for Health (OASH), Office for Human Research Protections (OHRP), is requesting a new approval from the Office of Management and Budget of an OHRP requirement that IRB records be submitted when an IRB or its institution requests a Department of Health and Human Services (HHS) consultation process for proposed research involving any of the following populations as subjects, and the research is not otherwise approvable by an IRB: (1) pregnant women, human fetuses and neonates; (2) prisoners; or, (3) children.

As permitted in the HHS Protection of Human Subjects Research regulations at 45 CFR part 46, subparts B, C, and D, respectively, the Assistant Secretary of Health, on behalf of the Secretary of HHS, may determine that such research can be conducted or supported by HHS after consulting with experts and allowing for public review of, and comment on, the proposed research. The new information collection request relates to obtaining the relevant IRB records when an IRB or its institution requests a HHS consultation process under these regulations. The annual burden estimated for collecting this information is 10 hours.

The notice invited interested persons to send comments on the proposed information collection on or before September 27, 2021, regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

You stated the following in your September 27, 2021 letter: "NCBC wishes to focus on policies pertaining to the accuracy of the estimated burden of proposed research on human subjects who are pregnant women, human fetuses and neonates, prisoners, or children. Such accuracies are essential to assure that the proposed research information to be collected represents the requisite quality, utility, and clarity to justify the proposal. We understand HHS may determine that such research can be conducted or supported by a revised HHS policy, after consulting with experts and allowing for future public comment on a more detailed presentation of proposed public policy," and, "We look forward to a later more detailed policy proposal to provide further public comment."

You expressed comments about the burden of research on human subjects and the provisions in the HHS Protection of Human Subjects Research regulations at 45 CFR part 46, subparts B, C, and D, respectively, which permit IRBs to refer certain categories of proposed research to OHRP (on behalf of HHS) for HHS consultation and approval consideration. Your comments do not pertain to the subject of the July 29, 2021 FRN, which relates to the estimated burden for IRB records to be provided to OHRP when an IRB or its institution requests a HHS consultation process under these regulations.

OHRP thanks you for your comments and will convey them to the OHRP staff working to interpret these provisions.

Respectfully,
Natalie

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