THE NATIONAL CATHOLIC BIOETHICS CENTER
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September 27, 2021

Ms. Sherrette Funn
Office of the Secretary
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U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: 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. Specific focus of respondents on: the accuracy of the estimated burden; and ways to enhance the quality, utility, and clarity of the information to be collected.

Dear Ms. Funn:

Thank you for the opportunity to provide public comment to the U.S. Dept. of Health and Human Services (HHS) on behalf of The National Catholic Bioethics Center. We wish to provide input on institutional review board reporting obligations pertaining to human subjects' research on pregnant women, human fetuses and neonates, prisoners, and children. We hope to facilitate accuracy in estimating the burden on subjects, thereby enhancing the quality, utility, and clarity of the information to be collected.

The National Catholic Bioethics Center (NCBC) is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences. The Catholic Church is the largest provider of non-governmental, non-profit health care in the United States. The NCBC serves numerous health care agencies in their development and analyses of policies and protocols, including research protocols consistent with the *Ethical and Religious Directives for Catholic Health Care services*. [U.S. Conference of Catholic Bishops, 2018]. The NCBC has 1300 members throughout the United States. These include numerous health care agencies representing thousands of persons involved in the delivery of health care, including related clinical research. Many of these agencies have institutional review boards and NCBC provides consultations and education to hundreds of institutions and individuals seeking its opinion on these and other matters.

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.

As we know the populations identified are populations at risk, especially risks pertaining to informed consent. [45 CFR 46 Subpart C] And existing law mandates that such populations, even if they consent (or in the case of the embryo/fetus, the mother), are not to be subjected to research that does not benefit them, or at least is neutral to impacting their health and wellbeing. Furthermore, even if the mother intends to abort her unborn child, under the law no research procedure can be conducted on the unborn child that does not meet these standards. [66 FR 56778, §46.201-8]

Any future more detailed proposal must assure that these standards are maintained. It is critical that specific detail in the policy proposal addresses reporting methods to assure that true informed consent, without coercion or incentives, is accomplished. Research proposals must be specific, detailing how this is to be documented in seeking proposal approval. For example, research proposals must contain documentation that:

No incentives are being provided to subjects.
Existing research (with documentation) demonstrates no anticipated negative side effects to any subject, including the unborn child.
Existing research (with documentation) demonstrates there is a potential benefit (or at least no harm) to the subjects, and how is it anticipated that the subjects, including the unborn child, would benefit by the research.

There is growing evidence of federal tax dollars being used to fund research utilizing aborted fetal tissue. There should be provisions that research proposals must indicate that, if there is a negative unanticipated outcome to the unborn child, or the mother decides to abort her unborn child, fetal remains from the research subjects will not be used for subsequent research, including but not limited to animal/human hybrid research.

We look forward to a later more detailed policy proposal to provide further public comment.

Respectfully submitted,

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