Celebrating our 36th year published every month - Now emailed!

Human Research Report™

PROTECTING RESEARCH SUBJECTS AND RESEARCHERS

Volume 36, No. 2 ISSN 0885-0615 February, 2021

IRBs and New Proposal to Change Current Human Subject Regulations (#1)

A number of proposals have been made to modify existing regulations on the protection of human research subjects for any studies involving fetal tissue and related matters.

More specifically, the change would alter 45 CFR 46 ("Protection of Human Subjects") by: (1) changing §46.202 ("Definitions"); (2) adding a new paragraph (k) to §46.204 ("Research involving pregnant women or fetuses") (including new subparagraphs (1)(i), (ii), (iii), and (iv), and (2) (i), (ii), (iii), and (iv); (3) seven new subparagraphs (c) through (i) for §46.206 ("Research involving, after delivery, the placenta, the dead fetus or fetal material"); and (4) changing 45 CFR Part 75 ("Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards"), paragraphs §75.364 ("Access to records") and §75.478 ("Expenses associated with acquiring human fetal tissue for research").

IRBs and Researchers Need More Time to Submit Comments

These changes are extensive, and their ramifications for IRBs, researchers, and others are substantial. In fact, the proposals are so sweeping in detail and scope that HHS took up more than 16,000 words in their January 13 FEDERAL REGISTER announcement to explain them (see 86 Fed. Reg. 2615-2633). This document appeared in small type and covered about 18 pages of triple columned text.

Regardless of their import, the proposed regulations appeared with only a minimal 30-day comment window for interested parties to submit their comments to HHS before the regulations become final.

Accordingly, we submitted an HRR comment primarily seeking an extension of the comment deadline to give the research compliance community more time to respond. We also notified our HRR subscribers about this important initiative in a special emailed "Subscriber Alert," along with supporting references to assist anyone in seeking an extension to the February 12 deadline.

As we noted in our note to HRR subscribers, the 30-day comment deadline is considered to be a short period even by federal government standards.

NOTE #1: Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, missing words, etc. However, we will on occasion insert words in brackets [ ] to make the material easier to read, to edit text or formatting, or to add an editorial comment.

NOTE #2: Emphases are added to articles by HRR by underlining or adding ***bold/italics*** to selected text, unless stated otherwise.

NOTE #3: Articles **T**o **B**e **C**ontinued **{TBC}** in subsequent issues are marked at the end with **{TBC}**.

ALSO IN THIS ISSUE

Published monthly by The Deem Corporation, P.O. Box 451117, Omaha, NE 68145. Editor and Publisher: Dennis M. Maloney, Ph.D.

Comments should be submitted via the Web to www.regulations.gov, following the instructions on that site and citing the material that we included in our January email alert to HRR subscribers.

For more information about this major human subjects development, contact Daniel Barry of HHS via email to daniel.barry@hhs.gov.

Regardless of one's opinion about fetal tissue research and related activities, we believe that a 30-day comment period is woefully insufficient.

Because of the complexity of the issues involved with this area of human subjects research, we begin in this article to excerpt from the FEDERAL REGISTER announcement what we consider to be the key background factors and practical impacts of any changes to the current regulations for IRBs and others.

Trump Administration and Fetal Tissue

We begin with background information that may be readily familiar to research compliance professionals of longstanding. However, such information is likely to be less familiar to those newer to the field.

In any event, it is advisable to understand this brief chronology to better respond to the new regulatory proposals and to best justify whatever position one might take on the direction of the proposed regulatory changes. Once established, federal regulations are not easily modified.

"In September 2018, the Department of Health and Human Services (HHS) terminated a contract that provided human fetal tissue from elective abortions to the Food and Drug Administration (FDA) for the development of testing protocols.

HHS terminated the contract because if was not sufficiently assured that the contract included the appropriate protections applicable to fetal tissue research or met all other procurement requirements.

HHS subsequently initiated a comprehensive review of all HHS research involving human fetal tissue from elective abortions to ensure consistency with the statutes and regulations governing such research and to ensure the adequacy of procedures and oversight in light of the serious regulatory, moral, and ethical considerations involved.

Promoting the dignity of human life from conception to natural death is one of the top priorities of President Trump's administration. The audit and review informed the policy process that led to the administration's decision, announced June 5, 2019,[1] to discontinue National Institutes of Health (NIH) intramural research -- research conducted within NIH by NIH researchers -- involving the use of human fetal tissue from elective abortions.

[FN #1: *See* Statement from the Department of Health and Human Services, June 5, 2019, available at *https://www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html*.]" (86 Fed. Reg. 2615-2633 at p. 2615, January 13).

New Layer of Federal Research Review

"With respect to extramural research (research conducted outside of, but funded by, NIH, e.g., at universities), the administration announced that, for new extramural research grant applications or current research projects in the competitive renewal process (generally every five years) that propose to use fetal tissue from elective abortions and that are recommended for potential funding through NIH's two level external scientific review process, an [additional] ethics advisory board will be convened to review the research proposal and recommend whether, in light of the ethical considerations, NIH should fund the research project -- pursuant to a law passed by Congress (42 U.S.C 289 a-1).

In the same policy statement, HHS announced that it would also undertake changes to its regulations and to NIH grants policy to adopt or strengthen safeguards and program integrity requirements applicable to extramural research involving human fetal tissue from elective abortions.[2]