

2020 Current Fiscal Year Report: NIH Human Fetal Tissue Research Ethics Advisory Board – FY2020

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1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2020

3. Committee or Subcommittee

NIH Human Fetal Tissue Research Ethics Advisory Board – FY2020

3b. GSA Committee No.

84589

4. Is this New During Fiscal Year?

Yes

5. Current Charter

03/06/2020

6. Expected Renewal Date

03/06/2022

7. Expected Term Date

09/17/2020

8a. Was Terminated During Fiscal Year?

Yes

8b. Specific Termination Authority

42 U.S.C. 289a-1

8c. Actual Term Date

09/17/2020

9. Agency Recommendation for Next Fiscal Year

Terminate

10a. Legislation Req to Terminate?

No

10b. Legislation Pending?

Not Applicable

11. Establishment Authority

Authorized by Law

12. Specific Establishment Authority

42 U.S.C. 289a-1

13. Effective Date

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee

Scientific Technical Program Advisory Board

16a. Total Number of Reports

1

16b. Report Date

08/18/2020

Report Title

Report of the NIH Human Fetal Tissue Research Ethics Advisory Board- FY2020

Number of Committee Reports Listed: 1

17a. Open 0 17b. Closed 0 17c. Partially Closed 1 Other Activities 0 17d. Total 1

Meetings and Dates

Purpose

To make recommendations regarding the ethics of research involving human fetal tissue (HFT) proposed in NIH grant and cooperative agreement applications and R&D contract proposals, as set forth in the NIH Guide Notice NOT-OD-19-128.

Start

End

07/31/2020 - 07/31/2020

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$2,600.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$98,799.00	\$0.00

18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$0.00	\$0.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$15,994.00	\$0.00
18d. Total	\$117,393.00	\$0.00
19. Federal Staff Support Years (FTE)	0.60	0.00

20a. How does the Committee accomplish its purpose?

The NIH Human Fetal Tissue Research Ethics Advisory Board - FY2020 reviewed applications proposing to use HFT from elective abortions (as defined in NOT-OD-19-128) within a fundable scoring range and proposals that had been identified through the Source Selection process as apparently successful offerors. The Ethics Board reviewed and verified the core ethical principles used in the process for obtaining informed consent for the donation of the tissue. The Ethics Board made findings and advised on whether HFT is being utilized for research only when scientifically justifiable, and in the least amount possible to achieve the scientific outcomes and provided a recommendation on whether the Secretary should withhold funds or not withhold funds from a proposed project because of ethical considerations.

20b. How does the Committee balance its membership?

The NIH Human Fetal Tissue Research Ethics Advisory Board - FY2020 was composed of 15 members. The 15 members included no fewer than one attorney; no fewer than one ethicist; no fewer than one practicing physician; and no fewer than one theologian. No fewer than one-third, and no more than one-half of the appointed members were scientists with substantial accomplishments in biomedical or behavioral research.

20c. How frequent and relevant are the Committee Meetings?

The NIH Human Fetal Tissue Research Ethics Advisory Board - FY2020 met one time. The meeting was open to the public except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b of Title 5 U.S.C. The Board met on July 31, 2020.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The NIH Human Fetal Tissue Research Ethics Advisory Board - FY2020 was established by the U.S. Department of Health and Human Services (HHS). The Ethics Board advised, consulted with, and made recommendations to the Secretary of HHS (Secretary)

regarding the ethics of research involving human fetal tissue (HFT) proposed in NIH grant and cooperative agreement applications and R&D contract proposals, as set forth in the NIH Guide Notice NOT-OD-19-128. Advice provided by the Ethics Board addressed whether HFT is being utilized for research only when scientifically justifiable, and in the least amount possible to achieve the scientific outcomes. No existing NIH advisory committee has the appropriate expertise and/or the ability to hold additional meetings to incorporate these new advisory duties stated in Section 492A. In order to meet legislative requirements in 492A, the NIH Human Fetal Tissue Research Ethics Advisory Board - FY2020 was created for this purpose.

20e. Why is it necessary to close and/or partially closed committee meetings?

The meeting of the NIH Human Fetal Tissue Research Ethics Advisory Board - FY2020 was partially closed to the public for the review of grant applications. Sections 552b(c)(4) and 552b(c)(6) of the Government in the Sunshine Act permits the closing of meetings where discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

21. Remarks

The NIH Human Fetal Tissue Research Ethics Advisory Board - FY2020 was established on February 20, 2020 as part of the Intent of Notice to Convene and Call for Nominations Federal Register Notice as required by statute. The establishment charter was filed on March 6, 2020 in accordance with FACA. This committee was terminated on 9/17/2020 in accordance with the statute. There are no projected costs as the committee was established and terminated in the same fiscal year. NIH Staff is in the process of archiving the committee website.

Designated Federal Officer

Cari E. Young Health Science Policy Analyst

Committee Members	Start	End	Occupation	Member Designation
BURKE, GREG	07/19/2020	09/17/2020	CO-CHAIR, CATHOLIC MEDICAL ASSOCIATION, ETHICS COMMITTEE	Special Government Employee (SGE) Member
CONDIC, MAUREEN	07/19/2020	09/17/2020	ASSOCIATE PROFESSOR, UNIVERSITY OF UTAH SCHOOL OF MEDICINE	Special Government Employee (SGE) Member
CUNNINGHAM, PAIGE	07/19/2020	09/17/2020	INTERIM PRESIDENT, TAYLOR UNIVERSITY	Special Government Employee (SGE) Member

DONOVAN, G. KEVIN	07/19/2020	09/17/2020	PROFESSOR AND DIRECTOR, PELLEGRINO CTR FOR CLINICAL BIOETHICS, GEORGETOWN UNIVERSITY MED CTR	Special Government Employee (SGE) Member Special
FERNANDES, ASHLEY	07/19/2020	09/17/2020	ASSOCIATE DIRECTOR, CENTER FOR BIOETHICS, THE OHIO STATE UNIVERSITY COLLEGE OF MEDICINE	Special Government Employee (SGE) Member Special
GOLDSTEIN, LAWRENCE	07/19/2020	09/17/2020	DISTINGUISHED PROFESSOR, UNIVERSITY OF CALIFORNIA, SAN DIEGO	Special Government Employee (SGE) Member Special
LAKSHMANAN, ASHWINI	07/19/2020	09/17/2020	ASSISTANT CLINICAL PROFESSOR OF PEDIATRICS AND PREVENTIVE MEDICINE, USC KECK SCHOOL OF MED, SECTION HEAD, FETAL & NEONATAL INST	Special Government Employee (SGE) Member Special
MEADE, THOMAS	07/19/2020	09/17/2020	THE EILEEN M. FOELL ENDOWED PROFESSOR OF CANCER RESEARCH, NORTHWESTERN UNIVERSITY	Special Government Employee (SGE) Member Special
MITCHELL, C.	07/19/2020	09/17/2020	GRAVES PROFESSOR OF MORAL PHILOSOPHY, UNION UNIVERSITY	Special Government Employee (SGE) Member Special
MURPHY, SUSAN	07/19/2020	09/17/2020	ASSOCIATE PROFESSOR OF OBSTETRICS AND GYNECOLOGY, CHIEF OF DIV OF REPRODUCTIVE SCIENCES, DUKE UNIVERSITY MED CTR	Special Government Employee (SGE) Member Special
PACHOLCZYK, TADEUSZ	07/19/2020	09/17/2020	DIRECTOR OF EDUCATION, THE NATIONAL CATHOLIC BIOETHICS CENTER	Special Government Employee (SGE) Member Special
PRENTICE, DAVID	07/19/2020	09/17/2020	VICE PRESIDENT AND RESEARCH DIRECTOR, CHARLOTTE LOZIER INSTITUTE	Special Government Employee (SGE) Member Special
SCHMAINDA, KATHLEEN	07/19/2020	09/17/2020	PROFESSOR, DEPT OF BIOPHYSICS, MEDICAL COLLEGE OF WISCONSIN	Special Government Employee (SGE) Member Special
SKOP, INGRID	07/19/2020	09/17/2020	PARTNER, NORTHEAST OBSTETRICS AND GYNECOLOGY ASSOCIATES	Special Government Employee (SGE) Member Special
YOST, H. JOSEPH	07/19/2020	09/17/2020	VICE CHAIRMAN FOR BASIC SCIENCE RESEARCH, ECCLES INST OF HUMAN GENETICS, UNIVERSITY OF UTAH MOLECULAR MEDICINE PROGRAM	Special Government Employee (SGE) Member

Number of Committee Members Listed: 15

Narrative Description

The NIH Human Fetal Tissue Research Ethics Advisory Board - FY2020 was established on February 20, 2020 by the Secretary of the Department of Health and Human Services.

This board operated in accordance of 42 U.S.C. 289a-1. The Ethics Board will consider the use of alternative models, and review and verify the core ethical principles and procedures used in the process to obtain written voluntary informed consent for the donation of the tissue. The ethical considerations the Ethics Board should consider are those related to whether the nature of the research involved is such that it is unethical to conduct or support the research.

What are the most significant program outcomes associated with this committee?

Checked if Applies

- Improvements to health or safety
- Trust in government
- Major policy changes
- Advance in scientific research
- Effective grant making
- Improved service delivery
- Increased customer satisfaction
- Implementation of laws or regulatory requirements
- Other

Outcome Comments

The purpose of the NIH Human Fetal Tissue Research Ethics Advisory Board – FY2020 is to make recommendations to the Secretary of HHS regarding the ethics of research involving the use of human fetal tissue in competitive NIH grant and cooperative agreement applications that are within a fundable scoring range and R&D contract proposals that have been identified through the Source Selection process as apparently successful offerors, as set forth in NOT-OD-19-128.

What are the cost savings associated with this committee?

Checked if Applies

- None
- Unable to Determine
- Under \$100,000
- \$100,000 - \$500,000
- \$500,001 - \$1,000,000
- \$1,000,001 - \$5,000,000
- \$5,000,001 - \$10,000,000
- Over \$10,000,000
- Cost Savings Other

Cost Savings Comments

What is the approximate Number of recommendations produced by this committee for the life of the committee?

14

Number of Recommendations Comments

The NIH Human Fetal Tissue Research Ethics Advisory Board – FY2020 submitted recommendations on 14 grant applications and contract proposals proposing to use human fetal tissue.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

%

% of Recommendations Fully Implemented Comments

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

%

% of Recommendations Partially Implemented Comments

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes No Not Applicable

Agency Feedback Comments

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

Reorganized Priorities

Reallocated resources

- Issued new regulation
- Proposed legislation
- Approved grants or other payments
- Other

Action Comments

The NIH Human Fetal Tissue Research Ethics Advisory Board – FY2020 submitted recommendations on 14 grant applications and contract proposals proposing to use human fetal tissue.

Is the Committee engaged in the review of applications for grants?

Yes

- What is the estimated Number of grants reviewed for approval 0
- What is the estimated Number of grants recommended for approval 0
- What is the estimated Dollar Value of grants recommended for approval \$0

Grant Review Comments

The Board reviewed the ethics of grant applications and contract proposals that proposed to use HFT. They did not perform a scientific review.

How is access provided to the information for the Committee's documentation?

Checked if Applies

- Contact DFO
- Online Agency Web Site
- Online Committee Web Site
- Online GSA FACA Web Site
- Publications
- Other

Access Comments