



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

**NIH HUMAN FETAL TISSUE RESEARCH ETHICS ADVISORY BOARD– FY2020
CHARTER**

COMMITTEE'S OFFICIAL DESIGNATION

NIH Human Fetal Tissue Research Ethics Advisory Board – FY2020

AUTHORITY

Authorized by section 492A of the Public Health Service (PHS) Act, 42 U.S.C. § 289a-1, as amended. The NIH Human Fetal Tissue Research Ethics Advisory Board (Ethics Board) – FY2020 is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Ethics Board will advise, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary) regarding the ethics of research involving human fetal tissue (HFT) proposed in NIH grant and cooperative agreement applications and R&D contract proposals, described below and as set forth in the NIH Guide Notice NOT-OD-19-128. Advice provided by the Ethics Board will address whether HFT is being utilized for research only when scientifically justifiable, and in the least amount possible to achieve the scientific outcomes.

Recommendations will address whether the Secretary should withhold funds or not withhold funds from a proposed project because of ethical considerations. In providing advice and recommendations on these matters, 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.

For purposes of the Ethics Board's review, "research involving HFT" is defined as set forth in NOT-OD-19-128, "Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research."

DESCRIPTION OF DUTIES

The Ethics Board will review applications proposing to use HFT within a fundable scoring range and proposals that have been identified through the Source Selection process as apparently successful offerors.

The Ethics Board will receive the applications and proposals, along with other relevant documentation, such as summary statements from peer review, and review the following information:

- Quantity, type, and source of the HFT;
- Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of acquisition process if cells/tissue were already obtained, including:
 - A sample of the Institutional Review Board (IRB)-approved informed consent form provided with the application or during the Just-in-Time process that includes language that: acknowledges that informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; acknowledges that no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and provides for the signature of both the woman and the person who obtains the informed consent. (Under the contract process, the IRB approved Informed Consent document is developed after contract award and therefore will not be included in the contract proposal justifications.); and
- Proposed research use of the primary and secondary human fetal cells/tissue and justification for the use of HFT in the proposed research, including:
 - Why the research goals cannot be accomplished using an alternative to HFT (including, but not limited to, induced pluripotent cells not developed from HFT, organoids not developed from HFT, neonatal human tissue, human tissue obtained from adults, human fetal tissue not derived from elective abortion, animal models, and in vitro models that are not developed from HFT, and computational models);
 - The methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments);
 - Results from a literature review used to provide justifications; and
 - Plans for use of HFT and the disposal of HFT when research is complete.

The Ethics Board will also review and verify the core ethical principles used in the process for obtaining informed consent for the donation of the tissue.

The Ethics Board will make findings and advise on whether HFT is being utilized for research only when scientifically justifiable, and in the least amount possible to achieve the scientific outcomes and will provide a recommendation on whether the Secretary should withhold funds or not withhold funds from a proposed project because of ethical considerations.

REPORTS

In accordance with Section 492A(5)(B)(ii) of the PHS Act, as amended, no later than 180 days after the date on which the statement announcing the intention of the Secretary to convene the Ethics Board and soliciting nominations is published in the Federal Register, the Ethics Board will submit to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate, a report describing the findings of the Ethics Board regarding the project(s) of research involved

and recommendations of whether the Secretary should or should not withhold funds for the project(s).

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Ethics Board will advise the Secretary.

SUPPORT

Management and support services will be provided by the Office of the Director, NIH.

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

The estimated annual cost for operating the Ethics Board, including compensation and travel expenses for members, but excluding staff support, is \$62,030. The estimated annual person-years of staff support required is 0.7, at an estimated annual cost of \$91,250.

DESIGNATED FEDERAL OFFICER

The Director, NIH will assign a full-time or permanent part-time NIH employee in the Office of Science Policy, Office of the Director to serve as the Designated Federal Officer (DFO) of the Ethics Board. In the event that the DFO cannot fulfill the assigned duties of the Ethics Board, one or more full-time or permanent part-time NIH employees will be assigned these duties on a temporary basis.

The DFO will approve or call all the Ethics Board's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Ethics Board and subcommittee meetings, adjourn any meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIH.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

At least one meeting will be held, subject to availability of relevant NIH grant or cooperative agreement applications or R&D contract proposals. Meetings will be 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. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, as amended, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Ethics Board's functions, dates and places of meetings, and a summary of the Ethics Board's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

Until termination, 30 days after the date of submission of the report required by Section 492A(5)(B)(ii) of the PHS Act, as amended.

TERMINATION

The Ethics Board will terminate 30 days after the date on which the required report is submitted to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate.

MEMBERSHIP AND DESIGNATION

The Secretary will appoint 15 individuals who are not federal employees, to serve as members of the Ethics Board. In making these appointments, the Secretary will consider recommendations from the public specifying the particular individuals who should be appointed to the advisory board, which will be solicited as part of the Federal Register notice announcing the Secretary's intention to convene an Ethics Board. The Secretary will not make appointments until the expiration of the 30-day period beginning on the date of the Federal Register notice.

The appointed members of the Ethics Board will include 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 will be scientists with substantial accomplishments in biomedical or behavioral research. The term of service as a member of the Ethics Board will be for the life of the board. If a member does not serve the full term of such service, the individual appointed to fill the resulting vacancy will be appointed for the remainder of the term of the predecessor of the individual. A member of the Ethics Board may be removed from the board by the Secretary for neglect of duty, malfeasance, or for other good cause shown.

The Secretary will designate an individual from among the members of the Ethics Board to serve as the chair of the board. A quorum for the conduct of business by the full Ethics Board will consist of a majority of currently appointed members. Federal employees are not eligible to be members of this Ethics Board. All members of this board will serve as Special Government Employees.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Ethics Board's jurisdiction. The advice or recommendations of a subcommittee/working group must be deliberated by the parent advisory committee. A subcommittee/working group may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. A quorum for a subcommittee

will be three members. Ad hoc consultants are not members of the Ethics Board or its subcommittees, do not count towards the quorum, and may not vote. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

Meetings of the Ethics Board and its subcommittees will be conducted according to the Federal Advisory Committee Act, as amended, other applicable laws and Departmental policies. Ethics Board and subcommittee records will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

ESTABLISHMENT FILING DATE

MAR 06 2020

APPROVED:

FEB 12 2020

Date



Alex M. Azar II