NATIONAL INSTITUTES OF HEALTH

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

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Human Fetal Tissue Research
Ethics Advisory Board- FY2020*
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The NIH Human Fetal Tissue Research Ethics Advisory Board – FY2020 (Board) was established on February 20, 2020, by the Department of Health and Human Services (HHS) to advise, consult with, and make 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 research and development (R&D) contract proposals, [1] described below and as set forth in the NIH Guide Notice NOT-OD-19-128. [2]

The Board is composed of 15 individuals appointed by the Secretary who are not federal employees. Section 492A(b)(5)(C) of the Public Health Service (PHS) Act establishes certain requirements for the composition of the Board. Pursuant to these requirements, the appointed members of the Board 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 are scientists with substantial accomplishments in biomedical or behavioral research.

The Board met on July 31, 2020. Part of the meeting was open to the public. The open session agenda included a welcome and charge to the Board, an introduction of Board members, a review of confidentiality and conflict of interest procedures, a review of the meeting procedures, and a public comment period. The remainder of the meeting was closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant and cooperative agreement applications and R&D contract proposals, and the discussions, could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant and cooperative agreement applications and R&D contract proposals. The disclosure of such information would constitute a clearly unwarranted invasion of personal privacy.

The Board discussed a total of 14 research proposals (including both grants and contracts) at the July 31 meeting. In making its findings and recommendations, the Board considered the information contained in the grant applications and contract proposals. The Board assessed considerations as to whether the nature of the research involved is such that it is unethical to conduct or support the research. In doing so, the Board assessed, among other things, the scientific justification for the use and quantity of HFT proposed and the use of alternative models; reviewed and verified the core ethical principles and procedures used in the process for obtaining written, voluntary, informed consent for the donation of the tissue; and voted on recommendations to the Secretary about whether, in light of the ethical considerations, NIH should withhold funds or not withhold funds from the research projects. The Board reviewed the applicants' and offerors' stated justifications for the use of HFT, which were required to address the following points with sufficient detail to permit meaningful review:

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[1] *See* HHS Notice of Committee Establishment, Notice of Intent to Convene, and Call for Nominations for the NIH Human Fetal Tissue Research Ethics Advisory Board for Fiscal Year 2020, 85 Fed. Reg. 9785 (Feb. 20, 2020).
[2] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html

- Indicate 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)
- Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments)
- Conduct and describe results from a literature review used to provide justifications
- Describe plans for treatment of HFT and the disposal of HFT when research is complete
- Describe planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. Include a sample of the IRB-approved informed consent form with the application or during the Just-in-Time (JIT) process. The informed consent for donation of HFT for use in research requires language that acknowledges 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; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent.

Consensus by the Board was not required, and recommendations were determined by a simple majority. The Board voted to recommend that the Secretary:

- withhold funds for thirteen of the research proposals.
- not withhold funds for one of the research proposals.

Board members only had two options in voting on proposals with which they had no conflicts of interest: recommending that the Secretary withhold funds for the proposal for ethical reasons or recommending that the Secretary not withhold funds for the proposal for ethical reasons. The Board was charged to consider only ethical aspects of the HFT use in the research proposals.

During discussion of a number of the proposals for which the majority of members ultimately voted to recommend withholding funds, some members expressed support for particular projects should the portion(s) involving HFT be removed. In particular, this was true of several projects that proposed direct comparison to models derived from human fetal tissue as encouraged in recent NIH solicitations focusing on research to develop, demonstrate, and validate alternate experimental human tissue models. Some of the proposals were constrained by the NIH requirement that HFT be used as a comparator.

Ultimately, the Secretary will make any funding decisions based on the recommendations of the Board, as it pertains to components of the proposals that use HFT. Under Section 492A of the PHS Act, the Secretary may not withhold funding for a research project because of ethical considerations unless the majority of the Board recommends that, because of such considerations, the Secretary withhold funds for the research project; or the majority of the Board recommends that the Secretary not withhold funds for the research project because of such considerations, but the Secretary finds, on the basis of this report, that the

recommendation is arbitrary and capricious.

In accordance with Section 492A(b)(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 as published in the Federal Register, the Board is required to submit to the Secretary, the Committee on Energy and Commerce of the U.S. House of Representatives, and the Committee on Health, Education, Labor and Pensions of the U.S. Senate, a report describing the findings of the Board regarding the project(s) of research involved and recommendations concerning whether the Secretary should or should not withhold funds for the project(s). The report must include the information considered in making the findings. As required by section 492A(b)(5)(K) of the PHS Act, this Ethics Board will terminate 30 days after the date on which this 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.

This document is the report describing the findings and recommendations of the NIH Human Fetal Tissue Research Ethics Advisory Board – FY2020. Recommendations in this report address whether the Secretary should withhold funds or not withhold funds from proposed projects because of ethical considerations. Pursuant to Section 492A(b)(1) and (6), the ethical considerations the Board deliberated 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 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."

This report does not include information about the grant and cooperative agreement applications and R&D contract proposals that could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Research Proposal 1

The Board voted to recommend that the Secretary withhold funds for this research proposal. In discussions about the proposal, multiple members of the Board indicated that they believed there were weaknesses in the justification for the use of HFT. Specifically, most of the Board members believed that the proposal did not adequately define and rationalize the quantity of HFT, because it did not specify the number of specimens to be used. One member expressed concern that this lack of specificity creates an open-endedness about the quantity that might be used. One member thought that the quantity of HFT was not an ethical consideration and that it can be difficult for scientists to anticipate the amount of resources that might be needed. However, other members disagreed and remarked that the research proposals were asked to address the quantity of tissue to be used to ensure that the least amount of tissue possible is being used, and that with a sensitive substance, such as HFT, quantity is an ethical consideration. In addition, one member highlighted what was perceived to be limitations in the explanation of the informed consent document that was used to collect the HFT that the researchers proposed to use, because it lacked language stating that donation of HFT would not affect the method of

abortion. One reviewer commented that the proposal lacked a sufficient explanation of why the research goals cannot be accomplished using an alternative to HFT proposal, because it gave no justification for using tissue from elective abortions rather than from miscarriages. This Board member noted that ethically derived tissue from non-elective abortions is a viable alternative to HFT with tissue of good quality available from well-established banks. However, other members thought that tissue from miscarriage was not a viable alternative due to the timing of tissue collection and tissue quality. These members noted that most spontaneous abortions are abnormal for a variety of reasons, including genetic abnormalities such as aneuploidy. In addition, one member said that the timing of spontaneous abortion relative to collection of the tissue is typically longer than in the cases of HFT collection from elective abortions, and therefore the quality of the tissue is not as high. Several members expressed enthusiasm for the proposal, outside of those elements that used HFT.

Voted to recommend withholding funding – 13 members

Voted to recommend not withholding funding – 2 members

Research Proposal 2

The Board voted to recommend that the Secretary withhold funds for this research proposal. In discussions about the proposal, some members of the Board thought that the justification for the use of HFT was ethically insufficient as to why the research goals could not be accomplished without using HFT, because the tissue was being used only to make the comparison. Some thought that the work could be accomplished without using HFT. Others noted that the proposal documented plans for treatment and disposal of HFT, and reviewed the limitations of other sources. Some members thought the literature review and discussion of the alternatives were good and presented a strong case for using the least amount of HFT possible while still achieving the goals. One member was concerned about the accuracy of statements in the informed consent that the method of abortion would not be altered, because the age of the tissue would necessitate certain abortion procedures that are not commonly used in order to preserve intact tissue. Another member also noted that members should consider whether the informed consent to donate fetal tissue for research could ever be valid given the vulnerability inherently present within the context.

Voted to recommend withholding funding – 8 members

Voted to recommend not withholding funding – 7 members

Research Proposal 3

The Board voted to recommend that the Secretary withhold funds for this research proposal. A member said that the investigator provided a thorough analysis and complied with the guidance, but the member had concerns that there appeared to be too much reliance on the tissue supplier to satisfy the NIH policy requirements. The proposal appeared to assume that the tissue supplier would follow policy guidelines. The procedure for retrieving tissue was not described. Another reviewer noted that two other source companies are mentioned in the proposal, but there is no further mention of them or their consent processes in the rest of the document. A Board member cited the costs quoted for the fetal cells and questioned the prospect of financial

gain, especially because no information was provided as to the breakdown of the costs. Another Board member said that this proposal came up short because of "punting the consent process" to the tissue source company. The proposal was also not clear about the number of samples sought.

In discussions about the proposal, there was consensus among members of the Board about the absence of required documentation about adherence to a number of NIH policy requirements. In particular, although the proposal included more than one source of HFT, documentation of consent documents were not included for all of them. In addition, members noted absence of required documentation related to the sources of HFT, a precise definition of the amount of HFT the researchers were proposing to use, and description of informed consent processes and procedures used to obtain the tissue. Some members expressed concerns with one of the companies providing HFT. One member suggested that tissue from miscarriage was a viable alternative to HFT.

Voted to recommend withholding funding – 15 members

Voted to recommend not withholding funding – 0 members

Research Proposal 4

The Board voted to recommend that the Secretary withhold funds for this research proposal. In discussions about the proposal, some members of the Board believed that the proposal did not include an ethically sufficient justification for the use of HFT, because it failed to explain why the research goals could not be accomplished using an alternative to HFT. One reviewer said that although the model comparisons were detailed and appeared rigorous, the ethical justification, i.e., that fetal tissue obtained from spontaneous miscarriages or stillbirths cannot be used, was incomplete. They thought that the option for other tissue sources was not acknowledged. One member raised serious ethical concerns about the adequacy of the informed consent, because there were questions about accuracy of the statements related to privacy. Specifically, it included promises of deidentification because the names of donors will be removed from documentation. However, the member expressed concern that, although the consent document noted that the patient's name would be removed, there were many other identifiers that would need to be removed to ensure privacy. Concerns were also raised based on the consent form language about the patient's medical records being accessible. One member disagreed about whether there was a privacy risk, and pointed out that the consent forms had already been reviewed and approved by an Institutional Review Board (IRB). Concerns were also raised about the ethical sufficiency of informed consent documents for tissue donation, because there was no explicit text assuring the donor that medical procedures would not be altered regardless of the decision on whether or not to donate the tissue.

Voted to recommend withholding funding – 14 members

Voted to recommend not withholding funding – 1 member

Research Proposal 5

The Board voted to recommend that the Secretary <u>not</u> withhold funds for this research proposal.

A member noted that the strength of the proposal is its attempt to improve an existing model and its accessibility and generalizability. The member noted that another strength was that the investigators are planning to use preexisting HFT stored in a biorepository and collected according to guidelines, with no need to acquire additional tissue for the planned studies. If successful, the research will obviate the need for HFT in future models. The member said that half of the research has been completed and questioned the need to replicate it. Given this, some members of the Board thought that the justification of the use of HFT to achieve the proposed aims (including the amount of HFT) was ethically sufficient. Ethical concerns regarding de-identification and privacy protections in the consent documents were also raised, and it was again noted that tissue from miscarriage was a viable alternative to HFT. Concerns were also raised about the ethical sufficiency of informed consent documents for tissue donation, because members thought that there was no explicit text assuring the donor that medical procedures would not be altered regardless of donation decision and there was no statement about the separation between the decision to donate and the decision to terminate.

Voted to recommend withholding funding – 6 members

Voted to recommend not withholding funding – 9 members

Research Proposal 6

The Board voted to recommend that the Secretary withhold funds for this research proposal. One member had concerns that the study was "too interwoven with the practice of abortion." In discussions about the proposal, some members believed the proposal did not include an ethically sufficient justification for why the research goals could not be achieved using alternatives to HFT, because those members believed that the literature review was scant, citing only two studies, and because some members believed that alternatives are in fact available, contrary to the assertions in the proposal. In addition, some members considered there to be weaknesses in the informed consent documentation, because there were vague descriptions of the ultimate use of the tissue and unclear language in the consent form regarding the source of the donated tissue. Another member noted that most IRBs ask for a broad description, so they considered the vagueness of the language in the documentation to be purposeful and ethical. Some Board members thought that the justification provided in the proposal was strong because the proposal described how the research could not be done with other models, including primates, and that in this case, HFT is essential. Another Board member expressed an opinion that miscarriage tissue could be used for this study and that although the investigators mentioned it, they dismissed it without an explanation.

Voted to recommend withholding funding – 10 members

Voted to recommend not withholding funding – 5 members

Research Proposal 7

The Board voted to recommend that the Secretary withhold funds for this research proposal. In discussions about the proposal, some members considered there to be a number of weaknesses in the justification of the use of HFT because some members perceived there to be a superficial literature review to document the methods used to determine that no alternatives to HFT can

be used. One member thought that the proposal did not thoroughly consider alternatives such as organoids. In addition, deficiencies in the consent form were noted on the basis that while the proposal asserts the independence of the decision to have an abortion from the consent to donate HFT, members thought that was not specified in the tissue donation consent form. Other members thought the ethical justifications provided were sound, and did not have any overt concerns regarding the justification, tissue disposal, and consents. Two of the members thought that it has been well-established that no alternatives to HFT exist for this purpose, including organoids. Board members noted that there was sufficient specificity of the tissue quantity, because the number of samples was specified in a table.

Voted to recommend withholding funding – 10 members

Voted to recommend not withholding funding – 5 members

Research Proposal 8

The Board voted to recommend that the Secretary withhold funds for this research proposal. A member noted that all of the human samples for this study have been previously collected and used in academic research. Both tissue suppliers provided documentation for tissue collection, disposal, and informed consent. In consideration of HFT alternatives, the investigators rejected the use of induced pluripotent stem (IPS) cells and organoid cultures because they did not have the full spectrum of subtypes needed for the study. A reference to a PubMed search was mentioned but not discussed. The informed consent process was described, but neither of the two forms indicated whether the research participant is an adult or minor. In discussions about the proposal, members considered there to be underlying ethical problems with the informed consent forms, because the forms did not specify who is consenting or state whether the method of abortion would be affected by the donation of HFT. One member also mentioned that one of the consent forms indicates that the clinic will share information with others but does not indicate with whom. In contrast, some members believed that the other consent form was very clear. One member pointed out that the consent forms had already been reviewed and approved by an IRB. In addition, a member believed that the amount of tissue in the proposal was not statistically or experimentally justified because the proposal was not clear about the actual number of fetal tissues needed to obtain confirmatory data; the need for tissues was likely substantially higher than the starting number. One member thought that the removal of identifiable information was robust and the plans for disposal of HFT were well articulated. Concerns were raised about the justification for the lack of alternatives to HFT, specifically that there was insufficient extrapolation from the literature review to say why alternatives were not appropriate. Some members thought that tissue from miscarriage was not sufficiently considered as a viable alternative to HFT.

Voted to recommend withholding funding – 11 members

Voted to recommend not withholding funding – 3 members

Conflict of interest – 1 member

Research Proposal 9

The Board voted to recommend that the Secretary withhold funds for this research proposal. Board members disagreed about the adequacy of the justification, in particular regarding the proposal's discussion of availability of alternatives to HFT. A Board member noted that the investigator stated that HFT was needed without discussing alternatives. Some members thought that there were other ways to achieve the aims of the project without the use of HFT, and that the proposal did not adequately address those alternatives. For example, one member suggested that the investigator could have considered a primate model, although primate studies also raise issues. Another member commented that the literature review was relatively sparse and that tissue from stillbirths and miscarriages should be available. One member was concerned about the potential for the institution to be making money from the use of HFT, because the proposal budgeted costs for obtaining tissue, although tissue was already in hand. Concerns were also raised that the project would inherently violate state law requiring issuance of a death certificate, burial of certain remains and prohibiting dissection of HFT after a certain age.

Voted to recommend withholding funding – 11 members

Voted to recommend not withholding funding – 3 members

Conflict of interest – 1 member

Research Proposal 10

The Board voted to recommend that the Secretary withhold funds for this research proposal. One of the Board members stated that while they believed the justification of the use of HFT was largely compelling, they thought there were several weaknesses in the consent process that was described. Specifically, one of the consent forms included conflicting or misleading statements because on one hand it asked the donor to state that the donation is made without any restriction regarding who may receive the donated tissue or for the purpose that may be used, and elsewhere it states that the tissue may be used for research. Additionally, one of the consent forms had no clear distinction between the decision to donate and the decision to terminate. One of the consent forms also did not address compensation. Concerns were also raised about the ethics of using broad or generic consent in the situation of donation of HFT without delineating the uses that the acquired tissues would be put to. One member also thought that the use of HFT as a control was not needed. However, other members thought that the proposal would have important scientific and medical value, and that it included a well-described and robust ethics process. One member also believed that no alternatives to HFT were possible for this application, and reported that while alternatives have been attempted for the past 10 to 15 years, none has been successful and that the work cannot be done with mice or organoids. There was disagreement between the members regarding whether the amount of HFT in the proposal was clearly delineated and justified.

Voted to recommend withholding funding – 12 members

Voted to recommend not withholding funding – 3 members

Research Proposal 11

The Board voted to recommend that the Secretary withhold funds for this research proposal. A member said that the investigators' primary justification, based only on a single publication over 10 years old, was an anticipated lack of adult tissue obtained from the relevant surgeries. The member did not think there was supporting documentation indicating that the sources for this tissue would cease to be available and no indication that the investigators looked for alternative sources. There was also a concern that the literature search was limited. In discussions about the proposal, multiple members considered there to be ethically insufficient evidence in the proposal that HFT is needed to achieve the research aims because multiple members thought the methods used to determine that no alternatives to HFT can be used were unconvincing, and believed alternatives were possible. For example, one member found in their own literature search that the type of surgery on adults from which the same tissue can be obtained was expected to be continued, rather than decreased as stated by the investigator. One member also raised issues related to compliance with state law regarding issuance of death certificate, dissection of the fetus and burial of fetal remains.

Voted to recommend withholding funding – 14 members

Voted to recommend not withholding funding – 1 member

Research Proposal 12

The Board voted to recommend that the Secretary withhold funds for this research proposal. A member said that the investigator's justification is weak because it does no more than state that the proposed model using HFT is the only one that will work. A member also noted that the investigator did not indicate that a literature search had been conducted. In discussions about the proposal, concerns were raised by multiple members regarding the justification for the use of HFT to best achieve the aims of the proposed research. In addition, some members believed that the literature review included in the proposal justifying the lack of alternatives to HFT was misleading and contradicted by multiple lines of evidence. For example, the investigator did not describe alternatives beyond providing data on a single cell line that they asserted, but did not demonstrate, would be inadequate for their design. One of the members also considered there to be an ethically insufficient justification for the amount of HFT that was proposed. The investigator provided no indication of the quantity of HFT needed to provide sufficient cells for the proposed experiments and did not discuss why the research goals cannot be accomplished without the use of HFT. A member also thought that the description of the consent process for the existing HFT donation was ethically insufficient in that it did not state that: 1) informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion; and 2) the donation would not affect the method of abortion.

Voted to recommend withholding funding – 15 members

Voted to recommend not withholding funding – 0 members

Research Proposal 13

The Board voted to recommend that the Secretary withhold funds for this research proposal. In discussions about the proposal, although some of the Board members remarked on the scientific value of the research, some of them thought that the justification for the use of HFT was

inadequate because the investigators did not discuss methods to determine alternatives to HFT; and the literature search cited only four papers. The member noted that the primary paper was from the investigator's laboratory, although another member remarked that it was a landmark paper. Another member also expected more from the literature search. A member remarked that the proposal did not discuss miscarriage tissue, which the member said could provide the same results.

Other members disagreed and believed that no equally effective alternatives were available, and that the literature review was sufficient given the space limitations and the strength of the literature that was cited. One Board member said the investigators were clear about the number of samples of archived tissue used and had calculated the least number of samples needed for each part of the research.

Voted to recommend withholding funding – 10 members

Voted to recommend not withholding funding – 5 members

Research Proposal 14

The Board voted to recommend that the Secretary withhold funds for this research proposal. In discussions about the proposal, several members considered there to be conspicuous weaknesses in the justification for the use of HFT, because they thought the proposal failed to justify the need for HFT and the lack of alternatives. A member had concerns about the investigators' statement that no alternative model is available. This seemed in conflict with the summary report that referred to a mouse model. The member also questioned the investigators' statements about a lack of basic parameters from computer modeling, and how diagnosis would be improved. There were seven consent forms. One seemed generic and not specific to the project. Three were in languages other than English with no translation, so the member could not verify that the consents met the requirements. Also, the member thought that the investigators did not address the least possible utilization of HFT. Another member agreed that the investigators made a poor attempt at justification, and only made assertions. One paper was self-referential. A concern was raised that possible HFT alternatives were not discussed. There was no mention of using banked tissue from miscarriage, although one of the consents specifically mentioned miscarriage tissue.

A member noted that the investigator referred to an alternative mouse model. Some members believed that viable alternatives to HFT were available for the purposes of the work that was proposed, including one member who suggested tissue from miscarriage or stillbirth. Two members specifically believed that the consent process for collection of the existing samples was unclear and documentation was incomplete. There was also concern that the project might stigmatize those who do not consent to research.

Voted to recommend withholding funding – 14 members

Voted to recommend not withholding funding – 1 member

Additional information:

Two members of the Board asked that a dissenting opinion be included for the record, as follows: "This board was clearly constituted …so as to include a large majority of members who are on the public record as being opposed to human fetal tissue research of any type. This was clearly an attempt to block funding of as many contracts and grants as possible, even those responding to the NIH solicitation for proposals responsive to the notice: "Characterizing and Improving Humanized Immune System Mouse Models (IMM-HIS)". This solicitation required comparison of current humanized mice made with human fetal tissue to proposed models that do not use human fetal tissue. The outcome of the Board's deliberations are thus clearcut and will paradoxically fail to reduce the use of human fetal tissue in the development of humanized mice needed for therapy development including for COVID19."

Appendix: Definition

For this purpose, research involving HFT is defined as research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions and includes the following:

- human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.
- animal models incorporating HFT from elective abortions, including obtaining such models from a vendor.
- derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts.
- any human extra-embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, *if obtained from the process of elective abortion.*

The definition of research involving HFT **does not** include the following:

- human fetal primary or secondary cell cultures, if cells were not derived from an elective abortion
- already-established (as of June 5, 2019) human fetal cell lines (e.g. induced pluripotent stem cell lines from human fetal tissue, immortalized cell lines, differentiated cell lines).
- derivative products from human fetal tissue or cells (e.g. DNA, RNA, protein) **if not derived** from elective abortion.
- human extra-embryonic cells and tissue, including, but not limited to, umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi **if not derived** from elective abortion.
- human fetal cells present in maternal blood or other maternal sources
- embryonic stem cells or embryonic cell lines.
- research on transplantation of HFT for therapeutic purposes (because of the statutory provision(s) addressing such research).

This definition implements the statute (42 U.S.C. Chapter 6A, Subchapter III, Part H, Sec. 289) and is consistent with the NIH Grants Policy Statement (4.1.14).