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Human Fetal Tissue Research: Frequently Asked Questions

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Policy Developments

This report is accurate as of the date of publication. On April 2021, the Department of Health and Human Services (HHS) reversed its 2019 decision to require review of all research applications for National Institutes of Health (NIH) grants and contracts proposing the use of human fetal tissue by an Ethics Advisory Board (as discussed in this report). Other requirements for NIH grants and contracts involving the use of human fetal tissue announced in 2019, such as reporting requirements, remain in effect. Additionally, NIH intramural researchers can conduct research involving human fetal tissue with prior approval from NIH.

Sources: NIH, *Update on Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research*, April 16, 2021, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-111.html, and NIH, *Policies on the Acquisition and Use of Human Fetal Tissue (HFT) for Research Purposes in the Intramural Research Program at NIH,* https://oir.nih.gov/sourcebook/ethicial-conduct/special-research-considerations/policies-procedures-use-human-fetal-tissue-hft-research-purposes-intramural/policies.

On June 5, 2019, the Department of Health and Human Services (HHS) announced—following an audit and review of all HHS research involving the use of human fetal tissue from elective abortions—that the Administration has decided to discontinue intramural research (i.e., internal) projects involving fetal tissue from elective abortions at the National Institutes of Health (NIH) and let expire an existing contract for human fetal tissue research with the University of California at San Francisco.[1] The Administration also indicated it would require additional ethics review for *new* extramural research (i.e., external) involving such tissue, pursuant to Public Health Service Act (PHSA) Section 492A.[2] In general, about 10% of NIH funding goes to intramural researchers at NIH-operated facilities and over 80% of NIH funding goes to extramural researchers at universities and other institutions, in the form of grants, contracts, and cooperative agreements.[3]

On July 26, 2019, NIH issued a notice announcing new requirements for extramural research involving human fetal tissue obtained from elective abortions. The new requirements apply to grant applications with due dates on or after September 25, 2019, or submissions for contract solicitations published after September 25, 2019. The requirements apply to new proposed projects involving human fetal tissue, or changes in scope to existing projects that would involve human fetal tissue but previously did not.[4] In addition, the requirements prohibit those receiving NIH training awards (such as graduate students or postdoctoral fellows) from proposing projects involving the use of human fetal tissue under such awards. New NIH grant, cooperative agreement, or contract awards involving the use of human fetal tissue must provide a justification of why such tissue is scientifically necessary; details regarding tissue procurement and costs (including details about informed consent obtained); and information about how human fetal tissue will be used in the proposed work and disposed of following its use.

[1] Department of Health and Human Services (HHS), "Statement from the Department of Health and Human Services," press release, June 5, 2019, https://www.hhs.gov/about/news/2019/06/05/statement-from-the-department-of-health-and-human-services.html.

[2] 42 U.S.C. §289a; ibid.

[3] National Institutes of Health (NIH), "What We Do: Budget," January 24, 2019, https://www.nih.gov/about-nih/what-we-do/budget.

[4] NIH, "Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research," NOT-OD-19-128, July 26, 2019, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html.

The proposed use of human fetal tissue is to be evaluated in both the scientific and technical review portion of grant application review (technical evaluation for contracts), as well as by a new ethics advisory board prior to awarding the grant or cooperative agreement, pursuant to PHSA Section 492A.[5] The ethics advisory board, to be comprised of scientists, ethicists, and others as specified in PHSA Section 492A, is to assess the proposed project's compliance with NIH policy, the scientific justification for the research, and the process and procedure for obtaining the fetal tissue, among other things, in order to make a recommendation to NIH on whether it should fund the project in light of ethical considerations. For new grants and cooperative agreements awarded, annual reporting requirements will require justification for the ongoing scientific necessity of human fetal tissue in the research.[6]

This report provides answers to frequently asked questions concerning the regulation and use of human fetal tissue in research, including a description of what constitutes human fetal tissue research, and how such tissue is acquired, along with rules and regulations governing the use and acquisition of fetal tissue. It also provides an overview of current research at NIH and other federal agencies that conduct medical research.

What is human fetal tissue?

PHSA Section 498A(g) defines "human fetal tissue" as "tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth." An *embryo* is defined as the product of conception (sperm and egg) from implantation until the eighth week of pregnancy, then the product of conception is called a *fetus* from the ninth week of pregnancy until birth.[7]

What are the uses of human fetal tissue in biomedical laboratory research?

Scientists use human fetal tissue in many ways in laboratory research. They may conduct studies on the tissue itself, particularly for studies of human development. Scientists may also use it to build models for studying disease. Fetal tissue cells are less specialized than adult cells, and therefore are more readily grown in the laboratory.[8]

Scientists have been conducting research using fetal tissue in the United States for decades. For example, dating back to the 1960s, fetal tissue was used to create two different cell lines (WI-38 and MRC-5) that have been used to develop vaccines, including for Hepatitis A, Rubella, Varicella (chickenpox), and Zoster (shingles). Scientists found that the cell lines derived from fetal tissue were more useful than existing animal cell lines for cultivating viruses needed to

[5] Ibid; For more information on the NIH peer review process for extramural funding see CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*.

[6] Ibid.

[7] The American College of Obstetricians and Gynecologists (ACOG), "How Your Fetus Grows During Pregnancy," April 2018, https://www.acog.org/Patients/FAQs/How-Your-Fetus-Grows-During-Pregnancy?IsMobileSet=false.

[8] Meredith Wadman, "The Truth about Fetal Tissue Research," *Nature*, December 7, 2015, https://www.nature.com/news/the-truth-about-fetal-tissue-research-1.18960#/box; and Michelle Andrews, "FAQ: How Does New Trump Fetal Tissue Policy Impact Medical Research?," *Kaiser Health News*, June 7, 2019, https://khn.org/news/faq-how-does-new-trump-fetal-tissue-policy-impact-medical-research/.

develop vaccines.[9] These cell lines are also used as tools for research, such as in aging and drug toxicity studies.[10] No additional fetal tissue has been added to these cell lines since they were first created.[11]

Fetal tissue is also used in infectious disease and immune system-related studies, such as on HIV, the dengue virus, Hepatitis C virus, Ebola virus, and tuberculosis.[12] Humanized mice engrafted with fetal tissue can serve as models for the human immune system, and can be used for studying disease and testing new therapeutics. Normally, mouse and human immune systems are quite different, and therefore regular mice can be inadequate for certain studies related to human immune systems. Animals with immune systems more similar to those of humans, such as primates, are more difficult and expensive to research, and may pose other ethical challenges. Humanized mice created with fetal tissue, therefore, serve as a way to conduct studies related to human immune systems using small animals in a laboratory-controlled setting.[13] One review of the role of humanized mice created with fetal tissue in HIV research asserted that they are "valuable models for the research and development of vaccine strategies and therapeutic interventions to control or eradicate HIV."[14]

Studies of human development can also use fetal tissue, such as studies of brain development, eye development, and diseases that begin early in human development, such as type 1 diabetes. In such research, scientists may study the fetal tissue itself in the laboratory to understand the early stages of human development.[15]

A *Nature* analysis of FY2014 NIH funding data found that research projects involving human fetal tissue were carried out in the following areas (percentage of total): HIV/AIDS (39%); developmental biology (18%); eye development and disease (14%); other infectious diseases (e.g., hepatitis C) (13%); miscellaneous (e.g., type 1 diabetes) (8%); *in utero* diseases, toxic exposures, and congenital conditions (7%); and fetal tissue repository (1%).[16] In FY2018, NIH funded 200 research projects involving human fetal tissue with $115 million. NIH estimates that it will spend $120 million on such research in FY2019.[17]

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[9] Shari E. Gelber, Laurence B. McCullough, and Frank A. Chervenak, "Fetal Tissue Research: An Ongoing Story of Professionally Responsible Success," *American Journal of Obstetrics and Gynecology*, December 2015, pp. 819-821.

[10] Meredith Wadman, "The Truth about Fetal Tissue Research," *Nature*, December 7, 2015, https://www.nature.com/news/the-truth-about-fetal-tissue-research-1.18960.

[11] History of Vaccines, "Human Cell Strains in Vaccine Development," January 10, 2018, https://www.historyofvaccines.org/content/articles/human-cell-strains-vaccine-development.

[12] Shigeyoshi Fujiwara, "Humanized Mice: A Brief Overview on their Diverse Applications in Biomedical Research," *Journal of Cellular Physiology*, vol. 233 (May 2017), pp. 2889-2901, and Kylie Su Mei Yong, Zhisheng Her, and Qingfeng Chen, "Humanized Mice as Unique Tools for Human-Specific Studies," *Archivum Immunologiae et Therapiae Experimentalis*, vol. 66 (2018), pp. 245–266.

[13] Shigeyoshi Fujiwara, "Humanized Mice: A Brief Overview on their Diverse Applications in Biomedical Research," *Journal of Cellular Physiology*, vol. 233 (2018), pp. 2889-2901.

[14] Marshall E. Karpel, Christian L. Boutwell, and Todd M. Allen, "BLT Humanized Mice as a Small Animal Model of HIV Infection," *Current Opinion in Virology*, vol. 13 (2015), pp. 75-80.

[15] Meredith Wadman, "The Truth about Fetal Tissue Research," *Nature*, December 7, 2015, https://www.nature.com/news/the-truth-about-fetal-tissue-research-1.18960#/box.

[16] Ibid.

[17] NIH, "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," April 19, 2019, https://report.nih.gov/categorical_spending.aspx.

What are the alternatives to fetal tissue in laboratory research?

Various alternatives to fetal tissue in biomedical research are currently in development, and may one day replace fetal tissue in certain research studies where the tissue is currently used. In December 2018, NIH announced up to $20 million in funding over two years for research on fetal tissue alternatives.[18] Still, many scientists and medical experts assert that for some areas of research, no alternative to fetal tissue will be sufficient, such as in studies of early human development or diseases that develop *in utero* (i.e., before birth).[19]

For immune system-related studies, some types of humanized mice can be created with adult stem cells and/or umbilical cord blood cells and are useful for some studies. Mice created with fetal bone marrow/liver/thymus cells (BLT; human fetal tissue) currently allow for the most representational model of a human immune system, and therefore, scientists rely on the BLT mice or other fetal tissue models for certain studies, including related to HIV/AIDS, Zika virus, and Hepatitis B and C virus infections.[20] Last year, scientists published a new way to create humanized mice using surplus neonatal thymus tissue from neonatal cardiac surgery patients—the NeoThy model. Further experiments are sought to compare this new model to the fetal tissue model, in order to determine whether and how it can serve as an alternative to the BLT model in future studies.[21] As stated by the lead author of the NeoThy study, Matthew E. Brown, in a December 2018 letter to the House Oversight and Government Reform Committee members,

> While I strongly stand behind the work presented in our paper and am excited about the potential of this model, it is premature to make generalizable conclusions about the NeoThy replacing fetal tissue (BLT type) models in all humanized mouse research applications. Further, in no way does our paper support the claim that fetal tissue research as a whole is no longer needed. I believe that it is possible, for certain research applications, that the NeoThy may prove a better model than the BLT, but at this point these are only hypotheses that would need to be tested in well-controlled side-by-side comparisons.[22]

Other potential alternatives to fetal tissue include reprogrammed adult stem cells (i.e., induced pluripotent stem cells; iPS cells) and organoids, three-dimensional lab-created models of human organs.[23] While promising, scientists are still endeavoring to get iPS cells and organoids to mimic the behavior of natural human cells and organs, as do those from fetal tissue naturally. iPS cell

[18] NIH, "Notice of Intent to Publish Funding Opportunity Announcements for Research to Develop, Demonstrate, and Validate Experimental Human Tissue Models that Do Not Rely on Human Fetal Tissue," NOT-OD-19-042, December 10, 2018, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-042.html.

[19] Sally Temple and Lawrence S.B. Goldstein, "Why We Need Fetal Tissue Research," *Science*, January 18, 2019, https://science.sciencemag.org/content/363/6424/207.full, and Meredith Wadman, "The Truth about Fetal Tissue Research," *Nature*, December 7, 2015, https://www.nature.com/news/the-truth-about-fetal-tissue-research-1.18960#/box.

[20] Todd M. Allen, Michael A. Brehm, and Sandra Bridges, et al., "Humanized Immune System Mouse Models: Progress, Challenges, and Opportunities," *Nature Immunology*, vol. 20 (2019), pp. 770-774.

[21] Matthew E. Brown, Ying Zhou, and Brian E. McIntosh, et al., "A Humanized Mouse Model Generated Using Surplus Neonatal Tissue," *Stem Cell Reports*, vol. 10, no. 4 (2018), pp. 1175-1183.

[22] Letter from Matthew E. Brown, Department of Surgery, University of Wisconsin-Madison, to Honorable Jim Jordan, Mark Meadows, Raja Krishnamoorthi, Gerry Connolly, Chairmen and Ranking Members, December 13, 2018.

[23] NIH, "Notice of Intent to Publish Funding Opportunity Announcements for Research to Develop, Demonstrate, and Validate Experimental Human Tissue Models that Do Not Rely on Human Fetal Tissue," NOT-OD-19-042, December 10, 2018, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-042.html.

technology has advanced since it was first discovered in 2006. Scientists continue working on ways to fully reprogram these cells to serve in disease modelling.[24] New gene editing technologies, such as CRISPR-Cas9 may help with such efforts.[25]

Organoids are created from stem cells, like iPS cells, and scientists have made advances in developing organoid models of many types of tissues, including the brain, retina, and intestine. However, these models remain incomplete and many others are still in early stages of development. Since organoids are created from stem cells, they also are constrained by limitations in stem cell technology.[26] Some scientists use fetal tissue to compare their stem-cell derived organoids with actual human organ development, in order to assess the adequacy of the new models.[27] Therefore, while iPS cells and organoids may one day replace the need for fetal tissue in certain areas of research, these technologies are still in development and some scientists rely on fetal tissue as a reference material when developing new organoids.

What is human fetal tissue transplantation research?

Human fetal tissue transplantation research is a distinct subtype of human fetal tissue research that explores the clinical use of human fetal tissue as a cellular therapy to replace damaged tissues or cells to treat or cure disease in humans. NIH does not currently fund any clinical research on human fetal tissue transplantation, and has not done so for many years.[28] However, several other entities including private institutions and foreign funders are currently financing human clinical trials for various treatments derived from human fetal tissue.

Since the late 1920s, researchers in several countries, including the United States, "have grafted fetal liver, nerve, thymus and pancreas tissue into children and adults in efforts to reverse various neurological disorders, spinal cord injuries, diabetes, immune deficiencies, cancers and life-threatening blood diseases."[29] Perhaps the most widely known application in the field of human fetal tissue transplantation has been the treatment of Parkinson's disease. The first such attempt, using the transplantation of human fetal brain cells, "took place in 1987 at Lund University in Sweden where the technique was pioneered."[30]

Throughout the late 1980s and 1990s, various entities supported clinical trials using fetal tissue grafts for Parkinson's disease. By 1997, about 200 patients around the world had received the treatment.[31] NIH was the main funder for U.S. trials of fetal tissue therapy for Parkinson's

[24] Grant R. Rowe and George Q. Daley, "Induced Pluripotent Stem Cells in Disease Modelling and Drug Discovery," *Nature Reviews Genetics*, 2019.

[25] Adenkunle Ebenezer Omole and Adegbenro Omotuyi John Fakoya, "Ten Years of Progress and Promise of Induced Pluripotent Stem Cells: Historical Origins, Characteristics, Mechanisms, Limitations, and Potential Applications," *PeerJ*, vol. 6 (2018).

[26] Natalie de Souza, "Organoids," *Nature Methods*, vol. 15, no. 1 (January 2018), p. 23.

[27] Sally Temple and Lawrence S.B. Goldstein, "Why We Need Fetal Tissue Research," *Science*, January 18, 2019, https://science.sciencemag.org/content/363/6424/207.full, and Hans Clevers, "Modeling Development and Disease with Organoids," *Cell*, vol. 165, no. 7 (June 2016), pp. 1586-1597.

[28] Personal Communication with the Department of Health and Human Services, June 10, 2019.

[29] Patricia Donovan, "Funding Restrictions on Fetal Research: The Implications for Science and Health," *Family Planning Perspectives*, vol. 22, no. 5 (September/October 1990), pp. 224-231; and, Dorothy E. Vawter and Arthur Caplan, "Strange Brew: The Politics and Ethics of Fetal Tissue Transplantation Research in the United States," *Journal of Laboratory Clinical Medicine*, vol. 120, no. 1 (July 1992), pp. 30-34.

[30] Allison Abbott, "Fetal-cell revival for Parkinson's," *Nature*, vol. 510 (June 12, 2014), pp. 195-196.

[31] Constance Holden, "Fetal cells again?," *Science*, vol. 326 (October 16, 2009), pp. 358-359.

disease.[32] As stated in a 1997 Government Accountability Office (GAO) report, from 1993 to 1996, NIH awarded over $6 million for five extramural projects involving therapeutic human fetal tissue research, two of which involved actual transplantation of fetal tissue into humans. The other three projects were to clinically observe Parkinson's patients after receiving fetal transplant surgery. The report noted that no intramural projects involving human fetal tissue transplantation had been funded, and no new projects were proposed for the following fiscal year.[33]

The results of these Parkinson's trials showed that some patients benefitted from the treatment, with some having improved to the extent that they were able to discontinue medication. However, some patients experienced a side effect known as dyskinesias, or uncontrolled, involuntary movements, that in rare cases were disabling and required surgery.[34] In addition, some trials found no difference between the treatment and placebo groups.[35] Because many patients did not benefit from the treatment, and it was unclear why this was the case, an international moratorium was imposed in 2003 on such replacement-therapy trials.[36]

Based on analyses of the long-term outcomes of patients who received fetal tissue transplants for Parkinson's and reexamining previous study methodologies, European researchers have decided to break the international moratorium on fetal tissue therapy trials.[37] Currently, a clinical trial—called TRANSEURO, funded by the European Union—involves grafting fetal brain tissue into patients with Parkinson's disease. The trial is ongoing, and as stated in an April 2019 update, a total of 11 patients received grafts in Cambridge, United Kingdom and Lund, Sweden with no further surgeries planned. The trial is estimated to be completed in 2021.[38]

Other recent clinical trials have involved cellular transplantation therapies using stem cells or *progenitor cells* derived from fetal tissue—progenitor cells are a type of fetal cell that is partially, but not fully, specialized as a particular cell type (e.g., a heart cell, brain cell).[39] Recent clinical trials use fetal stem cells or progenitor cells to treat various eye related diseases including age-related macular degeneration and retinitis pigmentosa.[40] Fetal-derived neural (e.g., brain) stem cells have also been used in clinical trials for brain and nervous system-related therapies including for Amyotrophic Lateral Sclerosis (ALS), spinal cord injury, and stroke.[41]

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[32] Constance Holden, "Fetal cells again?," *Science*, vol. 326 (October 16, 2009), pp. 358-359.

[33] U.S. Government Accountability Office, *NIH-Funded Research: Therapeutic Human Fetal Tissue Transplantation Projects Meet Federal Requirements*, GAO/HEHS-97-61, March 1997, https://www.gao.gov/assets/230/223721.pdf.

[34] Olle Lindvall and Anders Bjorklund, "Cell Therapy in Parkinson's Disease," *NeuroRx*, vol. 1 (October 2004), pp. 382-393.

[35] Constance Holden, "Fetal cells again?," *Science*, vol. 326 (October 16, 2009), pp. 358-359.

[36] Abbott, "Fetal-cell revival for Parkinson's," p. 195.

[37] Malin Parmar, Olof Torper, and Janelle Drouin-Ouellet, "Cell-based Therapy for Parkinson's Disease: A Journey Through Decades Towards the Light Side of the Force," *European Journal of Neuroscience*, vol. 49 (February 2019), pp. 463-471.

[38] *ClinicalTrials.gov*, "NCT01898390: TRANSEURO Open Label Transplant Study in Parkinson's Disease (TRANSEURO)," U.S. National Library of Medicine, April, 2019, https://clinicaltrials.gov/ct2/show/NCT01898390.

[39] Austin Smith, "A Glossary for Stem-Cell Biology," *Nature*, vol. 441, no. 1060 (2006), https://www.nature.com/articles/nature04954.

[40] Conor M. Ramsden, Michael B. Powner, and Amanda-Jayne F. Carr, et al., "Stem Cells in Retinal Regeneration: Past, Present and Future," *Development*, vol. 140 (2013); and *ClinicalTrials.gov*, "NCT02320812: Safety of a Single, Intravitreal Injection of Human Retinal Progenitor Cells (jCell) in Retinitis Pigmentosa," U.S. National Library of Medicine, https://clinicaltrials.gov/ct2/show/NCT02320812?term=cells&cond=Retinitis+Pigmentosa&cntry=US&rank=1.

[41] Alan Trounson and Courtney McDonald, "Stem Cell Therapies in Clinical Trials: Progress and Challenges," *Cell*

Though fetal tissue transplantation research is not currently supported by NIH, federal law allows HHS to fund research on new therapies that involve the transplantation of human fetal tissue if certain conditions are met (explained in "Which federal law and regulation governs the collection and use of fetal tissue for research?").

How is fetal tissue acquired for research?

Fetal tissue for research is collected from health care facilities and transferred to laboratories for research purposes, often through an intermediary such as a biotechnology company, a university, or a medical center.

Fetal tissue used in research is mostly obtained from elective (induced) abortions. Though statute (PHSA Section 498A(g))[42] also permits the collection of human fetal tissue from spontaneous abortions (e.g., miscarriages) or stillbirths for subsequent use in federally funded research, these events often occur during unpredictable circumstances where it is difficult to preserve the tissue for research purposes. In addition, the tissue from spontaneous abortions or stillbirths is more likely to have genetic or other abnormalities that preclude its use for research purposes.[43]

There are limited comprehensive studies on how researchers acquire human fetal tissue. In 2000, the Government Accountability Office (GAO) reported findings from a survey on fetal tissue acquisition among researchers, but it has not published another report on the topic since that time.

According to the 2000 GAO report, biomedical researchers at that time obtained human fetal tissue from central tissue suppliers (62%), academic medical center hospitals (31%), and health clinics (30%).[44] Central tissue suppliers identified in the report included entities that had received federal funding, as well as entities that were not federally funded. Three of such suppliers identified as receiving NIH funding included the Birth Defects Laboratory at the University of Washington, the Brain and Tissue Banks for Developmental Disorders at the University of Maryland, and the University of Miami School of Medicine/Children's Hospital of Orange County.[45] Central tissue suppliers that did not receive federal funds included Advanced Bioscience Resources, Inc. (Alameda, CA), and the Albert Einstein College of Medicine Human Tissue Repository (New York, NY). Alternatively, some researchers obtained fetal tissue directly from an academic medical center hospital or a health clinic.[46]

News reports suggest that fetal tissue acquisition practices have changed since 2000. A 2015 *Associated Press* article asserted that nonprofits and university labs used to serve as the primary intermediaries for transferring fetal tissue from health care facilities to scientific laboratories, but

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Stem Cell, vol. 17 (July 2, 2015), pp. 11-19.

[42] 42 U.S.C. §289g-1(g).

[43] Lynn Borgatta, David Kaufman, and Judith Parsells Kelly, et al., "Applications for Research Concerning Fetal or Placental Tissue and Expected Institutional Review Board Responses," *Journal of Empirical Research on Human Research Ethics*, vol. 12, no. 3 (2017), pp. 150-160; and Michelle Andrews, "FAQ: How Does New Trump Fetal Tissue Policy Impact Medical Research?" *Kaiser Health News*, June 7, 2019, https://khn.org/news/faq-how-does-new-trump-fetal-tissue-policy-impact-medical-research/.

[44] Sum is greater than 100% because some researchers had more than one supplier, from U.S. General Accounting Office, *Human Fetal Tissue: Acquisition for Federally Funded Biomedical Research*, GAO-01-65R, October 4, 2000, pp. 4-5.

[45] U.S. General Accounting Office, *Human Fetal Tissue: Acquisition for Federally Funded Biomedical Research*, GAO-01-65R, October 4, 2000, p. 4.

[46] U.S. General Accounting Office, *Human Fetal Tissue: Acquisition for Federally Funded Biomedical Research*, GAO-01-65R, October 4, 2000, pp. 4-5.

since 2010, for-profit companies have increasingly served as intermediaries for fetal tissue acquisition.[47]

A 2015 *New York Times* article explored how private intermediaries (both nonprofit and for-profit), which include StemExpress and Advanced Bioscience Resources Inc., collect the tissue from hospitals and health care facilities, process the tissue for research purposes (such as by isolating specific types of cells or tissues) and then charge laboratories for the cost of the service. Collecting and processing fetal tissue for research is only one component of their services, which involve the processing and development of a range of biological products for research. In the case of StemExpress, "fetal tissue accounted for about 10 percent of the company's business."[48]

According to the July 2019 NIH changes to requirements for extramural research involving human fetal tissue, funding applications for new projects (starting on September 25, 2019)[49] involving human fetal tissue are required to include detailed specifications about the costs, quantity, type, and source of the fetal tissue.[50]

Can fetal tissue be sold for research purposes?

Under the NIH Revitalization Act of 1993, it is "unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."[51] While this provision prohibits the sale or purchase of fetal tissue itself, the term *valuable consideration* "does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."[52] Thus, tissue companies may charge researchers to recover the costs associated with these types of activities.

Persons violating these provisions shall be subject to fines, imprisonment for not more than 10 years, or both.[53] Violations involving the payment of valuable consideration shall result in fines reflecting not less than twice the amount of the valuable consideration received.[54]

Biotechnology companies StemExpress and Advanced Bioscience Resources have reportedly paid small fees, less than $100 or less per specimen, for tissue from abortion providers.[55] The

[47] Carla K. Johnson, "Anti-Abortion Videos Draw Scrutiny to Fetal Tissue Brokers," *Associated Press*, September 16, 2015.

[48] Denise Grady and Nicholas St. Fleur, "Fetal Tissue from Abortions for Research Is Traded in a Gray Zone," *New York Times*, July 2015, https://www.nytimes.com/2015/07/28/health/fetal-tissue-from-abortions-for-research-is-traded-in-a-gray-zone.html.

[49] The new requirements apply to grant applications with due dates on or after September 25, 2019, or submissions for contract solicitations published after September 25, 2019.

[50] NIH, "Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research," NOT-OD-19-128, July 26, 2019, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html.

[51] PHSA §498B(a); 42 U.S.C. §289g-2(a).

[52] PHSA §498B(e)(3); 42 U.S.C. §289g-2(e)(3).

[53] PHSA §498B(d)(1); 42 U.S.C. §289g-2(d)(1).

[54] PHSA §498B(d)(2); 42 U.S.C. §289g-2(d)(2).

[55] Denise Grady and Nicholas St. Fleur, "Fetal Tissue from Abortions for Research Is Traded in a Gray Zone," *New York Times*, July 2015, https://www.nytimes.com/2015/07/28/health/fetal-tissue-from-abortions-for-research-is-traded-in-a-gray-zone.html.

tissue is processed and later sold to researchers at generally higher rates that reflect the processing performed by the companies.[56]

Who investigates the illegal sale of fetal tissue?

On the federal level, the Department of Justice, and more specifically the Federal Bureau of Investigation (FBI), would open investigations into individuals and entities suspected of violating federal law with respect to the illegal sale, or trafficking, of human fetal tissue and other organs. As noted earlier, federal law prohibits the sale or purchase of human fetal tissue in interstate commerce.[57] In 2000, the FBI reportedly investigated a Kansas clinic affiliated with Planned Parenthood for allegedly selling—and profiting from the sale of—fetal tissue; ultimately, no laws were found to have been broken.[58] In 2017, the Department of Justice (DOJ) reportedly requested Senate Judiciary Committee documents from a 2016 committee investigation on fetal tissue exchange,[59] but reports do not indicate whether DOJ took formal legal action in this instance.

Which federal law and regulation governs the collection and use of fetal tissue for research?

Federal law and regulation govern the conduct of federally funded research transplanting human fetal tissue specifically; the participation of human research subjects in any human fetal tissue research (i.e., the recipient of a human fetal tissue transplant); and the privacy and confidentiality of individually identifiable protected health information to the extent that it is generated in the course of human fetal tissue research.

Federal law specifies the conditions under which the Department of Health and Human Services (HHS) can fund *research on new therapies that involve the transplantation of human fetal tissue* using tissue derived from an elective or spontaneous abortion, or from a stillbirth (PHSA Section 498A).[60] HHS does not currently fund research on therapeutic fetal tissue transplantation and has not done so for many years.[61] According to federal law, human fetal tissue may be used in federally funded research involving fetal tissue for therapeutic transplantation only if the following conditions are met:

- The woman must provide her written consent that she is donating the fetal tissue for research, that the donation is being made without any restrictions on who may receive the tissue, and that she has not been informed of the identity of any such recipients.[62]
- The attending physician must declare in writing that, in the case of an induced abortion (1) the woman's consent for the abortion was obtained prior to requesting or

[56] Ibid.

[57] PHSA §498B; 42 U.S.C. §289g-2(a).

[58] Sandhya Somashekhar and Danielle Paquette, "Undercover video shows Planned Parenthood Official Discussing Fetal Organs Used for Research," *The Washington Post*, July 14, 2015.

[59] Nicholas Fandos, "Justice Dept. Investigating Fetal Transfers by Planned Parenthood and Others," *The New York Times*, December 8, 2017.

[60] PHSA §498A(a); 42 U.S.C. §289g–1(a).

[61] Personal Communication with the Department of Health and Human Services, June 10, 2019.

[62] PHSA §498A(b)(1); 42 U.S.C. §289g–1(b)(1).

obtaining consent to donate the fetal tissue for research; (2) the timing, method, or procedures used to terminate the pregnancy were not altered in order to obtain the tissue; and (3) the abortion was performed in accordance with applicable state law. In addition, the attending physician must declare that the tissue has been donated with the woman's consent and that the woman has been fully informed of the physician's interest, if any, in the research, and of any medical or privacy risks associated with the tissue donation.[63]

- The principal researcher must declare in writing that (1) he or she is aware that the tissue is human fetal tissue that may have been obtained from an elective or spontaneous abortion, or a stillbirth, and that it was donated for the purposes of research; and (2) prior to obtaining the informed consent of a research subject to be a recipient of the transplanted tissue (see discussion of Common Rule, below), he or she will provide the same information about the fetal tissue to the research subject and get written acknowledgement of receipt of such information.[64]

In addition to the above statutory requirements, fetal tissue research that involves human subjects is subject to the Common Rule.[65] In human fetal tissue transplantation research, the transplant recipient would always be a human research subject. In certain cases only, the donor or living relatives of the donor of the human fetal tissue in human fetal tissue research may also be considered human research subjects for purposes of federal regulation. Under the Common Rule, research protocols involving human research subjects typically must be approved by an Institutional Review Board (IRB) to ensure that the rights and welfare of the research subjects are protected.[66]

The Common Rule lists several criteria for IRB approval, including the requirement that researchers obtain the informed consent of their research subjects.[67] In addition, it sets out the types of information that must be provided to prospective research subjects during the informed consent process, for example, an explanation of the purpose of the research, a description of the research procedures, and a description of the risks and potential benefits of the research.[68] An IRB may decide to waive the informed consent requirement if it determines that (1) the research poses no more than minimal risk to the subjects, (2) the waiver will not adversely affect the rights and welfare of the subjects, and (3) the research is not practicable without a waiver, among other things.[69]

If the human fetal tissue to be used in the research is identifiable, such that information associated with the material links it to one or more living individuals (which often may be the case), then those individuals also become research subjects under the Common Rule.[70] Thus, an IRB may

[63] PHSA §498A(b)(2); 42 U.S.C. §289g–1(b)(2).

[64] PHSA §498A(c); 42 U.S.C. §289g–1(c).

[65] The Common Rule is the informal name given to core federal regulations governing the protection of human subjects in research supported or conducted by most agencies of the federal government. The regulations were first promulgated by HHS at 45 C.F.R. Part 46, Subpart A.

[66] 45 C.F.R. §46.109.

[67] 45 C.F.R. §46.111(a)(4).

[68] 45 C.F.R. §46.116(b).

[69] 45 C.F.R. §46.116(f).

[70] 45 C.F.R. §46.206.

have to review the protocol for collecting and testing the human fetal tissue, and the woman who is donating the tissue may have to provide informed consent (unless waived by the IRB).[71]

The researchers may also be required to obtain authorization from the Food and Drug Administration (FDA) by filing an Investigational New Drug (IND) application. An IND would be required if, for example, the research is testing a new diagnostic or therapeutic intervention in human clinical trials for the purposes of obtaining FDA marketing approval (see "What federal law and regulation governs the clinical use of fetal tissue?"). One of the IND requirements is that the researchers obtain IRB approval.

Importantly, if the purpose of the human fetal tissue research is solely to acquire new biomedical knowledge, and it is not being conducted under an IND or involving human research subjects, then the research is not subject to the Common Rule or FDA regulation.

Finally, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule applies if the researchers want access to individually identifiable protected health information about the woman from whose fetus the fetal tissue was obtained.[72] Under the Privacy Rule, an individual's protected health information may not be used or disclosed for research without the individual's written authorization unless an IRB (or equivalent Privacy Board) waives the authorization based on certain specified criteria.[73]

Who monitors researcher compliance with laws and regulations governing fetal tissue research?

When research is conducted in an *intramural,* or federal laboratory, that federal agency has direct responsibility for ensuring that research complies with relevant laws and regulations. For *extramural* research conducted through grants or contracts awarded to universities or other research institutions, the awardee institution is primarily responsible for ensuring compliance. NIH extramural grants are awarded to institutions, not directly to researchers. Institutions share responsibility for oversight of researchers along with the NIH.[74]

Federal agencies and federally funded institutions have Institutional Review Boards that review research protocols involving human subjects and are to ensure compliance with relevant laws and regulations (particularly the Common Rule). The HHS Office for Human Research Protections (OHRP) is the main office responsible for registering IRBs at HHS agencies and other HHS-funded institutions.[75] Most other federal agencies have codified versions of the Common Rule (42 C.F.R. Part 46) in separate regulations, and have their own agency policies and procedures regarding the protection of human subjects and IRB registration.[76] IRBs are required at all institutions conducting federally funded research. They are to approve research projects before

[71] 45 C.F.R. §46.204 specifies that in research involving pregnant women, among other things, "No inducements, monetary or otherwise, will be offered to terminate a pregnancy," and "Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy."

[72] 45 C.F.R. Part 164, Subpart E.

[73] 45 C.F.R. §164.512(i).

[74] CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*.

[75] HHS, "Office for Human Research Protections: History," https://www.hhs.gov/ohrp/about-ohrp/history/index.html.

[76] HHS, "45 C.F.R. 46 FAQs," https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/45-cfr-46/index.html.

they begin, and conduct periodic reviews to ensure compliance with laws and regulations regarding the protection of human subjects.

When an extramural researcher submits an application for an NIH grant involving human fetal tissue, the authorized organization representative's signature on the application is meant to certify that the institution will ensure compliance with laws and regulations in acquiring fetal tissue for research.[77] The NIH Division of Grants Compliance and Oversight in its Office of Extramural Research conducts compliance site visits and targeted site reviews to ensure that institutions understand and properly comply with relevant laws, regulations, and NIH requirements.[78]

The July 2019 NIH Notice added new reporting requirements for extramural research involving human fetal tissue, specifically human fetal tissue derived from elective abortions only. The notice further specifies that human fetal tissue subject to the new requirements includes the following:

- "human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.
- animal models incorporating HFT [human fetal tissue] 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."[79]

As stated in the notice, the requirements do not apply to research involving human fetal tissue or derivative products that are not obtained from elective abortions; human fetal cell lines established as of June 5, 2019; human fetal cells present in maternal blood or other maternal sources; and embryonic stem cells or embryonic cell lines, among other exclusions.[80] According to NIH, these requirements are designed to ensure researchers' compliance with all applicable laws, regulations, and policies regarding the use of human fetal tissue in research. Applicants for new projects (starting September 25, 2019)[81] involving fetal tissue must provide detailed budgets and plans for the costs, quantity, and source of human fetal tissue to be used in research; certification that valuable consideration has not been provided for acquisition of the fetal tissue; as well as detailed information of how informed consent was obtained at the time of fetal tissue collection, including an example of the IRB-approved consent form used.[82]

HHS OHRP also conducts oversight of HHS-funded researchers through surveillance activities, and investigating complaints about human subject protections in HHS-funded research. OHRP

[77] NIH, "4.1.14 Human Fetal Tissue Research," *NIH Grants Policy Statement,* October 2018, https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.14_human_fetal_tissue_research.htm.

[78] NIH, "Grants Compliance and Oversight," 2019, https://grants.nih.gov/policy/compliance.htm#activities.

[79] NIH, "Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research," NOT-OD-19-128, July 26, 2019, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html.

[80] Ibid.

[81] The new requirements apply to grant applications with due dates on or after September 25, 2019, or submissions for contract solicitations published after September 25, 2019.

[82] NIH, "Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research," NOT-OD-19-128, July 26, 2019, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html.

also promotes compliance through issuing guidance and education for institutions conducting research.[83]

What federal law and regulation governs the clinical use of fetal tissue?

Currently, fetal tissue is not being used in any clinical applications involving transplantation. Any such therapeutic use of human fetal tissue would be regulated by FDA's Center for Biologics Evaluation and Research (CBER) as an HCT/P, which stands for human cells, tissues, and cellular and tissue-based products. FDA regulations define an HCT/P as an article "containing or consisting of human cells and tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient."[84] HCT/Ps include bone, ligament, skin, dura mater, heart valves, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, and semen or other reproductive tissue.[85] Notably, the regulations do not specifically refer to human fetal tissue.

FDA regulates HCT/Ps primarily under its general authority to control the spread of communicable diseases in PHSA Section 361.[86] This authority allows FDA to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases.[87] FDA regulations governing HCT/Ps issued pursuant to this authority are codified in 21 C.F.R. Part 1271.

The HCT/P regulations are focused on (1) preventing the use of contaminated cells and tissues with the potential for transmitting infectious diseases; (2) preventing the improper handling or processing of cells and tissues that might contaminate or damage them; and (3) ensuring the clinical safety and effectiveness of cells and tissues. HCT/Ps that meet the requirements in 21 C.F.R. Part 1271 are not required to undergo FDA's premarket review process.[88] This is in contrast to other therapeutic products regulated by FDA (e.g., drugs, medical devices, and biological products), which generally must obtain approval, clearance, or licensure prior to marketing.[89]

[83] HHS OHRP, "45 C.F.R. 46 FAQs," https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/45-cfr-46/index.html.

[84] 21 C.F.R. §1271.3.

[85] Ibid. HCT/Ps do not include vascularized human organs for transplantation, which are regulated by the Health Resources and Services Administration (HRSA). Nor do they include plasma and blood or derivative products regulated by FDA under 21 C.F.R. Parts 606, 607, 630, and 640.

[86] 42 U.S.C. §264.

[87] PHSA §361; 42 U.S.C. §264. PHSA §361(a) authorizes the Surgeon General, with the approval of the HHS Secretary, to promulgate such regulations. This authority was delegated to FDA (see section titled "Legal Authority," 66 *Federal Register* 5449, January 19, 2001).

[88] 21 C.F.R. §1271.10.

[89] Drugs and medical devices are approved or cleared by FDA under Title V of the Federal Food, Drug, and Cosmetic Act (FFDCA). With some exceptions, biological products or biologics—medicines derived from living organisms—are licensed by FDA under Section 351 of the Public Health Service Act.

The regulations at 21 C.F.R. Part 1271 require establishments that manufacture[90] HCT/Ps for clinical purposes to register with FDA and submit a list of their products.[91] The regulations also establish eligibility criteria for donors of HCT/Ps, including donor screening and testing,[92] and set forth good tissue practices (GTPs) that govern the methods, facilities, and controls used for "the manufacture of HCT/Ps, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution."[93] The GTPs address personnel, procedures, environmental control and monitoring, equipment, supplies and reagents, recovery, processing and process controls, storage, shipment and distribution, records, tracking, and complaints.

There are exceptions from the requirements of 21 C.F.R. Part 1271, including establishments that use HCT/Ps solely for nonclinical scientific or educational purposes, or that remove HCT/Ps from an individual and implant such HCT/Ps into the same individual during the same surgical procedure.[94] An HCT/P that does not meet the criteria specified in 21 C.F.R. 1271.10 or the exceptions in 21 C.F.R. 1271.15 would be regulated as a drug, device, and/or biological product under the Federal Food, Drug, and Cosmetic Act (FFDCA) and/or Section 351 of the PHSA and would be subject to premarket approval, clearance, or licensure.[95]

Is the system for collecting nonfetal organs and tissue different from that for fetal tissue?

Yes. The federal government has established policies and a system for procuring organs for therapeutic transplantation that are separate from policies for the acquisition of fetal tissue. However, consent for organ and tissue donation for therapeutic, research, and other purposes is regulated at the state level, and in some states, such laws apply to human fetal tissue.

Organs are procured (or acquired) from living persons or cadavers. The National Organ Transplant Act (NOTA of 1984; P.L. 98-507, as amended)[96] provides authority for the Organ Procurement and Transplantation Network (OPTN), which is the federally supported system for organ sharing in the United States. HHS's Health Resources and Services Administration (HRSA) oversees organ procurement and transplantation through administration of the contract for the OPTN. Fetal tissue is not currently used for therapeutic transplantation.

An organ as defined by NOTA for the purpose of procurement and transplantation is "[a] human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small or large intestine, or any portion of the gastrointestinal tract), or vascularized composite allograft."[97] This definition does not explicitly include fetal organs. However, the definition of an organ in Section

[90] "*Manufacture* means, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor" 21 C.F.R. 1271.3(e).

[91] 21 C.F.R. Part 1271, Subpart B.

[92] 21 C.F.R. Part 1271, Subpart C.

[93] 21 C.F.R. Part 1271, Subpart D.

[94] These and additional exceptions are specified in 21 C.F.R. §1271.15.

[95] 21 C.F.R. §1271.20. See also, FDA Guidance for Industry and [FDA] Staff, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use*, December 2017, https://www.fda.gov/media/124138/download.

[96] PHSA Title III, Part H; 42 U.S.C. §§273-274g.

[97] 42 C.F.R. §121.2.

301 of the NOTA, which prohibits the purchase of organs, does explicitly include fetal organs and any subpart of an organ derived from a fetus.[98]

Consent for organ and tissue donation for therapeutic, research, and other purposes is regulated at the state level. All 50 states and the District of Columbia have enacted versions of model legislation referred to as the Uniform Anatomical Gift Act (UAGA) to create a regulatory framework for organ and tissue donation.[99] The UAGA, as adopted by some states, includes "fetus" in the definition of a deceased individual whose body or part is or may be the source of an anatomical gift.[100] The purpose of including "fetus" in this definition is to afford the statutory protections conferred by the UAGA (specifically the need for appropriate consent for donation) to fetuses as to other decedents.[101]

Does the Department of Veterans Affairs (VA) allow the use of human fetal tissue in research conducted by VA researchers?

The Veterans Health Administration (VHA) of the VA generally permits "research in which the focus is either a fetus, either in-utero or ex-utero ... [to be] conducted by VA [researchers] while on official VA duty, at VA facilities, or at VA-approved off-site facilities."[102] However, VHA follows the same policies on the use of human fetal tissue, and human stem cells set by NIH for recipients of NIH research funding.[103] Therefore, the research conducted by VA researchers while on official VA duty, at VA facilities, or at VA-approved off-site facilities would need to align with NIH policies. According to VHA, VA researchers cannot conduct "research involving the creation of a human embryo or embryos solely for research purposes or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death"[104] greater than those currently permitted by federal regulations that govern the collection and use of fetal tissue for research and the Common Rule.[105] VA is a signatory to the Common Rule (Title 38 C.F.R. Part 16).

[98] 42 U.S.C. §274e(c)(1).

[99] The Uniform Law Commission, which drafted the Uniform Anatomical Gift Act, is a nonprofit organization, comprised of state commissions on uniform laws from each state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. The purpose of the Uniform Law Commission is to study and review the law of the states to determine which areas of law should be uniform. The Commission proposes uniform legislation which states can choose to adopt. The Uniform Anatomical Gift Act is one such example of a uniform law that was adopted, in some form, by all states.

[100] An anatomical gift as defined in the Uniform Anatomical Gift Act is "a donation of all or part of a human body to take effect after the donor's death for the purpose of transplantation, therapy, research, or education."

[101] National Conference of Commissioners of Uniform State Laws, *Revised Uniform Anatomical Gift Act (2006)*, 2009, p. 14, https://www.uniformlaws.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=6705441e-40b7-fbd4-edd5-5748c63fbd79&forceDialog=0.

[102] Department of Veterans Affairs, Veterans Health Administration, "Requirements for the Protection of Human Subjects in Research," VHA DIRECTIVE 1200.05, January 7, 2019, p. 37.

[103] Ibid. Following the Administration's directive to NIH to place a hold on the funding and conducting of fetal tissue research, and following NIH policy, no fetal tissue research has been funded by the VHA since December 2018 (personal communication with VA Office of Congressional and Legislative Affairs, May 2019).

[104] Ibid.

[105] PHSA §498A(a); 42 U.S.C. §289g–1(a) and 45 C.F.R. §46.206.

Does the Department of Defense use fetal tissue in medical research?

Currently, DOD funds extramural medical research utilizing fetal tissue.[106] There are no statutory or regulatory prohibitions on the Department of Defense (DOD) for using fetal tissue in medical research. However, DOD policy requires any research using fetal tissue to (1) "comply with sections 289g–289g-2" of title 42, *United States Code*[107]; (2) undergo an *administrative review* prior to commencing research activities; and (3) be approved by the appropriate DOD component.[108] DOD is a signatory to the Common Rule (Title 32 C.F.R. Part 219).

Does the Food and Drug Administration (FDA) use fetal tissue in research?

FDA has used fetal tissue to create humanized mice for research, including for investigating the immune response or immune-related adverse events that result from new drugs (such as new immunotherapies or biosimilar products), and to evaluate the immune response from experimental Ebola vaccines.[109] The agency has reportedly had contracts with Advanced Biosciences Resources, Inc. (ABR) for fetal tissue acquisition since 2009.[110] In September 2018, HHS terminated the ABR contract with FDA, stating, "HHS was not sufficiently assured that the contract included the appropriate protections applicable to fetal tissue research or met all other procurement requirements."[111] As communicated to CRS, "Since the canceling of the contract in September 2018, FDA has not acquired new human fetal tissue or engaged in research that would require new acquisition of human fetal tissue. In compliance with applicable requirements, FDA has continued to pursue those aspects of this research that do not require the acquisition of new human fetal tissue."[112] FDA has ongoing research (through an agreement with Johns Hopkins University) to create a new nonfetal tissue humanized mouse model to replace the fetal tissue model for drug testing.[113]

An FDA staff manual guide includes guidelines and responsibilities for research involving human fetal tissue. Among other things, the guide provides that FDA researchers who seek to conduct research involving human fetal tissue must describe the research in an application to FDA's

[106] *Extramural medical research* are projects funded by DOD, but performed by non-DOD research entities (e.g., academic institutions, medical centers, and research laboratories).

[107] PHSA §§498-498B.

[108] Department of Defense Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research," updated October 15, 2018, https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf?ver=2018-10-30-073713-903. DOD policy describes an *administrative review* as a process to ensure the institution engaged in research "has met the requirements of all applicable regulations and policies."

[109] Personal communication with FDA Office of Legislation, August 6, 2019.

[110] Jennifer Haberkorn and Brett Norman, "NIH, FDA Tied to Fetal-Tissue Firm," *Politico*, August 6, 2015, https://www.politico.com/story/2015/08/fetal-tissue-firm-has-federal-contracts-121066.

[111] HHS, "Statement from the Department of Health and Human Services", press release, September 24, 2018, https://www.hhs.gov/about/news/2018/09/24/statement-from-the-department-of-health-and-human-services.html.

[112] Personal communication with FDA Office of Legislation, August 6, 2019.

[113] Ibid.

Institutional Biosafety Committee for review, and submit an attestation form that they will comply with relevant legal and policy requirements.[114]

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[114] FDA, "Staff Manual Guide, Agency Program Directives, Volume IV, 9001.3: Research Involving Human Fetal Tissue," February 11, 2016, https://www.fda.gov/about-fda/staff-manual-guides/agency-program-directives-volume-iv-4000-9100.