FAQs on Fetal Tissue Research

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What is fetal tissue research?

Fetal tissue is derived from legal abortions that would otherwise be disposed. Fetal tissue donation is voluntary; donors sign informed consent forms in advance of the donation. Once donated, the tissue is used for biomedical research into fundamental biological processes and human development. In addition, researchers use fetal tissue to study potential treatment of life-threatening diseases.

Is fetal tissue research legal?

Fetal tissue research is legal in the United States. Scientists have used fetal tissue in research since the 1930s. In 1975, federal law was clarified to say such research is permitted if "conducted only in accordance with any applicable State or local laws regarding such activities (45 CFR 46, Sec. 210). In addition, the law states that fetal tissue can only be used for "the development of important biomedical knowledge which cannot be obtained by other means" (45 CFR 46, Sec. 209).

In 1993, Congress passed the U.S. National Institutes of Health Revitalization Act (P.L. 103-43) formalizing President Bill Clinton's lifting of the 1988 moratorium on federal funding for fetal tissue transplantation research. This legislation made it unlawful for any person to knowingly acquire, receive or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.[1] Valuable consideration is not defined but it is generally agreed that it means profiting from the sale of fetal tissue.

Why is fetal tissue research important?

Fetal cells hold unique promise for biomedical research due to their ability to rapidly divide, grow, and adapt to new environments. This makes fetal tissue research relevant to a wide variety of diseases and medical conditions.

Infectious Diseases

Cell lines derived from fetal tissue have been instrumental in the development of vaccines for the following diseases: measles, mumps, rubella, chicken pox, polio, hepatitis A, rabies, shingles, and adenovirus (for military personnel).

[1] http://www.hhs.gov/ohrp/regulations-and-policy/guidance/public-law-103-43/index.html

Currently, fetal tissue is being used in the development and testing of vaccines and for possible treatments for infectious diseases including HIV/AIDS, influenza, dengue fever, and hepatitis B and C.

Fetal tissue is vital for research into viruses that infect *only* human cells and in particular *only* specific types of human brain cells. It serves a critical role in this area of scientific study because alternative methods of studying these viruses in the lab do not currently exist. Examples include:

- How HIV and Parkinson's disease affect the brain.
- The elimination of HIV from its reservoir in the brain.
- Increased understanding of JC, or John Cunningham, virus which causes progressive multifocal leukoencephalopathy (PML), a rare and usually fatal viral disease characterized by progressive damage or inflammation of the brain. PML is normally a rare disease but is more common in people with diseases resulting in compromised immune systems, including AIDS, multiple sclerosis, Crohn's disease, and rheumatoid arthritis.

Neurodevelopment

The use of fetal-derived cells is vital to answering specific scientific questions that cannot be answered using alternative methods alone. Intact tissue contains information about cell structure and brain architecture that cells grown in a lab cannot provide. Fetal tissue is often used as a reference standard to help in the identification of properties of other cells which are the focus of study. In addition, it is critical to understand typical cellular development in order to have a clearer understanding of atypical development.

Research using fetal tissue has been critical in advancing the understanding of gene expression (when particular genes are turned on and turned off) during brain development. Understanding the location and time when a particular gene is turned on can help researchers understand how genes are disrupted in mental illness. Understanding when genes are turned on and off has revealed information that could not be discovered by studying the adult brain.

Premature infants often show a delay in neurodevelopment, particularly a slow development of the cerebral cortex, a critical portion of the brain which plays a key role in memory, attention, perception, awareness, thought, language, and consciousness. Using fetal brain tissue, researchers have discovered that the production of new brain cells, which normally continues in the third trimester, is halted by premature birth. With this knowledge, researchers are making progress in the development of a drug strategy that mimics the *in utero* environment and may lead to the development of critical treatments for premature infants.

Research funded by the U.S. National Institutes of Health (NIH) is currently examining changes in gene expression, epigenetic variations, and genomic alterations across regions of the brain. This research will provide crucial insights into the molecular underpinnings of autism spectrum disorders (ASD).

Vision-Related Disease

The study of human retinal degeneration heavily depends on the use of human fetal retinal pigment epithelium (RPE) tissue. Damage or loss of RPE tissue in adults can lead to age-related macular degeneration, the leading cause of blindness in the United States.

Herpes Simplex virus can have serious implications for the cornea of the eye, causing scarring and sometimes blindness. Researchers are using fetal tissue to better understand the virus in the hopes of being able to treat this problem.

Research using fetal tissue is critical for understanding nearsightedness and learning more about how the eye develops.

Liver Disease

Researchers supported by the NIH are using human adult and fetal liver cells to understand diseases of the liver, such as drug-induced liver disease and viral hepatitis. Using a mouse model, scientists have been able to transplant cells with properties similar to human fetal liver cells into mice suffering from acute liver failure. The transplanted liver cells showed signs of the recovery of some liver function in the mice.

Clinical Trials for Neurodegenerative Diseases

Transplantation of neural stem cells derived from fetal tissues is currently being tested as a therapy for a variety of neurodegenerative diseases that do not have any other effective therapies. Clinical trials transplanting fetal derived neural stem cells are ongoing for people with Amyotrophic Lateral Sclerosis (ALS), a fatal neurodegenerative disease, spinal cord injury, stroke, age related macular degeneration, and other diseases affecting the brain. These fetal derived cells are also being tested in the laboratory to potentially begin clinical trials for Alzheimer's disease, Parkinson's disease, multiple sclerosis and traumatic brain injury. Fetal tissue derived neural stem cells are critical for modeling diseases of the brain in the laboratory and are used to test drugs that could be used as treatments for neurodegenerative diseases.

Other Areas of Research

Researchers are also using fetal tissue to:

- Develop new drugs to prevent cognitive deficits that often accompany Down's syndrome.
- Better understand aneuploidy, which is the leading cause of pregnancy loss and congenital birth defects.
- Increase understanding the immune system of the mother and fetus, including an examination of what takes place during the third trimester as the fetal immune system is transitioning to an adult-like immune system.
- Better understand Early Pregnancy Failure (EPF), which causes more than one million fetal deaths each year in the United States.