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# **Ethical Research Involving Fetal Human Subjects**

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**ABSTRACT:** Fetal tissue research refers to research using several types of tissue, including but not limited to samples obtained from aborted fetuses, cell lines derived from aborted fetuses, and in rarer cases, living pre-viable neonates who have survived an abortion attempt. The ethical questions surrounding each type of tissue procurement are not identical, but do share similarities.

This guideline on fetal tissue research discusses the moral status of the human fetus, the state of ethics for medical research on vulnerable subjects, aspects of medical research using human fetal tissue, and the necessity of including fetuses as a protected class under vulnerable populations in research. The debates connected to embryo stem cell research and other research related to embryos are beyond the scope of this document.

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## **Background**

The embryonic period and the fetal developmental period are divided by the eighth week after fertilization (ten gestational weeks). The first eight weeks after conception are focused on the basic differentiation of organ systems whereas the fetal period of about thirty weeks is focused on organ development to adapt to extrauterine life. Human fetal tissue research is regarded by some of the scientific community as cornerstone to medical advances, due to the unique properties of fetal tissue, such as the capacity to give rise to human cell lines. Similar to all research on human subjects, fetal tissue research involves important ethical principles and a knowledge of the historical development of ethical safeguards. Research in human subjects has produced substantial clinical and social benefits

throughout history, especially after its expansion in the late 19th century. The aspirations of ethical research are noble, as described by the French physiologist Claude Bernard: “The principle of medical and surgical morality consists in never performing on a man an experiment that might be harmful to him to any extent, even though the result might be highly advantageous to science.”<sup>1</sup> Unfortunately, this primary goal of medical research has failed to consistently adhere to this original aspiration.<sup>2</sup>

The history of medical research involving human subjects involves ample instances of ethically questionable or blatantly unethical research, most notably during and after the Second World War. Ethical guidelines were then established to ensure human subjects are selected and treated according to ethical and moral standards that would guarantee their safety and well-being. The Code of Nuremberg<sup>3</sup> and the Declaration of Helsinki<sup>4</sup> are the two oldest documents securing patients’ medical research rights. The first document established the basic ethical principles that should be followed to promote and ensure respect for all human subjects and protect their health and rights. While the second is an authoritative guideline that stated that no national, ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects outlined earlier in the Declaration.<sup>5</sup>

The challenge for human subject researchers is to continue to conduct their work while remaining faithful to foundational principles of ethics, justice, and human rights. Despite the substantial progress in safeguards and protections, one group of human subjects has been left on the fringes: humans in their first stages of development.

## The Moral Status of the Fetus

Discussions on medical research on fetal tissue must first determine whether a human fetus has moral status as a human organism, thereby requiring similar ethical obligations as toward any other human subject. “Moral status” ascribes equal obligations and rights based on membership in a protected group. Such status can be applied not only to living beings but also to cadavers and cemeteries which reveal the moral standing due to law, ethics, and duties

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<sup>1</sup> Jones DS, Grady C, Lederer SE. “Ethics and Clinical Research” — The 50th Anniversary of Beecher’s Bombshell. *N Engl J Med*. 2016;374(24):2393-2398. doi:10.1056/nejmms1603756

<sup>2</sup> Snead OC. What is Public Bioethics? History and Human Context. In: *What It Means to Be Human*. 2020:15.

<sup>3</sup> Shuster E. Fifty Years Later: The Significance of the Nuremberg Code. *N Engl J Med*. 1997;337(20):1436-1440. doi:10.1056/nejm199711133372006

<sup>4</sup> World Medical Association Declaration of Helsinki. *JAMA*. 2013;310(20):2191. doi:10.1001/jama.2013.281053

<sup>5</sup> Axelin A, Salanterä S. Ethics in Neonatal Pain Research. *Nurs Ethics*. 2008;15(4):492-499. doi:10.1177/0969733007086017

of respect.<sup>6</sup> Moral status in the case of human fetuses continues to be debated with regard to research and abortion and the history and some principles are outlined below.

Michael Tooley and Mary Anne Warren proposed a view of reality called *body-self dualism* in the 1980s. This argument proposes that biology alone does not confer moral status to a human being and personhood is acquired with consciousness, concluding that human fetuses should not be considered a person and therefore do not have moral status and the right to life.<sup>7,8</sup> This argument was buttressed by Alberto Giubilini and Francesca Minerva, who also deny moral status to newborns because they lack the properties that justify an individual's right to life.<sup>9</sup> These arguments are based on arbitrary limits that define personhood, including the physical development of a heartbeat, developmental milestones like the ability to feel pain, or the development of consciousness, such that being deprived of life would represent a loss to oneself. This utilitarian argument has permeated legislation regarding abortion and the legal framework of the last 50 years.

The dualistic and utilitarian view of fetuses as non-persons without a moral claim to life is countered by an argument based on embryology. This view claims that human fetuses are simply human beings at different degrees of maturation in their species-specific developmental trajectory.<sup>10</sup> Robert George and Christopher Tollefsen support this position that all persons are *human animals*, therefore from the moment of sperm-egg fusion within fertilization, a new human being begins existing with personhood and all the rights and dignity associated with it.<sup>11</sup> The same moral status would be conferred to all members of the human species in any stage of development because they share the same nature. *Nature* for George and Tollefsen resembled a traditional Aristotelian understanding: nature is an intrinsic, species-specific *cause* for an organism's behavior including its development, capabilities, and higher order mental capacities, like consciousness, rationality and goal-seeking. Thus, even though human fetuses do not share the same capabilities or higher behaviors as adult humans due to their developmental stage, they share the same nature and essential orientation as members of the same species, whereas other ani-

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<sup>6</sup> Annas GJ. The Politics of Human-Embryo Research – Avoiding Ethical Gridlock. *N Engl J Med*. 1996;334(20):1329-1332. doi:10.1056/nejm199605163342012

<sup>7</sup> Tooley M. Abortion and Infanticide. 1974;52-84. doi:10.1515/9780691233161-004

<sup>8</sup> Warren MA. On the Moral and Legal Status of Abortion. 1973;57(1):43-61. doi:10.5840/mo-nist197357133

<sup>9</sup> Giubilini A, Minerva F. After-birth abortion: why should the baby live? *J Med Ethics*. 2013;39(5):261-263. doi:10.1136/medethics-2011-100411

<sup>10</sup> George RP, Lee P. Embryonic human persons. *EMBO Rep*. 2009;10(4):301-306. doi:10.1038/embor.2009.42

<sup>11</sup> George RP, Tollefsen C. *Embryo: A Defense of Human Life*. Doubleday; 2008.

mal fetuses do not have the same developmental trajectory, despite being at the same developmental stage.

The embryological basis supporting moral status for embryos is as follows: at fertilization, when a sperm cell unites with an ovum, the two gametes cease to be, and a zygote is formed in its original one-celled stage. The zygote begins to grow by differentiated cell division into an embryo, including all its genetic and epigenetic constitution.<sup>12</sup> From the zygote stage onwards, this new human organism proceeds in a continuum of regular, predictable, and coordinated bodily development, progressing invariably towards the mature stage of human development, if not deprived of suitable external circumstances. Even in the beginning of an embryo's life, what exists is not a mere bundle of homogeneous cells; rather, gene expression already differs at the two-cell stage, even more so at the four-cell stage and so on.<sup>13,14</sup> Unlike gametes, which die if they do not fuse, every stage of embryonic and fetal differentiation is oriented toward holistic growth and development of these predetermined human capacities. Thus, each human embryo and fetus is a living human organism, doing exactly what he or she is meant to do at his or her particular stage of life. In fact, the same can be said of infant development, child and adolescent development, even adult development. There is no point in time at which a human being is any more or less of a human being based on developmental milestones.

While embryology cannot answer philosophical or ethical questions, it does support the moral status of human beings in earliest stages of development and inform the ethical debate of research in fetal tissue. If a human embryo or fetus is categorically a human being, it raises the question of whether it is just to kill or perform medical experimentation on such human subjects, when there is no proportionate medical benefit to the subject.

## The State of Ethics for Medical Research

The history of bioethics in general, and American bioethics specifically, is marked by a succession of political and legal reactions to the reported abuse and exploitation of the weakest and most vulnerable members of the human population, beginning with the practice of research in human subjects.

In studying the gross abuses committed during the Second World War and exposed during the Nuremberg Trial, Henry Beecher, a Harvard professor

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<sup>12</sup> Zernicka-Goetz M. Patterning of the embryo: the first spatial decisions in the life of a mouse. 2002;129(4):815-829. doi:10.1242/dev.129.4.815

<sup>13</sup> Zimmermann JW, Schultz RM. Analysis of gene expression in the preimplantation mouse embryo: use of mRNA differential display. *Proc Natl Acad Sci USA*. 1994;91(12):5456-5460. doi:10.1073/pnas.91.12.5456

<sup>14</sup> Memili E, First NL. Zygotic and embryonic gene expression in cow: a review of timing and mechanisms of early gene expression as compared with other species. *Zygote*. 2000;8(1):87-96. doi:10.1017/s0967199400000861

of Anesthesiology and clinical researcher, was the pioneer in identifying the lack of protection for human subjects in the United States. His findings, published in the landmark article “Ethics and Clinical Research,”<sup>15</sup> demonstrated that “unethical or questionably ethical procedures are not uncommon.” He cited twenty-two published research papers in which human subjects received no therapeutic benefits. Most studies did not mention consent, most subjects were not aware they were being studied and many were members of vulnerable populations (e.g., soldiers, indigent patients, prisoners, institutionalized children with severe intellectual disabilities, the elderly, and the terminally ill). Even though his assessment concluded with a positive assurance about the state of the medical field in America and his proposals for change were modest, the article shocked the medical community and the public.

As a result of Beecher’s study, accompanied soon after by the Tuskegee syphilis study scandal and the public outrage it caused, American research for human subjects entered a new era, characterized by ample intervention of Congress and the Federal government. Federal law<sup>16</sup> defines human subjects research as a systematic investigation designed to develop or contribute to generalized knowledge. By its own logic, the primary goal is not to care for or cure said subjects but to acquire understanding from observation or intervention. This framework challenges researchers to reconcile the need for medical advances with the foundational principles of medical ethics and human rights.

The four ethical principles originally laid out by Thomas Beauchamp and James Childress are beneficence, nonmaleficence, autonomy, and justice.<sup>17</sup> The principle of beneficence is the obligation to treat human subjects ethically by respecting their autonomous decisions and protecting them from harm. Medical research should ultimately be oriented towards the good of patients. In distinction to nonmaleficence, this principle is one of positive requirements, meaning that the research team has an active duty to benefit subjects when possible. In contrast, nonmaleficence rests in the Hippocratic maxim to do no harm, and it manifests itself in risk assessment and careful oversight in the context of research studies.

The principle of respect for persons, also described as autonomy, derives from the understanding that all persons have intrinsic and unconditional worth and, therefore, should have the power to make rational decisions and moral choices, namely, self-determination. Certain persons have built-in or

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<sup>15</sup> Beecher HK. Ethics and Clinical Research. *N Engl J Med.* 1966;274(24):1354-1360. doi:10.1056/nejm196606162742405

<sup>16</sup> 45 CFR 46. HHS.gov. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>. Accessed August 7, 2022.

<sup>17</sup> Varkey B. Principles of Clinical Ethics and Their Application to Practice. *Med Princ Pract.* 2021;30(1):17-28. doi:10.1159/000509119

external factors that diminish their capacity to exert their autonomy, and are entitled to additional protections as they are vulnerable to abuse. One example is incomplete development of judgment such as in childhood or severe intellectual disability. Another is that of power disparities such as exist for incarcerated persons. These groups are entitled to additional protection.<sup>18</sup> Some authors even argue that these protections need to be so extensive as to exclude them as human research subjects, especially in cases when the benefit to the individual is assumed to be minimal or null.

The last ethical principle presented by Beauchamp and Childress is justice. There are several categories of justice, but the most relevant type used in human subject research and clinical ethics is distributive justice, which refers to the fair, equitable, and appropriate distribution of health care resources.<sup>19</sup> The Belmont Report, an US Department of Health and Human Services (HHS) guideline for ethical research, does not expand in detail on the principles of justice, but does make general claims about just and unjust practices. It states that imposing burdens exclusively on a specific population is unjust, using the Tuskegee study as an example since the subjects—underprivileged black men—had life-saving treatment withheld in order not to interrupt the observational study, even long after such treatments became generally available. The principle of justice is at the heart of the debate on research ethics in human subjects and is specifically relevant in the use of fetal tissue.

## Medical Research Using Fetal Tissue

Fetal tissue obtained from aborted fetuses has been used in medical research for many decades. In the last sixty years, there has been an effort to apply a utilitarian and pragmatic approach to its use and transform it into “the right tools for the job,” as described by sociologist Anselm Strauss.<sup>20</sup> Human fetal tissue research proponents claim its use has led to significant advances in science and medicine. Even if true, as discussed previously in Beecher’s paper, medical progress does not excuse abuses of human subjects and researchers must uphold ethical standards, lest history repeat itself.

In the early 1970s, there were several research reports on just-aborted but still-living previable infants.<sup>21</sup> Once these facts were made known to the public, scientists justified these practices by appealing to the valuable knowledge that might yield in service of maternal-fetal health and by stating that just-aborted

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<sup>18</sup> The Belmont Report. HHS.gov. <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>. Accessed August 7, 2022.

<sup>19</sup> Blustein J. The History and Moral Foundations of Human-Subject Research. 2007;86(2):82-85. doi:10.1097/phm.0b013e31802f00cd

<sup>20</sup> Strauss A. Work and the Division of Labor. *The Sociological Quarterly*. 1985;26(1):1-19. doi:10.1111/j.1533-8525.1985.tb00212.x

<sup>21</sup> Snead OC. *What It Means to Be Human*. Harvard University Press; 2020:23-27.



infants were too biologically immature to survive outside of the womb (the gestational ages in these experiments were between 20-23 weeks<sup>22,23</sup>). The findings from these studies were brought to a Congressional hearing, and in 1973, the National Research Act imposed a moratorium on federally funded research on living human fetuses, before or after induced abortion, unless such research is done to support that individual fetus' survival.

The initial aim of a committee tasked with studying these events was to obtain information about the means, ends, benefits, and harms of fetal tissue research and to explore how it related to the topic of abortion. Protections for the preborn were not extended further because the Supreme Court decision on *Roe v. Wade* was released just eighteen months prior. This decision disrupted the legal and policy landscape by introducing a constitutional right to abortion and a new jurisprudential framework for its regulation, thereby altering the laws of all fifty states.<sup>24</sup> Nonetheless, the Supreme Court's decision on abortion did not eliminate ethical issues related to fetal tissue research, but only covered them with a "veil of silence" due to a lack of legal protection for fetuses before and after abortion.<sup>25</sup>

There are several additional considerations regarding fetal tissue research: Fetal tissue economy, legal protection guidelines, and consent. The NIH has governing policies on the acquisition and use of human fetal tissue for research purposes,<sup>26</sup> and these guidelines aim to avoid abuse and ethical improprieties. Nonetheless, there are very little data available regarding the processes of selection, acquisition, or distribution of fetal tissue for research in America. The lack of transparency in this field is a frequent cause of public concern and distrust, as corroborated by Catherine Waldby and Robert Mitchell in their book *Tissue Economies*. According to these authors, fetal cell tissue research transforms an unwanted pregnancy into a "valued resource" by using the female reproductive labor as tools for research that will bring no benefit to pregnant women or the fetus.<sup>27</sup> The transactional approach to using female bodies to extract research material is cited as a grave ethical and moral concern

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<sup>22</sup> Ramsey P. *The Ethics of Fetal Research*. New Haven: Yale University Press; 1975:71.

<sup>23</sup> Adam PAJ, Raina N, Rahiala E-L, Kekomaki M. Oxidation of glucose and D-B-OH-Butyrate by the early human fetal brain. 2008;64(1):17-24. doi:10.1111/j.1651-2227.1975.tb04375.x

<sup>24</sup> Chamberlain G. An artificial placenta. *American Journal of Obstetrics and Gynecology*. 1968;100(5):615-626. doi:10.1016/s0002-9378(15)33387-1

<sup>25</sup> Snead OC. *What It Means to Be Human*; 2020:33-35.

<sup>26</sup> Policies on The Acquisition And Use Of Human Fetal Tissue (HFT) For Research Purposes In The Intramural Research Program At NIH | NIH Office Of Intramural Research. <https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/policies-procedures-use-human-fetal-tissue-hft-research-purposes-intramural/policies>. Accessed August 7, 2022.

<sup>27</sup> Waldby C. *Tissue Economies*. Durham: Duke University Press Books; 2006:1-31.

to the authors and demands oversight to protect the pregnant woman and her fetus from predatory situations and abuse.

Julie Kent, a UK sociologist, cites the importance of transparency in an article focusing on the fetal tissue economy.<sup>28</sup> The tissue acquisition process deserves to be better understood and considered in discussions about how fetal tissue research transforms the connections between life and death. Similar to what is observed in the US, the author concludes there is very little oversight of this type of research and that the path from the collection site to the laboratory is unclear.<sup>28</sup> The collection and transparent distribution of such data are imperative for ethical discussions regarding fetal tissue.<sup>28</sup>

Regarding protections for research on human subjects, the National Institutes of Health (NIH) provides regulations and guidelines that include a subsection on pregnant women, human fetuses, and neonates.<sup>29</sup> Nonetheless, the guideline promotes the “research imperative,” allowing experimentation on fetuses and non-viable neonates if “the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.”<sup>29</sup> However, the NIH guidelines fail to define what constitutes important biomedical knowledge. Since fetuses currently have no legal rights under American law, these NIH protections are insufficient and would be deemed unethical if applied to any other vulnerable population. It has been a long-standing ethical value in the research that “utter helplessness demands utter protection,” but the NIH guideline fails to provide this kind of protection to fetal life.<sup>29</sup>

Another critical concern is the NIH guideline fails to define the standards for fetal viability for research purposes. Fetal viability is usually defined as the point when a human fetus can survive outside the mother’s body. Due to development in medical technology, this threshold has been reduced substantially in the last few decades (for example, it was 28 weeks by the time *Roe v Wade* was decided, and the consensus is now around 23-24 weeks; some centers of medical excellence have successfully discharged infants born at 22 weeks). This definition is problematic, especially in using fetuses acquired after abortion for research purposes since most fetuses are viable in all stages of pregnancy unless removed from their natural environment. For this reason, some have proposed a gestational age of viability for research purposes, limiting the use of fetuses 4-6 weeks before medical viability due to possible dating errors.<sup>30</sup> Even

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<sup>28</sup> Kent J. The fetal tissue economy: From the abortion clinic to the stem cell laboratory. *Social Science & Medicine*. 2008;67(11):1747-1756. doi:10.1016/j.socscimed.2008.09.027

<sup>29</sup> Subpart B - Additional Protections for Pregnant Women, Human. HHS.gov. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html>. Accessed August 7, 2022.

<sup>30</sup> Ramsey P. *The Ethics of Fetal Research*. New Haven: Yale University Press; 1975:75-78.



this mild limitation to using fetuses and previable neonates for research has been denied on claims that any protection would limit abortion rights.

## Conclusion

Human fetuses are a group of human subjects that remain without full ethical and legal protections. Until the existing laws guiding fetal tissue research are amended, human subject research as a whole is inadequate and harms vulnerable subjects. Public trust in research is highly dependent on ethical and legal protections and on the perception of autonomy, beneficence, nonmaleficence, and justice. Extending protections to human fetuses strengthens the rights of human subjects and the ethical foundation and validity of the critical research.

### ***Q. Are Women Allowed to Consent to Research on Fetal Tissue on Behalf of the Fetus if They are Obtained Through Induced Abortion? Is this Similar to Use of Embryos Obtained During In Vitro Fertilization?***

Voluntary informed consent is the cornerstone of ethical research. The question of voluntary informed consent in human fetal tissue research is must reach certain standards, namely, the research subject must have the legal capacity to consent and should be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior forms of constraint or coercion.<sup>31</sup> It is also essential to provide the research subject with sufficient knowledge and comprehension of the elements involved in the research to enable the person to make an informed decision.<sup>32</sup> In the case of fetal tissue research, research requirements are lowered since the requirement for consent is limited compared to what is required in fetal research outside of the context of induced abortion.<sup>33</sup>

First, little information is given to women seeking abortion on what fetal research entails. In one study analyzing women's views on fetal tissue research in the US, all information provided to the research subjects is quoted as follows "Sometimes scientists conduct research using the tissue remains of the pregnancy to study different diseases. Scientists call it fetal tissue research.

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<sup>31</sup> Blustein J. The History and Moral Foundations of Human-Subject Research. 2007;86(2):82-85. doi:10.1097/phm.0b013e31802f00cd

<sup>32</sup> Trials of War Criminals Before The Nuernberg Military Tribunals Under Control Council Law No. 10 (Volume 2) - Digital Collections - National Library Of Medicine. <http://resource.nlm.nih.gov/01130400RX2>. Accessed August 7, 2022.

<sup>33</sup> 42 U.S. C. § 289g-1 & 289g-2; 42 CFR § 46.201. <https://www.govinfo.gov/content/pkg/USCODE-2020-title42/pdf/USCODE-2020-title42-chap6A-subchapIII-partH-sec289g-1.pdf>. Accessed August 7, 2022.

Research is allowed if the woman provides consent.”<sup>34</sup> This researcher concluded that women’s perspectives on fetal tissue research were nuanced and can be viewed as a choice that is both respectful to the fetus and meaningful to the woman whose pregnancy has ended. Still, the question remains, how much is understood about the realities of fetal research?

Another qualitative focus-group,<sup>35</sup> study solicited the opinion of women on the use of fetal tissue for research. Women initially expressed enthusiasm for donating aborted fetuses for experimentation, which was understood as a good thing, but as participants gained information and thought more carefully about the implications of such a decision, the support radically diminished. The lack of knowledge about how aborted fetuses are handled in the laboratory was one of the main issues for changing opinions, as it invoked in participants a perceived *duty of care* that women feel towards their offspring. Regarding fetal stem cell research, participants described troubling feelings associated with renewal, regeneration, and immortality of the tissue, which was understood as somehow reinstating and even developing the fetus’ physical existence and social biography, the very thing abortion is meant to eliminate. The author concluded that participants had co-produced a tendency to refuse to donate aborted fetuses by the end of the focus groups, once more knowledge on the topic had been acquired.

This study exemplifies the concerns that generalized consent is not fully informed, truly voluntary consent. Proper consent would require more specific discussion between the woman and the health care team about fetal tissue storage, research aims, and methods of research. Such disclosure would potentially change the woman’s mind in consenting to research but would at least meet minimum requirements for disclosure.<sup>36</sup>

Another essential point is the suitability of a woman to consent to the use of fetal tissue obtained after induced abortion. Fetuses, infants, and children are a protected class in human research because they cannot provide informed consent due to developmental immaturity. It is understood that medical research should only be allowed in this population if the experiment brings direct benefit and minimal risk of harm. Parents are required to consent because they are viewed as proxies acting in the child’s best interest, but this is not the case in the context of abortion. In this situation, it would be most appropriate to use the standard applied to children with no guardians available to participate

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<sup>34</sup> Spach NC, Jaffe EF, Sullivan KA, et al. Pregnant Individuals’ Views on Fetal Tissue Research in the United States. 2021;138(5):755-761. doi:10.1097/aog.0000000000004576

<sup>35</sup> Pfeffer N. What British women say matters to them about donating an aborted fetus to stem cell research: A focus group study. *Social Science & Medicine*. 2008;66(12):2544-2554. doi:10.1016/j.socscimed.2008.01.050

<sup>36</sup> Ramsey P. *The Ethics of Fetal Research*. New Haven: Yale University Press; 1975:89-99.

in consent and thus categorically exclude fetuses obtained from elective abortions from participation in experimental research.

Clinical testing after miscarriage or stillbirth is not part of this ethical challenge, so long as the tissue is treated with respect. Further ethical work is necessary to determine whether donation of fetal remains after spontaneous pregnancy loss should aid scientific research, much like parents' decision to donate the body of a recently deceased child to science or medical education. In this situation, the moral repugnance associated with performing research after an iatrogenic death is absent.

### ***Q. What Changes Should be Put in Place to Protect Fetal Research Subjects?***

Ethics in research using fetal tissue does not compare equitably with human tissue research, which has a well-established history of safeguards that are absent for embryos and fetuses. For this reason, changes are necessary not only in fetal research but in the legal, ethical, and social climates within which such research occurs. Firstly, there is a need for change in our culture to value life and the overturn of *Roe v Wade* by the *Dobbs v Jackson* decision in June of 2022 allows society us to address legal and ethical spheres to include fetuses, a much-needed action that has been halted for 50 years.

The first step to ascribing equality and fundamental human rights to fetuses is to acknowledge their moral status and to grant them the same legal and ethical protections given to all other members of our species when subjected to research. In doing so, fetal tissue research is, in fact, medical research involving a human subject that is vulnerable and not yet developmentally capable of agency or choice. Human subjects deemed vulnerable should receive specifically considered protections, and to require this level of protection to human fetuses is to apply the ethical principle of justice. A just society requires standards to be applied in a consistent matter, so any protections granted by national and international guidelines for medical research involving human subjects should be extended to fetuses and fetal tissue.

According to the Declaration of Helsinki, corroborated by the Belmont Report, "medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subject," and that "medical research with a vulnerable group is only justified if this group should stand to benefit from the knowledge, practices or interventions that result from the research." As it currently stands, fetal tissue research fails to comply with both standards since fetuses are used in a utilitarian fashion as tools to produce medical progress in general, without any benefit to them or maternal-fetal specific conditions. This is ethically reprehensible and demands to be corrected immediately.

One argument from proponents of fetus tissue research is that it should be viewed as a donation of biological tissue. There are two main reasons why this premise is invalid. First, the fetus is not a part of the mother's body but a whole new individual with moral status, worthy of rights and respect. For this reason, it is unjust to treat a fetus simply as organs or body parts. Secondly, there is the question of appropriate informed consent and a suitable surrogate or proxy for this consent. Fetuses, especially in the context of abortion, are the most vulnerable class in human research because they cannot give informed consent due to developmental immaturity and they lack of proxies that are acting in their best interest. In this situation, the standard applied to children with no guardians is appropriate, requiring categorical exclusion of fetuses from induced abortions from participation in experimental research. If this is not done, the industry complies with a utilitarian perspective of life and death that is detrimental to a culture that values equality and justice.

Finally, guidelines for research on human subjects are well-established in treatment of the dying and the condemned. These disenfranchised groups deserve and are granted respect, and it is a breach of research ethics to misuse, coerce, or abuse them. Even in extreme cases, such as prisoners on death row, our society has long established it is unethical and, in most cases, illegal to subject them to research or organ donation. The punishment of death, a controversial topic in jurisprudence, is still seen as a solemn event that ought to preclude inhumane treatment or abuse of both the person and the subsequent corpse. In places where abortion remains legal, fetal tissue should be viewed with the same respect as condemned prisoners: their remains should be humanely treated and disposed with human dignity

## **Summary of Recommendations and Conclusion**

### ***The Following Recommendations are Based on Good and Consistent Scientific Evidence (Level A):***

- 1) Informed consent specific to fetal tissue research should be broadly available to women after spontaneous abortion. It should briefly describe the existing types of fetal tissue, the manner of use of fetal tissue, and the possible implications the research might produce.

### ***The following recommendations are based on limited and inconsistent scientific evidence (Level B):***

- 1) Fetuses should be held by the same standards applied to other human research subjects and protected as a vulnerable class according to national and international guidelines.
- 2) Fetal tissue research should be permissible only in fetuses derived from spontaneous abortion or previable preterm labor.

***The Following Recommendations are Based Primarily on Consensus and Expert Opinion (Level C):***

- 1) Fetal tissue research in fetuses resulting from induced abortion should be proscribed, and fetal organs and remains should be disposed of in a dignified manner.