Begging the Question: Fetal Tissue Research, the Protection of Human Subjects, and the Banality of Evil

Thomas John Babbo

Follow this and additional works at: https://via.library.depaul.edu/jhcl

Recommended Citation
Thomas J. Babbo, Begging the Question: Fetal Tissue Research, the Protection of Human Subjects, and the Banality of Evil, 3 DePaul J. Health Care L. 383 (2000)
Available at: https://via.library.depaul.edu/jhcl/vol3/iss3/2

This Article is brought to you for free and open access by the College of Law at Via Sapientiae. It has been accepted for inclusion in DePaul Journal of Health Care Law by an authorized editor of Via Sapientiae. For more information, please contact wsulliv6@depaul.edu, cmccure@depaul.edu.

Thomas John Babbo*

INTRODUCTION

Atreus, that wellspring of Greek legend, visited a curse upon his house following a feast that he gave for his brother and mortal enemy Thyestes. The pie that Atreus prepared as the main course of the

*Assistant General Counsel, Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois. B.A., Loyola University Chicago, 1994; J.D., Loyola University Chicago School of Law, 1998. The author wishes to thank Max D. Brown for his continuing support and his assistance in formulating this paper. He also wishes to acknowledge the invaluable research assistance of Catherine DeLair, Mary Anne Boley, Angelina Ristanovic, and Danielle Hilgers; and also Lisa Lipsky. Most importantly, Mr. Babbo wishes to express his love and gratitude to his wife, Heidi, and his children, Mary Grace and Joseph.

See Joint Association of Classical Teachers, The World of Athens: An Introduction to Classical Athenian Culture 305 (1984). The fall of the house of Atreus is a favorite subject of many classical Greek tragedies, including the Orestian Trilogy of Aeschylus:

Pelops had two sons, Atreus and Thyestes. Thyestes commits adultery with Atreus' wife and to punish him, Atreus serves up all but one of Thyestes' children to him in a pie (Aigisthos survives). Atreus' son Agamemnon has to sacrifice his own child Iphigeneia in order to get a favorable wind for the expedition to sail to Troy and win back Helen for his brother Menelaos and restore the family honor. When Agamemnon returns, his wife Klutaiméstra has married Aigisthos and slaughters Agamemnon in revenge for his sacrifice of Iphigeneia. But Agamemnon's surviving son Orestes returns to take his due revenge on Klutaiméstra.

Id.
dinner contained a secret ingredient, the meat of Thyestes' butchered children. Thyestes found this pie absolutely delicious, and, between each belch and extra helping, begged Atreus for the recipe. Waiting until Thyestes had gorged himself to capacity, Atreus finally disclosed the true contents of the meal—whereupon Thyestes was consumed by such violent revulsion and vomiting that he died.

There exists between this feast of Atreus and the transplantation of human fetal tissue in federally-sponsored experimentation a certain resonance. The meal that Atreus served Thyestes was certainly nourishing, and Thyestes found it particularly delicious. Likewise, human fetal remains, by virtue of their humanity, promise unique treatments for such ailments as polio, juvenile diabetes, aplastic anemia, thymic aplasia, AIDS, leukemia, thalassemia, Hurler's Syndrome, Parkinson's Disease, Alzheimer's Disease, Multiple Sclerosis, spinal cord injury, and stroke. But whereas Thyestes could only fully enjoy his dinner so long as he remained ignorant of its ingredients, we continue to stomach the transplantation of aborted fetal remains. Current federal law and regulations upon experimentation involving human fetal tissue, as well as the proposed regulations regarding human fetal stem cell research, allow us to create a class of humans not deserving of the protections afforded to other subjects of research, living and dead.

And yet, when taken as a whole, the entire body of federal regulations regarding clinical research articulates a notion of the human person wholly inconsistent with federal fetal tissue policy. This article will show that the view of the human person adopted by the regulations for the protection of human subjects borrows in large part the concept

---

2 See id.
3 See id.
4 See id.
of humanity utilized by the Nuremberg Code—a definition that is itself provided stark relief by the medical experiments for which the

\[8\] See THE NUREMBERG CODE, TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10 181-82 (1949) [hereinafter NUREMBERG TRIALS].

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constrain or coercion; and, should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
Nazis were prosecuted following the Second World War. This article will then illustrate how the fetal tissue regulations fail to adopt this view of the human person, and instead maintain an artificial blindness to the humanity of the aborted fetus. The practical effect of this deliberate ignorance is the creation of a class of human beings for whom the customary precautions and formalities followed in clinical research do not apply. Finally, in light of the above, this article argues for the renewed ban of fetal tissue research, both for the sake of philosophical consistency with the vast body of federal human subject protections and to avoid the creation of a scientific environment that denigrates the humanity of any class of persons.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if she has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Id.  

9 See NUREMBERG TRIALS, supra note 8, at 181-82.
BACKGROUND

The Influence of the Nuremberg Code and its Progeny on U.S. Regulation of Medical Research

At the end of the summer of 1947, in the then-West German city of Nuremberg, a panel of three American jurists sat in judgment over twenty-three Nazi physicians and bureaucrats. The defendants in United States v. Karl Brandt et al. stood accused of conducting grisly medical experiments upon Jews, Gypsies, the mentally retarded, and prisoners of war. The experimental atrocities read like a litany of horrors: to determine how long a person could live without fresh water, subjects were forced to drink seawater until they desiccated completely; to learn how long a Luftwaffe pilot might survive if shot down over the English Channel, subjects were immersed in icy water until they slowly froze to death; to observe the effects of bailing out of an airplane at high altitudes, subjects were placed in vacuum chambers and allowed to burst. Other Nazi experiments included: exposing subjects to bio-warfare agents, infecting subjects with pathogens and disease, testing new sterilization and castration methods, and transplanting limbs and bones onto healthy subjects.

In handing down its ruling, however, the Nuremberg tribunal went far beyond merely condemning the defendant Nazi doctors for war crimes and atrocities. Rather, to prevent the reemergence of the kind of scientific environment under which Nazi research thrived, the final judgment in Brandt enumerated ten conditions upon the practice of medical experimentation, the so-called Nuremberg Code. Significantly, the Brandt court derived these principles not from an

---

10 See id.
12 See id.
14 See id. at 26.
15 See NUREMBERG TRIALS, supra note 8, at 95-102.
16 See id. at 102-03.
existing code of medical ethics, nor from precedential case law, but rather from the "natural law" of all human persons.17

The most influential of the Nuremberg Code's conditions, holding primacy above the others both in number and importance, was the necessity of obtaining authentic, uncoerced informed consent from human subjects.18 All codes and regulations to follow concerning the rights of human research subjects, both ethical and regulatory, would import this notion of informed consent with varying degrees of strictness and success.19 For instance, at the signing of the Charter of the United Nations (UN) in December 10, 1948, the UN's fifty-one original signatory nations adopted the provisions of the Nuremberg Code, if only in principle.20

In 1953, the Clinical Center of the National Institutes of Health (NIH) produced the first U.S. federal policy regarding research on human subjects, adopting for its intramural research program the Nuremberg Code's emphasis on the use of healthy, competent volunteers in clinical research.21 According to promotional materials published by the NIH at the time, the Clinical Center's guidelines viewed the Nuremberg Code as the "ten commandments" of human medical research.22 Pursuant to these directives, the Clinical Center mandated that the human subject of medical research be "considered a member of the research team and...afforded an understanding suited to his comprehension of the investigation contemplated, particularly any potential danger to him."23

The next year, during its 8th General Assembly, the World Medical Association (WMA) proposed its "Principles for Those in

17 See PROCTOR, supra note 13, at 181-82.
18 See id.
Fetal Tissue Research

Research and Experimentation" (Principles). The WMA Principles introduced notions of surrogate or substituted consent by a subject’s next-of-kin or legal representative into the Nuremberg Code’s informed consent model. Ultimately, these Principles would lead to the WMA’s promulgation of the Declaration of Helsinki at its 18th World Assembly in 1964. Heeding the wishes of the medical research establishment, the Declaration’s “Recommendations Guiding Doctors in Clinical Research” softened the strident, legal statements of the Nuremberg Code. Instead, the Declaration of Helsinki stressed that its “standards as drafted [were] only a guide to physicians.”

By order of priority, the Declaration of Helsinki placed scientific expertise and the goals of medicine before the informed consent of the research subject. In fact, the Declaration does not require physicians to obtain informed consent at all for clinical research considered “therapeutic” to the subject. However, the Declaration of Helsinki could not avoid the influence of the Nuremberg Code. In sections 9 and 10 of its Basic Principles, the Declaration articulates the policy of authentic, uncoerced informed consent voiced by the Nuremberg Code, and proposes procedures to obtain such consent.

---

25See id. at 16.
28For a detailed discussion of the application of the Nuremberg Code to civil and criminal law, see GEORGE J. ANNAS, INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT’S DILEMMA 20 (1977).
29See Declaration of Helsinki, supra note 26, at 331.
30See id. at § I, 1-3; § II, 1; § III, 1.
31See id. at § I, 9-11.
32See id. at § II, 5.
33See Declaration of Helsinki, supra note 26.
34See id. at § I, 9-10:
The Declaration of Helsinki, primarily because of its non-legal, advisory nature, received wide acclaim from the medical community. For instance, in a panel discussion reported in the YALE JOURNAL OF BIOLOGY AND MEDICINE in 1964, one physician described the Nuremberg Code as "...a wonderful document to say why war crimes were atrocities, but...not a very good guide to clinical investigation which is done with high motives." Henry Beecher, the noted Harvard physician and advocate for research subjects, saw the Helsinki Declaration as liberating Western medicine from "...the imposition of the Nuremberg Code." In 1966, the American Medical Association’s Ethical Guidelines for Clinical Investigators endorsed the legally unenforceable presentation of the Declaration of Helsinki over that of the Nuremberg Code.

During that same year, both the U.S. Food and Drug Administration (FDA) and the NIH promulgated policies and regulations dealing with the rights of human research subjects. The FDA established its 1966 regulations pursuant to the Drug Amendments Act of 1962. Passed in response to the tragic birth defects that resulted from pregnant women taking the experimental

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits, and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject’s freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.

35 See ANNAS, supra note 27, at 204-06.
36 See id.
37 See Goldner, supra note 19, at 91.
38 See id.
39 See id.
anti-nausea medication, Thalidomide, the Drug Amendments Act required the FDA to establish informed consent procedures sufficient to ensure that patients would only take investigational new drugs with full knowledge of any hazardous side effects. In promoting these new regulations, statements by the FDA reflected the trend of medical researchers throughout the 1960s toward promoting the Declaration of Helsinki over the Nuremberg Code. Yet, in its definition of informed consent, the 1966 FDA regulations imported far more actual language from the Nuremberg Code than from the Helsinki Declaration. This borrowing is still apparent in the current incarnation of the FDA regulation entitled, "Informed Consent of Human Subjects," last amended March 8, 1999:

[N]o investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

As for the NIH, its 1966 guidelines expanded to extramural investigations the protections of human subjects that it had imposed upon intramural research in 1953. Under the 1966 Public Health Service Policy Regarding the Protection of Human Subjects, the NIH would only approve extramural research grants of those institutions with an internal board that would review the protections afforded the research subject. These protections were to include the provision of informed consent to human subjects in a manner open to scrutiny by

40 See id.
41 See GLANZ, supra note 22, at 186.
42 See Morin, supra note 23, at 171.
44 See id.
45 See id.
the internal review board. This 1966 NIH policy was the harbinger of the current practice of Institutional Review Boards required by federal regulation.

The NIH guidelines and FDA regulations continued to receive revision and amendment through the early 1970s. In 1974, reports of unethical research involving human fetuses around the world and of secret deliberations about undertaking similar research within the NIH led to the enactment of the National Research Act. Passage of this law required the Department of Health, Education, and Welfare (DHEW), the predecessor agency to Health and Human Services, (HHS) to codify into federal regulation the NIH guidelines on the protection of research subjects. The National Research Act also created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, whose charge was to study the ethics of biomedical research in general, and of fetal research in particular. Pending the National Commission’s report on the moral propriety of human fetal research, Congress placed a moratorium on all research related to the human fetus, living or dead.

The National Commission issued its Report and Recommendations: Research on the Fetus on July 25, 1975. Underlying the findings of this report were the Nuremberg Code, the Helsinki Declaration, and the views of ethicists, legal scholars, medical researchers, and theologians. In light of the U.S. Supreme Court’s ruling in Roe v. Wade, the National Commission’s Report avoided an overt declaration of the “personhood” of the fetus. Nevertheless, the

46See NIH GUIDELINES, supra note 7, at 7.
47See Morin, supra note 23, at 172, 174.
48See Sarkos, supra note 5, at 390.
50See id. § 202(a)(1)(B)(v).
51See id. § 202(a).
52See id. § 202(a)(3).
53See id. § 202(a)(3)(b).
55See id. at 3.
56See id. at 26-27.
Commission firmly established that the fetus was to be considered a human subject in the context of medical research:

Throughout the deliberations of the Commission, the belief has been affirmed that the fetus as a human subject is deserving of care and respect....[T]he members of the Commission are convinced that moral concern should extend to all who share genetic human heritage, and that the fetus, regardless of life prospects, should be treated respectfully and with dignity.57

The National Commission's Report then went on to issue sixteen conclusions,58 which were adopted on July 29, 1975 as federal regulation, and remain so to this day.59 Recognizing the inherent vulnerability of the fetus, these regulations adopt wholeheartedly the provisions of the Nuremberg Code,60 and establish a bifurcated analysis for permissible research on the human fetus.61 For any fetus in utero, the regulations permit only research that (1) will benefit the health of the fetus, and (2) will pose no more than minimal risk to the fetus.62 An ex utero fetus may never serve as a research subject, as any such research would either artificially maintain the life of the fetus or hasten his or her death.63

So completing the first aspect of its congressional mandate, the National Commission continued with its evaluation of the ethics of medical research generally.64 Deliberating for a period of nearly four years on such considerations as the difference between research and medicine, the role of risk-benefit analyses in medical research, the selection of research subjects, and the nature and importance of informed consent, the National Committee finally issued its findings on

57See id. at 61-62.
58Id. at 73-76.
59See Sarkos, supra note 5, at 390.
60See GLANZ, supra note 22, at 189.
61See id.
64See Sarkos, supra note 5, at 399-408.
April 18, 1979. Contained within The Belmont Report: Ethical Principals and Guidelines for the Protection of Human Subjects of Research (the Belmont Report), these findings recognize three basic underlying ethical principles which ought guide the actions of medical researchers: (1) respect for persons, (2) beneficence, and (3) justice.

The Belmont Report did not see its purpose as providing researchers a rationale for its ethical directives of respecting persons, doing good, and upholding justice. In fact, the National Commission purposefully avoided definitions that might answer the threshold questions: "What is a person?" and "What makes a person deserving of respect, beneficence, and justice?" Rather, by promulgating its basic ethical principles, the Belmont Report provided what could be described as the "regulatory" counterpart of the Nuremberg Code. In its introduction, the Belmont Report establishes its function as elucidating the principles of the Nuremberg Code, and the Declaration of Helsinki by implication, through the interpretive "lens" of categorical moral imperatives.

This code [the Nuremberg Code] became the prototype of many later codes intended to assure that research involving human subjects would be carried out in an ethical manner....The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply.

---

66See id. at 23193-94.
67Id.
68Id.
69Id.
70The use of this term here is intentional, signifying the Kantian undercurrents of the Belmont Report. See Ruth Macklin, Universality of the Nuremberg Code, in THE NAZI DOCTORS AND THE NUREMBERG CODE 245 (George Annas & Michael Grodin, eds. 1992); IMMANUEL KANT, THE FOUNDATIONS OF THE METAPHYSICS OF MORAIS (1785). To further strain my "regulation" metaphor, I submit that Kant's philosophy, which postulates concepts within the mind that structure our perception of reality, is itself regulatory—i.e., providing an organizational framework for the dictates of experience.
Broader ethical principles will provide a basis on which specific rules may be formulated, criticized, and interpreted.\textsuperscript{71}

For instance, the Belmont Report interpreted the Nuremberg Code’s penultimate requirement of informed consent in terms of its ethical principle, “respect for persons.”\textsuperscript{72} According to the Belmont Report, this principle incorporated at least two basic assumptions: (1) that human beings are generally autonomous, and (2) that individuals with diminished autonomy require protection.\textsuperscript{73} In deference to this general notion of autonomy, the Belmont Report’s guidance with regard to informed consent required that the researcher provide the subject with sufficient information, in a manner suitable to the subject’s level of comprehension, so that the subject could freely decide to enroll in a given study.\textsuperscript{74} For those subjects with diminished autonomy, like children or the mentally disabled, the Belmont Report added to the above the additional requirement of seeking permission for enrollment from those in a position of protecting the subjects, \textit{i.e.}, the subject’s parents or guardians.\textsuperscript{75}

The “regulatory” character of the Belmont Report allowed it to integrate itself far more easily into the format of federal regulation than the unequivocal commandments contained in the Nuremberg Code. In light of the findings of the Belmont Report, as well as those found in similar reports by the National Commission concerning research on pregnant women, children, the mentally disabled, and prisoners, the Department of Health and Human Services\textsuperscript{76} (DHHS) began work on revising its regulations in 1979.\textsuperscript{77}

Two years later, on January 26, 1981, DHHS promulgated new regulations concerning research on human subjects.\textsuperscript{78} For the next twelve years, these regulations governed only research sponsored by

\textsuperscript{71}See The Belmont Report, \textit{supra} note 65, at 23192-93.
\textsuperscript{72}See id. at 23193-94.
\textsuperscript{73}See id. at 23193.
\textsuperscript{74}See id. at 23193-94.
\textsuperscript{75}See id. at 23193.
\textsuperscript{76}The DHHS succeeded the DHEW.
\textsuperscript{77}See NIH GUIDELINES, \textit{supra} note 7, at Appendix 1.
However, on June 18, 1991, sixteen federal agencies, including the FDA, the Department of Defense, and the Department of Energy, incorporated the regulations of DHHS into their own codes regarding the protection of human subjects. As such, these regulations, 45 C.F.R. § 46, effectively govern all federally sponsored research, as well as any commercially-sponsored research conducted on behalf of pharmaceutical companies and medical device manufacturers.

The current federal regulations establish three basic mechanisms to ensure the protection of research subjects:

(1) federal regulatory oversight of a research facility’s “project assurance” by DHHS’s Office for the Protection of Research Risks (OPRR),

(2) internal approval of studies by a federally-sanctioned Institutional Review Board (IRB), and

(3) voluntary informed consent for human subjects.

Of these, the operative regulatory mechanism is the requirement for authentic, uncoerced informed consent—the oversight of OPRR and the approval of an IRB merely providing the government the opportunity to check compliance.

The federal regulations outline the federal government’s general requirements for the informed consent of research subjects. Accordingly, the researcher may only enroll those subjects who have consented to participation in the study based on full disclosure of the following:

---

79See id.
83See id.
84See 45 C.F.R. § 46.116(a) (1999).
(1) the treatments or procedures utilized in the study are experimental;

(2) these treatments or procedures involve a number of reasonably foreseeable health benefits, risks, and discomforts;

(3) the subject’s condition may be alleviated by other approved, non-experimental treatments or procedures;

(4) the subject may contact an identified individual with any questions regarding the study, including any questions regarding medical treatment in the event of a study-related injury; and

(5) the subject’s consent to participate is entirely voluntary, specifically allowing the subject the option to refuse or discontinue participation in the study, at any time, without loss of benefits.\textsuperscript{85}

Additionally, the researcher must inform the subject (1) whether he or she will receive any financial benefits by participating in the study; and (2) whether, in the event of a study-related injury, he or she will receive any medical treatment.\textsuperscript{86}

In addition to the heightened protection of unborn research subjects promulgated by the National Commission in 1975, current federal regulations impose more stringent informed consent standards upon the enrollment of other “vulnerable populations,” such as women, children, and prisoners.\textsuperscript{87} Because of the possibility that a female research subject may become pregnant, 45 C.F.R. § 46.116(b) requires that the researcher include in the consent of women of childbearing potential any known risks to the fetus, and a statement that some risks to the fetus may be unforeseeable.\textsuperscript{88} For women who are in fact pregnant, sections 45 C.F.R. §§ 46.207 and 46.208 restricts enrollment

\textsuperscript{86}See 45 C.F.R. §§ 46.116(a)(6) to (7) (1999).
to studies involving only minimal risk, due to dangers to which the woman's unborn child might be exposed.\textsuperscript{89}

With regard to children, Subpart D of 45 C.F.R. § 46 affords additional protections dependent upon the risks and benefits inherent in the research.\textsuperscript{90} For research on children that involves no more than minimal risk, the researcher need only abide by the slightly higher informed consent standard set forth in 45 C.F.R. § 46.408.\textsuperscript{91} Borrowing the view of the Belmont Report that the child research subject falls under both the regulatory protection of the government and the natural protection of parents,\textsuperscript{92} this regulation requires that the researcher seek the consent of the child's parent or guardian, and of both parents if possible.\textsuperscript{93} If the child is old enough to understand at least some of the risks of the research, 45 C.F.R. § 46.408 requires that the researcher obtain the assent of the child in addition to the consent of the child's parent or guardian.

If a research protocol would expose a child to anything more than minimal risk, the regulations require the IRB at the researcher's institution to submit the proposed study to a risk-benefit analysis.\textsuperscript{94} In cases where the investigational treatment or device might benefit the child, the IRB must determine whether the risks are warranted and the benefits are at least as favorable as those presented by approved treatments.\textsuperscript{95} However, where the research poses no benefits to the child, the IRB's risk analysis must show that the risks pose only a "minor increase over minimal risk."\textsuperscript{96}

Recognizing the severe constraints upon freedom imposed by incarceration,\textsuperscript{97} 45 C.F.R. § 46, Subpart C affords to prisoners protections rivaled only by those offered to the fetus in utero.\textsuperscript{98} This subpart restricts even the subject matter of research on prisoners,
allowing only studies of criminality, the psychological and social effects of incarceration, health problems particular to prison populations, and only such innovative treatments which have a reasonable probability of improving the health of the incarcerated. An IRB reviewing such research must assure that prisoners are not unethically induced to participate in research studies with promises of better quality food, accommodations, or health care.

ANALYSIS

Nuremberg Metaphysics:
Implicit Definitions of the Human Person in Both the Nuremberg Code and Federal Regulation

On February 17, 1994, President Clinton issued an executive memorandum to the heads of all federal departments and agencies that undertake or fund research involving human subjects, urging these departments and agencies to strictly enforce the provisions of 45 C.F.R. § 46. In this memorandum, Clinton described the history of the protection of human subjects, from the Nuremberg Code to the current federal regulations, as a continuum:

Since 1947, when guidelines for research with human subjects were promulgated, there has been increasingly widespread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects....

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education and Welfare's regulations in 1974, 45 C.F.R. § 46. In 1991, 16 agencies formally adopted the core of these

100 See 45 C.F.R. § 46.305 (1999)
regulations in a common Federal Policy for the Protection of Human Subjects.

The kind of evolution to which the President refers would necessitate a common view of the research subject between the 1947 Nuremberg Code and the 1991 C.F.R. The Nuremberg Code’s derivation from natural law theory provides the basis for this consistency. To discover this common view of the human person, we must examine what the Nuremberg Code’s ten directives imply concerning the nature of humanity and the practice of scientific research. In other words, the ruling in Brandt can provide us the answer to the underlying question, “Why protect individuals who act as research subjects?”

The answer to this question begins in the Nuremberg Code’s primary tenet: the requirement that medical researchers obtain uncoerced, authentic informed consent from all research subjects. To so require informed consent presumes that human beings are generally capable of making choices based on the use of reason. Stated in terms of inherence, having the capability to make decisions means that human beings by nature possess an intellect and a free will.

The remaining provisions of the Nuremberg Code place this notion of the freely-acting, intellectual human person in the context of medical research. For instance, the Nuremberg Code’s second provision states that “[t]he experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.” So following the “absolutely essential” requirement of informed consent, this provision places both medical progress and the good of society subservient to the dignity of individual human persons.

---

103 See id.
104 See id.
105 See id.
106 See id.
107 See GLANTZ, supra note 22, at 197 (referencing the conclusions of Nuremberg Tribunal):
The protections afforded to research subjects under 45 C.F.R. § 46 further this view of the Nuremberg Code of the human person as an inherently free-thinking and dignified creature. By requiring that researchers provide subjects full disclosure of a study's benefits, risks, and discomforts, and by allowing research subjects the ability to cease participation in a study at any time without penalty, the general rules for informed consent show respect for both the intellect and the free will of the research subject. The additional protections afforded to the unborn, children, and prisoners under the federal rules exhibit a recognition on the part of the federal regulations that impairments of freedom or intellection do not serve to dilute the dignity of the research subject. Rather, 45 C.F.R. § 46 requires heightened protection in the face of a human subject's increased vulnerability.

And yet, these considerations do not complete the portrait of the human person painted by the Nuremberg tribunal. In order to fully comprehend the view of the human person articulated by the Nuremberg Code, we must look back to the atrocities which the Nuremberg tribunal prosecuted. The science practiced by the Nazis and its philosophical underpinnings provide stark relief and surprising support to the view of the Nuremberg Code as to the worth of the human research subject.

In the interest of the advancement of medicine and science, the Nuremberg defendants took advantage of a social and political environment that declared particular minority groups unworthy of the law's protection. Despite all the rationalizations used by the Nazi doctors in their own defense—the lack of moral absolutes in the context

Thus, the judges concluded that even if research is good, it is an optional good that must be balanced against respect for human beings, which is not optional but mandatory. Where the welfare of human beings is threatened by research, the research must not be done.

Id.

106 See id.
112 See NUREMBERG TRIALS, supra note 9.
of "total war," the impending death of subjects awaiting execution, the excuse of "just following orders"—the actions of Brandt and the other Nazi researchers clearly articulated one belief: the permissibility of sacrificing to science the life and dignity of any minority declared "inferior" by the state.

Yet, if we examine the Nazi experiments in terms of the goals of medical research, we find that the Nazis, by their very exploitation of the humanity of their research subjects, voiced simultaneously an inadvertent admission of these subjects' inherent value. In other words, the scientific merit of the Nazi doctors' experiments derived precisely from the humanity of the research subjects whose personhood these researchers denied. In response to this perverse rearrangement of values, it was the mission of the Nuremberg Code to make certain that scientific utility and medical advance never again took precedence over the dignity of the human person.

Federal Law and Regulation Regarding Fetal Tissue Transplantation: Begging the Question

Yet, despite the consistent tradition of respect for human persons transmitted from the Nuremberg Code through the federal regulations, at least one area of medical research finds itself strangely exempt. The

---

114 See id.
115 See id. at 266-68.

What transpired at Auschwitz and Tuskegee would not have led to regulations of the human experimentation process had these events been viewed as isolated occurrences, ascribable to causes utterly distinct from ordinary contemporary research practices. The regulations were a response to contemporary research. They were also a response to the realization, questioned by some, that reliance on the ethical conscience, inculcated in physician-investigators during their medical education, provided insufficient protection to the human rights of subjects of medical research.

Id.
practice of fetal tissue transplantation operates to place the advancement of medical science in a position of mastery over the dignity of the human person. Whereas the body of federal research regulations incorporate the Nuremberg Code's concept of human dignity, current federal policy regarding fetal tissue research has the effect of both eroding our societal intolerance for evil and denying our universal concept of humanity.

The historical origins of federal fetal tissue policy began with the regulations promulgated by NIH pursuant to the National Commission's Report in 1975.\textsuperscript{117} Comparatively, the National Commission's Report allotted very little space and analysis to the use of fetal tissue in research.\textsuperscript{118} Nevertheless, the National Commission's recommendation to permit research on human fetal remains, in a manner "...consistent with local law, the Uniform Anatomical Gift Act (UAGA),\textsuperscript{119} and commonly held convictions about respect for the dead"\textsuperscript{120} was incorporated into the body of federal regulations.\textsuperscript{121}

However, the two paragraph discussion contained in the National Commission's Report failed to develop a sufficiently detailed analysis as to the application of the UAGA to the donation of aborted fetal tissue.\textsuperscript{122} At the time of the National Commission's Report, the UAGA was a fairly recent development.\textsuperscript{123} In fact, only years earlier, American law dealt with organ donation and transplantation through existing common law concepts.\textsuperscript{124}

In harvesting organs from the living, the physician was required by the common law to obtain informed consent from the donor, or else face a claim of "medical battery."\textsuperscript{125} After death, matters became

\textsuperscript{117}See National Commission, supra note 54.
\textsuperscript{118}See id.
\textsuperscript{119}See 45 C.F.R. § 46.210 (1999) [hereinafter UAGA].
\textsuperscript{120}See National Commission, supra note, at 54.
\textsuperscript{121}See 45 C.F.R. § 46.210 (1999).
\textsuperscript{122}See National Commission, supra note 54, at 75.
\textsuperscript{124}See id. at 535.
somewhat more complicated. By will or by contract, one had the right to dispose of one’s own body, but only within the confines of social propriety. In lieu of testamentary instructions by the decedent, state courts would also recognize a so-called “quasi-property” right in the family of a decedent: the right to possession of the cadaver in an undisturbed condition for the purpose of proper burial of the cadaver in a manner consistent with the wishes of the decedent.

In 1965, when organ transplantation was becoming more commonplace, the National Conference of Commissioners on Uniform Law began to organize and modify these common law and statutory sources to directly address the circumstance of organ donation. By 1968, the Commissioners had developed the UAGA, which, as of 1971 had been adopted by all fifty states and the District of Columbia.

127See id. at 439-42
128See National Commission, supra note 54.
The UAGA specifically granted the right of an individual to donate, via a testamentary document, all or part of the individual’s body upon death. In the absence of such documented testamentary intent, the UAGA set up a hierarchy of individuals who could donate a decedent’s organs in an extension of the common law “quasi property” right granted to the decedent’s family. In such situations, however, as Professor Alexander Capron noted in the National Commission’s Report, the right of a decedent’s family to donate a decedent’s organs under the UAGA must be seen in light of common law notions of informed consent.

In the context of donating fetal tissue, however, the mother of an unwanted, aborted fetus does not share the same status as a family member under the common law or the UAGA. By acting to end the life of her fetus, the mother has essentially renounced her maternal interest with respect to the fetus, and consequently has not the standing to provide surrogate consent for the fetus for the purpose of organ donation. Furthermore, state common law and statutory views of the standard of care required from a surrogate decision maker require the surrogate to consider the best interests of the patient.

Prior to 1985, federally-funded research on the dead fetus was comparatively scarce, and largely non-therapeutic. Thereafter, research involving human fetal remains began more and more to take the form of transplantation of fetal tissues into adult research subjects. The premise for these investigations was that fetal tissue, due to its immunological naivete, can incorporate itself without


See UAGA, supra note 118, at 33-34.

See id. at 40.

See National Commission, supra note 54, at 25.

See id. at 25-29.

See id. at 25.

See id. at 26-29.


See Sarkos, supra note 5, at 400.

See id.
rejection into the tissues of diseased adults.\textsuperscript{139} Technically, all fetal remains, including those resulting from miscarriage, could similarly resist rejection from the donee.\textsuperscript{140} However, researchers prefer to use fetal remains which are the most intact, statistically healthy, and recently dead.\textsuperscript{141} As such, fetal tissue for transplantation generally comes as the result of elective abortions, with caesarian section abortions providing the method most scientifically advantageous.\textsuperscript{142}

In the next several years, articles began to appear in the popular press raising the concern that, in order to obtain optimal fetuses for transplantation, researchers might induce the relatives of potential transplant recipients to become pregnant for the sole purpose of abortion.\textsuperscript{143} Concurrently, similar concerns by officials within the NIH led to an internal moratorium on the funding of fetal tissue transplant research pending a review concerning the morality of this research by an external advisory group.\textsuperscript{144} Among the issues to be considered by this group was the morality of utilizing fetal tissue from induced abortions and whether donation of fetal tissue would encourage abortion.\textsuperscript{145}

On September 14, 1988, the Human Fetal Tissue Transplantation Research Panel (Panel) convened to begin what resulted in a six day deliberation of the issues.\textsuperscript{146} Three months later, the majority of the Panel issued its findings, proclaiming as a matter of public policy the moral permissibility of fetal tissue research.\textsuperscript{147} In arriving at this conclusion, the Panel’s majority made the following argument: (1) because \textit{Roe v. Wade}\textsuperscript{148} made abortion legal in the U.S., and (2)

\begin{itemize}
\item \textsuperscript{139}See id.
\item \textsuperscript{140}See id.
\item \textsuperscript{141}See id.
\item \textsuperscript{142}See Gregory Gelfand & Toby R. Levin, \textit{Fetal Tissue Research: Legal Regulations of Human Fetal Tissue Transplants}, 50 Wash. & Lee L. Rev. 647, 650-54 (1992).
\item \textsuperscript{144}See Sarkos, \textit{supra} note 5, at 403.
\item \textsuperscript{145}See id.
\item \textsuperscript{146}See id. at 406.
\item \textsuperscript{147}See id.
\item \textsuperscript{148}See \textit{Roe v. Wade}, 410 U.S. 113 (1973).
\end{itemize}
because fetal tissue transplantation promises considerable medical gains, then (3) transplantation of fetal remains is appropriate so long as the decisions, respectively, to abort and to donate are kept separate.  

By making this argument, the Panel abandoned the reasoning adopted consistently from the Nuremberg Code, from the National Commission’s Report to all other current federal regulation, for an “end-justifies-the-means” utilitarianism. As we have seen, all of these previous works premised their protections on a view of the human research subject as inherently dignified, and then developed regulations designed to support that dignity. The Panel majority, however, deliberately avoided the issue of fetal worth, choosing instead to focus on the scientific benefit of fetal tissue transplantation.

The findings of the Panel would ultimately provide the structure to current federal law governing fetal tissue transplantation, although not until January 22, 1993. On that date, President Clinton lifted the ban instituted by the NIH in 1988, which was previously upheld by executive order through the Reagan and Bush administrations. President Clinton’s directive was incorporated into federal law by the NIH Revitalization Act of 1993, sponsored by Sen. Edward Kennedy, and enacted by the President on June 10, 1993.

The NIH Revitalization Act of 1993 added section 498A to the Public Health Service Act (42 U.S.C. § 289g-1). Pursuant to this section, a woman may donate the remains of the fetus that she has aborted for use in transplantation research, but may not receive any remuneration in cash or in kind for the donation of her aborted child. When, in the euphemism of the law, “providing the tissue,” the woman must assert the following in a signed, written statement: (a) that she has

\[\text{149} \text{See Sarkos, supra note 5, at 406.} \]
\[\text{150} \text{See id.} \]
\[\text{151} \text{See 58 Fed. Reg. 7457 (1993).} \]
\[\text{152} \text{See Sarkos, supra note 5, at 406; Joanna H. Kinney, Restricting Donative Choice: Fetal Tissue Transplantation and Respect for Human Life, 10 J.L. & HEALTH 259, 259 (1996).} \]
\[\text{153} \text{See Sarkos, supra note 5, at 406.} \]
\[\text{154} \text{See id.} \]
\[\text{155} \text{See 58 Fed. Reg. 7457 (1993).} \]
\[\text{156} \text{See National Institutes of Health Revitalization Act, Pub. L. No. 103-43.} \]
\[\text{157} \text{See 42 U.S.C. §§ 289g-1 – 3 (1994).} \]
\[\text{158} \text{See 45 C.F.R. § 46.206(b) (1999).} \]
donated the fetal tissue for use in fetal tissue transplantation research, (b) that she made the donation without any restriction regarding the identity of individuals who may be the transplant recipient of the tissue, and (c) that she has not been informed of the identity of any such recipients.\(^{159}\)

Additionally, the law prohibits the researcher, the abortionist, the prospective donee, and any other "individual involved in the research" from having any influence on (1) the woman's decision to abort, (2) the timing or method of the abortion, and (3) the determination of viability of the fetus.\(^{160}\) The abortionist must also sign a written affidavit which verifies the above and the following: (1) that the woman gave her consent to the abortion prior to her consent to the donation, (2) that the abortion was performed in accordance with applicable State law, and (3) that the abortionist has disclosed to the woman his financial interest in providing the fetal tissue to the researcher.\(^{161}\) Finally, the researcher must put procedures in place to prevent transplantation of the fetus into a blood or adoptive relation.\(^{162}\)

The effect of current U.S. policy on fetal tissue transplantation is the maintenance of a formalistic ignorance between the mother of the aborted fetus and the donee. These "protections" seem merely intended to silence specific criticisms, without addressing underlying issues. For instance, the temporal separation of the choice to abort and the choice to donate eliminates the possibility that a woman's intention to abort will be influenced by considering the social benefits of fetal tissue transplantation. Furthermore, the prohibition against paying the mother for her donation of the aborted fetus prevents an unseemly dead fetus market. Finally, the ban on donation of fetal tissue to relations serves to prevent the distasteful practice of becoming pregnant only in order to abort the fetus for donation to a loved one.

The prevention of these situations notwithstanding, the fetal tissue law and regulations give no consideration to the view of the human

\(^{159}\)See 42 U.S.C. § 289g-1(b) (1994).
\(^{161}\)See 42 U.S.C.A. § 289g-1(c) (1994).
person articulated by the remainder of 45 C.F.R. § 46. As such, the fetal tissue laws and regulations append a caveat to the protections afforded to human subjects. Valid informed consent must still be obtained from the majority of research subjects: general informed consent for healthy subjects, and more protective versions of informed consent for pregnant women, living fetuses, children, and prisoners. However, because the unwanted fetus is “going to die anyway,” and this death is legal, the fetal tissue regulations allow researchers to take advantage of this situation for the advancement of medicine. The aborted fetus is thereby given the status of an exploitable minority.

CONCLUSION

Divorced from a definition of fetal worth, the fetal tissue law and regulations serve merely to assuage taboo, to spare us the nausea of Thyestes. But this is neither the mission nor the history of legal restrictions on the practice of research. Beginning with the Nuremberg Code, the United States started a tradition of placing the human person above scientific progress and medical advance. The Declaration of Helsinki, the National Commission's Report, and the Belmont Report all support this view—affording respect and protection universally to all human beings, born and unborn, healthy and impaired, free and imprisoned. The current 45 C.F.R. § 46 did support this view until 1993 when the Clinton administration introduced a discordant view of humanity into the regulations: that a specific class of human beings, unwanted aborted fetuses, are not worthy of the same respect as other human beings.

Disparate and inconsistent provisions are no stranger to the law. However, regulations of medical research need philosophical consistency in order to prevent abuse of the research subject. A renewed ban on the practice of fetal tissue transplantation by Congress would provide this consistency, and would prevent similar discrimination against other classes of persons.

---

163 See id.
164 See id.
165 See id.