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THE UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS: PROMOTING INTERNATIONAL DISCUSSION ON THE MORALITY OF NON-THERAPEUTIC RESEARCH ON CHILDREN

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Act in such a way that you treat humanity, whether in your own person or in the person of another, always at the same time as an end and never simply as a means.

-- Immanuel Kant, *Grounding for the Metaphysics of Morals*¹

***630** The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent

-- Nuremberg Code²

States Parties shall protect the child against all other forms of exploitation [in addition to economic and sexual exploitation], prejudicial to any aspects of the child's welfare.

-- Convention on the Rights of the Child³

I. Introduction

On October 19, 2005, the United Nations Educational, Scientific, and Cultural Organization (UNESCO) adopted an international declaration of universal norms for bioethics as a possible model for a future multinational treaty.⁴ This Universal Declaration on Bioethics and Human Rights (Declaration) is an important international expression of a moral commitment to fundamental principles governing the development and application of science and technology.⁵ The Declaration is important not only as a precursor to an international convention but also as a contribution to the growing body of international, national, and regional standards for scientific research involving human subjects.⁶ By providing *631 a “universal framework of principles and procedures to guide states in the formulation of their legislation, policies or other instruments in the field of bioethics,” the Declaration could affect national laws and policies on bioethics, even though in its current form it does not bind states to its norms.⁷ Policymakers in states around the world are already responding to the Declaration by considering ways in which to implement its principles domestically. Just a few months after the Declaration's signing, bioethics experts, professors, and national policymakers from 47 states met in Tokyo to discuss its impact and implementation.⁸

Potentially problematic aspects of the Declaration should continue to receive immediate attention in the international discourse on bioethics. One troublesome Declaration provision that this Note will address concerns experimentation on human subjects, such as children, who are incapable of giving consent. The Declaration should spark a reexamination at the international level of the historical and current norms concerning experimentation on children. Any future binding treaty on human experimentation should improve upon the Declaration by including an outright ban of non-therapeutic research on children, while allowing therapeutic research under certain conditions. International standards should protect children from non-therapeutic research, which offers them no direct health benefit. Parental consent, minimal risk limitations, and ethics committee discretion are poor proxies for informed consent, which children lack the legal capacity to give.

*632 After describing the Declaration and its drafting history, this Note will summarize several international, national, and regional guidelines regarding children as research subjects. The Note then argues for a prohibition of non-therapeutic research on children and concludes that international human rights law offers the most appropriate basis for the development of regulations on human experimentation.

II. The Drafting of UNESCO's Universal Declaration on Bioethics and Human Rights (2005)

The Declaration's origins can be traced back to October 2001, when participants in the Round Table of Ministers of Science on “Bioethics: International Implications” invited UNESCO to examine the possibility of developing a universal instrument on bioethics, with UNESCO's Universal Declaration on the Human Genome and Human Rights as a starting point.⁹

UNESCO is a specialized agency of the United Nations and was “[f]ounded on the belief that there can be no peace without the intellectual and moral solidarity of humankind.”¹⁰ From the 1980s to the late 1990s, critics frequently described UNESCO as the most “politicized” of the UN specialized agencies.¹¹ Recently, however, UNESCO has undergone a revitalization, partly because of consensus within the organization with respect to its 1997 Universal Declaration on the Human Genome and Human Rights.¹²

In 1993, UN member states gave UNESCO a mandate to work in the area of bioethics.¹³ After the UN General Assembly endorsed UNESCO's *633 Universal Declaration on the Human Genome and Human Rights in 1998 and UNESCO's General Conference unanimously adopted the International Declaration on Human Genetic Data in 2003, the General Conference decided in October 2003 to begin work on a declaration concerning universal norms in bioethics.¹⁴ The UNESCO Director-General entrusted the International Bioethics Committee (IBC) with initiating the Declaration's drafting.¹⁵ The IBC, created in 1993, is a body of 36 independent experts, appointed by the Director-General of UNESCO, with the mandate to "follow[] progress in the life sciences and its applications in order to ensure respect for human dignity and freedom."¹⁶ The UNESCO General Conference selects the experts, who serve four-year terms, by considering cultural diversity, balanced geographical representation, and the state nominations of qualified specialists in the life, social, and human sciences.¹⁷ The Director-General convenes the IBC at least once a year.¹⁸ The Declaration's elaboration also involved UN member states, the UN itself, specialized UN agencies, intergovernmental organizations such as the UN Inter-Agency Committee on Bioethics, nongovernmental organizations, and national bodies and specialists.¹⁹ The drafters used international human rights law as the "essential framework" and "starting point for the development of bioethical principles."²⁰

The IBC engaged UNESCO member states and intergovernmental and nongovernmental organizations during the nearly two years of drafting and finalizing the Declaration. Beginning on January 20, 2004, the IBC sent questionnaires to the 190 UNESCO member states to gather their preliminary views on the scope and structure of the Declaration.²¹ By June 2004, 67 member states had completed and returned questionnaires.²² *634 From April 27-29, 2004, the IBC held an Extraordinary Session to conduct hearings on the scope and structure of the Declaration, with participation by approximately 200 representatives of intergovernmental organizations, international nongovernmental organizations, and national bioethics committees from 70 states.²³ From April 30, 2004, through January 2005, the IBC drafters met six times at UNESCO Headquarters in Paris and elaborated four draft outlines.²⁴ During this period, the UN Inter-Agency Committee on Bioethics and the Intergovernmental Bioethics Committee (IGBC) each met twice to discuss the drafts.²⁵

The IGBC, created in 1998 under the auspices of the IBC, consists of 36 member states whose representatives meet at least once every two years to examine the advice and recommendations of the IBC.²⁶ The IGBC submits its opinions to the IBC and the Director-General of UNESCO for transmission to member states, UNESCO's Executive Board, and UNESCO's General Conference.²⁷ UNESCO's General Conference elects the 36 member states, which serve terms of four years, again considering cultural diversity and balanced geographical representation.²⁸ Participation and attendance at both IBC and IGBC sessions are open to UNESCO member states, the UN, and other organizations of the UN system that *635 have an agreement with UNESCO for reciprocal representation.²⁹ At the invitation of the Director-General, non-member states with a permanent observer mission at UNESCO and international governmental and nongovernmental organizations may also attend the meetings.³⁰

From March 2004 to January 2005, the IBC drafters conducted national and regional consultations with experts.³¹ On August 23-24, 2004, the IBC heard the views of representatives of religious and spiritual perspectives: Confucianism, Judaism, Hinduism, Islam, Buddhism, and Catholicism.³² On October 19, 2004, UNESCO launched a written consultation process that generated 75 contributions from interested parties.³³ On February 9, 2005, the IBC finalized and approved the Preliminary Draft Declaration on Universal Norms on Bioethics.³⁴ On April 4-6, 2005, bioethics experts from around the globe met at the first intergovernmental meeting of experts to finalize a draft of the Declaration.³⁵ The next month, 55 member states met to "pave the way for consensus," reconciling their often conflicting views.³⁶ On June 20-24, 2005, the second intergovernmental meeting of experts finalized the draft declaration.³⁷ Finally,

on October 19, 2005, during its 33rd session, the General Conference of UNESCO adopted by acclamation the Universal Declaration on Bioethics and Human Rights.³⁸

From the inception of the drafting process, the IBC maintained that the international instrument would not take the form of a treaty but rather a nonbinding declaration expressing broad principles.³⁹ At the same time, the IBC acknowledged that a declaration could serve as a model for a binding treaty:

***636** The tradition of international instruments on human rights is that treaties are preceded by declarations which contain guidelines and an invitation to States to follow them. This was the case with the two International Covenants of 1966 on Civil and Political Rights and on Economic, Social and Cultural Rights, the International United Nations Convention on the Elimination of All Forms of Racial Discrimination (1965), the United Nations Convention on the Elimination of All Forms of Discrimination Against Women (1979) and the United Nations Convention on the Rights of the Child (1989).⁴⁰ The Declaration's provisions thus demand close scrutiny as they are refined by international debate into a potential treaty.

III. The Substance of UNESCO's Universal Declaration on Bioethics and Human Rights (2005)

The Declaration addresses its provisions to states, and its scope comprises “ethical issues related to medicine, life sciences and associated technologies as applied to human beings.”⁴¹ Its aims are, *inter alia*, to provide a framework of principles to guide states in the formulation of bioethics legislation and policies; to promote respect for human dignity and protect human rights; to foster pluralistic dialogue about bioethical issues; to promote equitable access to medical, scientific, and technological developments (with particular attention to the needs of developing states); and to underline the importance of biodiversity.⁴² The Declaration requires respect for the following principles: human dignity and human rights; maximization of benefit and minimization of harm to patients, research participants, and other affected individuals; autonomy and individual responsibility; informed consent to medical intervention and scientific research; special protection for persons without the capacity to consent; human vulnerability and personal integrity; privacy and confidentiality; equality, justice, and equity; non-discrimination and non-stigmatization; cultural diversity and pluralism; solidarity and cooperation; social responsibility and health; the sharing of benefits from scientific research; protection of future generations; and protection of the environment, the biosphere, and biodiversity.⁴³ Article 27 is a general exception provision that allows a state to limit these principles, by law, “in the interest of public safety, for the investigation, detection and ***637** prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others.”⁴⁴ Moreover, any law that limits the principles of the Declaration must itself be consistent with international human rights law.⁴⁵ After sketching its principles in broad terms, the Declaration provides guidelines for their application, calling for transparent decisionmaking by ethics committees comprising members of diverse backgrounds, among other procedural ideals.⁴⁶ The Declaration also furnishes standards for transnational research practices.⁴⁷

The Declaration relies on UNESCO, the IBC, the IGBC, and member states to promote and disseminate its principles and procedures in accordance with international human rights law.⁴⁸ In honor of its commitment, on December 15, 2005, UNESCO launched the Global Ethics Observatory (GEO), comprising four databases of experts in ethics, ethics institutions, ethics teaching programs, and ethics-related legislation and guidelines.⁴⁹ The Declaration has already helped create a network of experts and interested persons who will continue to refine its articles. UNESCO hopes the

Declaration will “inspire and stimulate further ethics debates and their resolution within the member states in order to expand the scope of this declaration and its usefulness.”⁵⁰

One area requiring further consideration encompasses the Declaration's standards for experimentation on persons who are incapable of giving informed consent--especially children. These provisions need strengthening and clarification.

IV. Children as Research Subjects under the Declaration

The Declaration requires “prior, free, express and informed consent” of the person who will serve as a subject of scientific research.⁵¹ The information should be “adequate” and “comprehensible,” and the human subject should be allowed to withdraw his consent at any time and for *638 any reason.⁵² Some people, however, such as the mentally handicapped and children, lack the legal capacity to consent to treatment or experimentation.⁵³ This Note focuses on children.

The Declaration's protections for children should be analyzed according to two categories of research: therapeutic and non-therapeutic. A scientist performs therapeutic research when she approaches a child with the mindset of a physician--that is, she conducts an experiment because of its expected therapeutic effects on the child. This necessarily means that the child suffers from the condition the researcher hopes to alleviate and illuminate through her experiment. Gathering data on a new procedure, medicine, or biochemical reaction is not the primary aim of therapeutic research, although it might be a useful byproduct. The Declaration allows therapeutic research on children so long as a legally-defined surrogate gives proxy consent on behalf of the child in accordance with domestic law and international human rights law.⁵⁴ UNESCO's Explanatory Memorandum clarifies that “the domestic law of Member States should provide for consent to be given by members of the family, an official or court where the person concerned [is] incapable of doing so.”⁵⁵ Moreover, “the [child] should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent.”⁵⁶

In contrast, a U.S. state court has defined non-therapeutic research as research that

generally utilizes subjects who are not known to have the condition [that] the objectives of the research are designed to address, and/or is not designed to directly benefit the subjects utilized in the research, but, rather, is designed to achieve beneficial results for the public at large (or, under some circumstances, for profit).⁵⁷

In a non-therapeutic experiment, the researcher does not approach the child with the mindset of a physician but rather acts solely as a scientist seeking to gather data for the benefit of others. The Declaration's treatment of non-therapeutic research seems incoherent. First, the Declaration categorically states that research involving a child should only be *639 conducted for the child's “direct health benefit” (i.e., it permits only therapeutic research). Then the Declaration allows experiments with no potential direct health benefit (i.e., non-therapeutic research) “by way of exception”--without defining the “exception.”⁵⁸ The Declaration does provide a few protective measures for children in the context of non-therapeutic research: A surrogate must provide proxy consent on behalf of the child, and children may serve as subjects of non-therapeutic research only if the researcher exercises the “utmost restraint, exposing the [child] only to a minimal risk and minimal burden.”⁵⁹ Additionally, non-therapeutic research must be “compatible with the protection of the individual's human rights,” and “[r]efusal of such persons to take part in research should be respected.”⁶⁰

The second half of this Note argues that the Declaration should have banned non-therapeutic research on children altogether; an experiment exposing a child to even minimal risk should be prohibited if it offers no direct therapeutic

benefit. In this regard, however, the Declaration is not inconsistent with most prior international and Council of Europe approaches to non-therapeutic research involving children.

V. International and Council of Europe Standards

Legal protections for research subjects in the past century began with the trial of 23 Nazi scientists for war crimes and crimes against humanity at Nuremberg, Germany, immediately after the Second World War.⁶¹ The trial judges, American attorneys appointed by the Military Governor of the American Zone, promulgated their opinions as international criminal law.⁶² Sixteen of the defendants were found guilty, and seven were hanged.⁶³ The Nuremberg judges employed a set of 10 standards for medical research, which have come to be known as the Nuremberg Code.⁶⁴ Of the 10 points of the Nuremberg Code, the absolute requirement of informed consent receives the most treatment and the first position:

***640** 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 constraint 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.⁶⁵

By requiring that the person involved have “legal capacity to give consent,” the Nuremberg Code effectively prohibits any research on children, whether therapeutic or non-therapeutic, since they cannot give legal consent. The Nuremberg Code requires that consent be voluntary, competent, informed, and comprehending.⁶⁶ Strongly interpreted, this requirement bars surrogate consent; had it envisioned otherwise, the Nuremberg Code would have provided distinct guidelines for research on incapacitated adults and children.

By itself, the Nuremberg Code has no legally binding force, and no international or domestic legislative body has ever adopted it.⁶⁷ It is the product of a military tribunal in response to a specific historical situation, and drafters of subsequent norms of medical research regarded its absolute requirement of consent as undesirable.⁶⁸ Departing from the Nuremberg Code's strong consent principle, later international standards imply that research involving children may be desirable if it is crucial to developing cures for childhood ailments.

Western European physicians established the World Medical Association (WMA) in 1946 in direct response to the “medical war crimes” perpetrated by Nazi scientists.⁶⁹ In 1964, the WMA adopted the Helsinki Declaration on Ethical Principles for Medical Research Involving Human Subjects,⁷⁰ which deviates from the Nuremberg Code by allowing experimentation on children provided a surrogate gives informed consent ***641** and the child assents.⁷¹ “Assent” means simply any agreement to participate in an experiment with less than full understanding, while informed consent requires full understanding.⁷² Unlike the Nuremberg Code, the Helsinki Declaration distinguishes between “medical care” and “medical research” and permits medical research in conjunction with medical care “only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value.”⁷³ In this respect, it is questionable whether the Helsinki Declaration permits non-therapeutic research at all, since it allows “medical research” only if the research has some therapeutic value. Like the Nuremberg Code, the Helsinki Declaration requires the patient's informed consent for both medical care and medical research.⁷⁴ Yet it departs from the Nuremberg Code by permitting, for a legally incompetent minor, “informed consent from the legally authorized representative in accordance with applicable law” in

lieu of the child's consent.⁷⁵ The Declaration also requires the researcher to obtain the child's "assent," but only when the child "is able to give assent to decisions about participation in research."⁷⁶ As a set of self-imposed professional regulations, the Helsinki Declaration is not binding on members of the World Medical Association.⁷⁷ It has, however, influenced the formation of national legal requirements.⁷⁸

To give effect to the Helsinki Declaration, in 1993 the Council for International Organizations of Medical Science (CIOMS) and the World Health Organization (WHO) issued International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS Guidelines).⁷⁹ The WHO and UNESCO jointly established the CIOMS in 1949 as a *642 nongovernmental, nonprofit representative of the international biomedical community.⁸⁰ Unlike the Helsinki Declaration, the CIOMS Guidelines explicitly permit non-therapeutic research on children under certain conditions.⁸¹ David Weisstub, Simon Verdun-Jones, and Janet Walker summarize the conditions as follows: (1) researchers will not involve children in experiments that might equally well be carried out with adults; (2) the purpose of the research is to obtain knowledge relevant to the health needs of children; (3) a parent or legal guardian of the child has given proxy consent; (4) researchers have obtained the consent of the child to the extent of the child's capabilities; (5) researchers must respect the child's refusal to participate in research unless the research provides the child with therapy for which there is no medically-acceptable alternative; (6) the risk presented by an experiment not intended to benefit the child is low and commensurate with the importance of the experiment's results; and (7) experiments intended to provide therapeutic benefit must be at least as likely to provide benefits to the child as any available alternative.⁸² Like the Helsinki Declaration, the CIOMS Guidelines are not binding.

The only binding treaty on bioethics is European, not international. On April 4, 1997, the Committee of Ministers of the Council of Europe⁸³ signed a binding treaty governing research on human subjects.⁸⁴ The *643 Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine took effect on December 1, 1999, and has been ratified by 19 European states.⁸⁵ Like the CIOMS Guidelines and UNESCO's recent Declaration, the Council of Europe's Convention allows, in exceptional cases, non-therapeutic research on children:

Exceptionally . . . where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised . . . if the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition, [and] the research entails only minimal risk and minimal burden for the individual concerned.⁸⁶

The Convention also provides additional safeguards: The child's legal representative must provide informed consent, it must be impossible to perform the experiments on adults capable of giving consent, the child must assent, and the research must entail only minimal risk and minimal burden.⁸⁷ These safeguards afford greater protection to children than the UNESCO Declaration, which requires only that non-therapeutic research on children be conducted "with the utmost restraint, exposing the [child] only to a minimal risk and minimal burden" and "subject to the conditions prescribed by law and compatible with the protection of the individual's human rights."⁸⁸

The same year the Council of Europe signed its Convention on Human Rights and Biomedicine, UNESCO adopted the Universal Declaration on the Human Genome and Human Rights.⁸⁹ At its adoption, the Declaration on the Human Genome was the "most thorough global initiative . . . addressing the need to protect human rights with respect to genetic

advances.”⁹⁰ The Declaration on the Human Genome allows both *644 therapeutic and non-therapeutic research involving children and their genome. The Declaration also allows interventions that may alter a child's genome after consultation with a third party who is “guided by the person's best interest.”⁹¹ Experimentation on such vulnerable persons “may only be carried out for his or her direct health benefit” or if “[it] is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition.”⁹² The Declaration has received criticism for its alleged failure to adequately address human rights considerations.⁹³ Some critics argue that it elevates the protection of the human genome over the protection of individual human rights.⁹⁴

No international, European, or U.S. law or standard has adopted the Nuremberg Code's absolute requirement of informed consent and effective ban on any and all research involving children. Thus, UNESCO's permission of non-therapeutic research involving children in its recent Declaration on Bioethics and Human Rights is not out of line with the other post-Nuremberg standards discussed above. This makes sense, given that UNESCO's prior Declaration on the Human Genome provided some inspiration for the Declaration on Bioethics and Human Rights and that UNESCO regards the Helsinki Declaration, the CIOMS Guidelines, and the Council of Europe's Convention on Human Rights and Biomedicine as identifying “acknowledged principles and standards commonly adopted at the international level.”⁹⁵ The Declaration on Bioethics and Human Rights classifies non-therapeutic research on children as an “exception” and requires the following: (1) surrogate consent in accordance with domestic law; (2) the “utmost restraint” by the researcher; (3) exposure of the child to no more than a minimal risk and minimal burden; (4) compatibility with the protection of the child's human rights; and (5) respect for the child's refusal to take part in the research (assent).

Even though the Declaration provides these safeguards for research on children, the Nuremberg Code's overarching emphasis on informed consent should not be forgotten. The Declaration on Bioethics and Human Rights presents an opportunity to revisit the principles underlying informed consent and reevaluate whether researchers should ever subject children to non-therapeutic experimentation.

***645 VI. The Prohibition of Non-Therapeutic Research Involving Children**

Non-therapeutic research involving children should be prohibited for two main reasons. First, individuals who lack the capacity to consent should not be treated as instruments for the service of society. Second, parental consent, “minimal risk” limitations, and ethics committee discretion do not provide adequate protections for children.

A. Children and Informed Consent

Psychiatrist Jay Katz wrote in his exhaustive anthology and casebook, *Experimentation with Human Beings* (called “the most thorough collection of materials on research ethics and law ever assembled between two covers”⁹⁶), that “the concept of informed consent has been accepted in case and commentary as a cardinal principle for judging the propriety of research with human beings.”⁹⁷ Informed consent derives from the principle of autonomy, one of the four principles--along with beneficence, nonmaleficence, and justice--from which contemporary medical ethics has grown, according to Beauchamp and Childress in *Principles of Biomedical Ethics*.⁹⁸ The principle of autonomy is central to both biomedicine and human rights law.⁹⁹

Two conditions are essential in most theories of autonomy: (1) liberty (lack of control by others) and (2) agency (capacity for independent action).¹⁰⁰ Children are incapable of giving informed consent because they lack complete autonomy.¹⁰¹ Because of their vulnerability, immaturity, lack of knowledge, and physical weakness with respect to adults, children require care from others and are therefore partially controlled by others.¹⁰² Children do not have the capacity for fully independent action. This does not mean, however, that children lack all autonomy. They are capable of making

some decisions for themselves, and they will one day become fully autonomous adults. The law should respect children's nascent, potential autonomy.

Informed consent and autonomy are linked to notions of human dignity and human rights. In its Explanatory Memorandum, UNESCO *646 describes human dignity as follows: "Respect for human dignity flows from the recognition that all persons have unconditional worth, each having the capacity to determine his or her own moral destiny. Showing disrespect to human dignity could lead to the instrumentalization of the human person."¹⁰³ The Declaration's third article, on "Human Dignity and Human Rights," declares that "[t]he interests and welfare of the individual should have priority over the sole interest of science or society."¹⁰⁴ Thus, placing the interests of science or society over the interests and welfare of a child turns the child into an instrument. Such instrumentalization occurs in a non-therapeutic context because the child, who is incapable of granting consent, receives no benefits from the research; he merely gives of himself (sometimes quite literally) to science or society.¹⁰⁵ This is exploitation, the use of someone for the benefit of another.¹⁰⁶ The United Nations Convention on the Rights of the Child of 1989 requires states parties to "protect the child against all . . . forms of exploitation prejudicial to any aspects of the child's welfare."¹⁰⁷ What is the utilization of children, at the mercy of a surrogate's consent, for non-therapeutic research if not exploitation in violation of the Convention on the Rights of the Child?

B. Exploitation and Children

Historically, the "powerless and disadvantaged," including children, have been most likely to suffer exploitation through unethical human experimentation.¹⁰⁸ Hippocrates is said to have performed an experiment on a boy; while removing splinters from the boy's exposed cortex, he is said to have scratched the surface of the cortex with his fingernail to observe the resulting movements on the other side of the boy's body.¹⁰⁹ Prisoners have been used throughout history for experimentation.¹¹⁰ In *647 the late 1980s in New Zealand, the low social status of female subjects was shown to be a factor in their selection by doctors for an experiment in which treatment was withheld from women with carcinoma in situ of the cervix.¹¹¹ The first mother of a "test-tube baby" was a factory worker who was not even informed that she was the subject of an experiment.¹¹²

During the past 50 years, even after U.S. judges expounded the Nuremberg Code, non-therapeutic experiments have taken place in the United States to the detriment of children's dignity. From 1956 to 1972, researchers performed experiments on children at Willowbrook State School, an institution for developmentally disabled children in Staten Island, New York.¹¹³ Due to overcrowding and lack of toilet training, virtually all susceptible children contracted a mild strain of hepatitis within six to twelve months after moving to the school. Saul Krugman, Joan Giles, and their team of researchers intentionally infected 750 to 800 healthy children at Willowbrook with strains of the hepatitis virus, rationalizing that the children would probably contract the virus within a year at the school anyway. Krugman and Giles sought to study the incubation period of hepatitis and test the effectiveness of gamma globulin in treatment.¹¹⁴ Although the U.S. physician Henry Beecher called this experiment "ethically dubious" in 1966, nothing was done to stop the experiments, and the work continued. After all, the study had approval from the New York State Department of Mental Hygiene, the New York State Department of Mental Health, and the human experimentation committees at the New York University School of Medicine and the Willowbrook School.¹¹⁵ Criticism did not halt the experiments until after 1970, when Beecher questioned them again in his book, *Research and the Individual*, ethicist Paul Ramsey lambasted them, and Dr. Stephen Goldby published a critical letter in *The Lancet*.¹¹⁶ In his letter, Goldby called the work "unjustifiable" and asked, "Is it right to perform an experiment on a normal or mentally retarded child when no benefit can result to the individual?"¹¹⁷

In fact, Krugman and Giles justified their research by contending that it offered therapeutic benefits to the subjects. They claimed the children would receive excellent medical care, avoid exposure to other *648 diseases, and acquire immunity from stronger forms of hepatitis.¹¹⁸ Such explanations futilely grasp at a therapeutic hook on which to hang questionable research--and do not justify intentionally infecting children with hepatitis. Although Krugman and Giles obtained written informed consent from the children's parents, some critics have suggested the parents did not understand the nature of the study.¹¹⁹ Surrogate consent thus did not prove much of a safeguard against this humiliating subjection of healthy children to the hepatitis virus. The willingness of researchers to use children in such a fashion, and the readiness of officials to offer support for the experiments, should caution against extending any latitude for non-therapeutic research.

Even more egregious than the Willowbrook case were the Human Radiation Experiments, which the U.S. government funded and conducted on more than 4,000 unsuspecting individuals from 1944 to 1974.¹²⁰ Although many studies did not significantly harm the subjects, several exposed children to an increased risk of cancer over their lifetime, and the experiments as a whole directly or indirectly caused the deaths of hundreds of adult subjects.¹²¹ Yet the U.S. government rationalized the experiments by claiming they might help the United States win or survive a nuclear war.¹²² In one of the studies, conducted from 1945 to 1947 at the Manhattan District Hospital in Oak Ridge, Tennessee, researchers injected 18 patients with plutonium.¹²³ One subject was only five years old.¹²⁴ The patients did not give their informed consent, and the researchers neither sought surrogate consent nor uttered the word "plutonium" to the patients.¹²⁵

In 1961, researchers from Harvard Medical School, Massachusetts General Hospital, and Boston University School of Medicine administered radioactive iodine to 70 children at the Wrentham State School, a Massachusetts facility for developmentally disabled children.¹²⁶ The scientists had received funding from the U.S. Public Health Service to test a proposed countermeasure to nuclear fallout, even though children are more susceptible than adults to harm from low levels of radiation.¹²⁷ The *649 non-therapeutic research described by the Advisory Committee on Human Radiation Experiments also included experiments involving the use of iodine 131 for the evaluation of thyroid function.¹²⁸ Little was known at the time about the causal relationships between radiation exposure and cancer and between iodine 131 and thyroid cancer, and the researchers may have thought they were exposing the children to only minimal risk.¹²⁹

D. "Minimal Risk" Limitations as Inadequate Protections for Children

Leonard Glantz describes a 1997 research study that exemplifies the "vagueness" of the concept of minimal risk when applied to research on children.¹³⁰ Scientists conducted a "minimal-risk" experiment on 34 impoverished African American and Hispanic boys from 7 to 11 years of age to study the relationship of adverse-rearing conditions, aggression, and serotonin in children.¹³¹ The scientists selected the boys solely because they were the younger brothers of "delinquents."¹³² The subjects underwent psychiatric assessments to detect oppositional defiant disorder, conduct disorder, or attention-deficit hyperactivity disorder.¹³³ The investigators ensured the boys were free of all medications for at least one month, placed them on a low-monoamine diet for four days, and had the boys fast for the night before the test (referred to as the "challenge").¹³⁴ On the day of the "challenge," researchers inserted intravenous catheters into the boys, and they remained in place for approximately five and a half hours.¹³⁵ The researchers orally administered fenfluramine hydrochloride to the boys and took blood samples every hour from the catheters.¹³⁶ The researchers conducted the experiments "to replicate results that have suggested that aggression in prepubertal children is positively correlated with central serotonergic activity."¹³⁷

This study should not have been performed, as it offered the boys no possible benefit and subjected them to discomfort and possible harm. *650 The social dimensions of the experiment (the boys' status as minorities and younger brothers of delinquents) and the probable incompleteness of the parents' understanding highlight the boys' instrumentalization. Moreover, the drug, fenfluramine hydrochloride, had previously been documented to cause adverse reactions in adults.¹³⁸ Glantz asks, "Why should a parent have the authority to submit a child to such nonbeneficial procedures?"¹³⁹

It is unclear why the researchers in the experiment described above identified the risk level to the boys as "minimal." Definitions of "minimal risk" pose problems themselves. U.S. federal regulations define "minimal risk" as a level of risk where "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."¹⁴⁰ Glantz points out that many adolescents engage in sex without condoms and many children ride bicycles without helmets, then questions whether research studies that randomize condom use in a group of adolescents or randomize helmet use in bicycle-riding children would be "minimal risk" studies--after all, such studies only expose the minor subjects to risks occurring in everyday life.¹⁴¹ Glantz concludes that "[g]iven the variability in how minimal risk can be applied . . . a technical reading of the definition in the federal regulations would permit some research that would present substantial risks to [some] children."¹⁴²

E. Surrogate Parental Consent as Inadequate Protection for Children

Unfortunately, because of ignorance, neglect, mistake, or some other reason, parents cannot always be trusted to act in the best interests of their child. In a 1953 experiment, a mother gave her surrogate consent for scientists to study the influence of phenylalanine intake on her two-year old daughter's phenylketonuria, a condition the doctors suspected had caused her developmental disability.¹⁴³ When the scientists instructed the mother to give her daughter a special diet low in phenylalanine, the mother reported that the girl's mental state improved within a few *651 months: "she learnt to crawl, to stand, and to climb on chairs; her eyes became brighter; her hair grew darker; and she no longer banged her head or cried continuously."¹⁴⁴ Thus far, the doctors had been performing therapeutic research. The scientists did not conclude the experiment at the therapeutic result, however. Instead, they reintroduced phenylalanine into the child's diet to determine whether the clinical improvement was due to the diet and not to natural development.¹⁴⁵ They did this without the mother's knowledge and noted:

A definite deterioration in the child's condition ensued, the mother reporting with distress that her daughter had lost in a few days all the ground gained in the previous ten months; that within six hours of starting the fresh supply of "food" the child had begun to cry and to bang her head as in the past, and within twenty-four hours could no longer stand and could scarcely crawl.¹⁴⁶

Then, even after she had learned of the deception and seen the deleterious effect of phenylalanine on her child, the mother agreed to allow the doctors to repeat the same experiment at a hospital, where the girl's biochemical reactions could be more frequently recorded. After observing the girl improve on a low-phenylalanine diet for a few days, the scientists again increased her phenylalanine intake. Once again, "[w]ithin twenty-four hours the patient became irritable and drowsy, lost interest in her food and surroundings, developed facial eczema, and salivated profusely. She also became ataxic and vomited repeatedly. By the sixth day she could no longer stand or crawl."¹⁴⁷ Fortunately, the child "almost completely recovered" within three weeks after the researchers discontinued the additional phenylalanine. Yet the researchers did not know with certainty that the girl would recover at all. If the girl had not recovered, how could the mother have justified, morally, her consent to the second imposition of this phenylalanine diet?

Another problem with allowing surrogate consent for non-therapeutic research on children is linked to the inequities in research itself. Studies show that better educated and wealthier individuals are more likely to refuse to consent to experimentation.¹⁴⁸ Conversely, in research on children, *652 studies show that parents who consent to research on their children have little education and are underrepresented in the professional and managerial occupations.¹⁴⁹ Such parents may not be well-equipped to provide truly informed consent on behalf of their children in any case.

F. Institutional Review Boards as Inadequate Protection for Children

In the United States, Institutional Review Boards, or IRBs, are responsible for approving medical research involving human subjects and determining the guidelines for such research.¹⁵⁰ Some commentators argue that IRBs tend to underestimate risk.¹⁵¹ Reasons for this possibility include the fact that IRB members may be researchers themselves and so may be biased in favor of the value of research.¹⁵² Second, IRB members work in a group to classify the risks of research, and empirical evidence has shown that groups are more willing to take chances than the average individual within the group.¹⁵³ Dale Moore, an IRB member, provides telling insight into the mindset of a medical researcher:

One of my colleagues sometimes relates an argument she had with an investigator during an IRB meeting. She insisted on the disclosure of a particular risk and the investigator vehemently resisted her demand. Finally, in great frustration, the investigator exclaimed: "If I tell them what you want me to, then they won't want to participate!" Her response: "That's precisely the point!"¹⁵⁴ Sometimes medical researchers lose sight of protecting their research subjects in favor of conducting the research.

***653 G. Two U.S. State Court Cases Limiting Non-Therapeutic Research Involving Children**

In 1995, a New York state court limited the use of children and mentally disabled individuals as research subjects. In *T.D. v. New York State Office of Mental Health*, after the lower court observed that "we have had deplorable instances of over-reaching medical research in this country,"¹⁵⁵ the appellate court, affirming the lower court's decision, held that

a parent or guardian . . . may not consent to have a child submit to painful and/or potentially life-threatening research procedures that hold no prospect of benefit for the child and that may have the same result as a denial of necessary medical treatment. . . . We emphasize, however, that our holding is limited to non-therapeutic greater than minimal risk experimentation.¹⁵⁶ The court did not prohibit all non-therapeutic research but only non-therapeutic research posing greater than minimal risk.

In 2001, the Maryland Court of Appeals went even further than the T.D. court and held that a "parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject."¹⁵⁷ In response to the conduct of the Kennedy Krieger Institute (KKI) and Johns Hopkins University (Hopkins), the court in *Grimes v. Kennedy Krieger Institute, Inc.* followed the informed consent principles of the Nuremberg Code as the "preferred standard for assessing the legality of scientific research on human subjects."¹⁵⁸ In that case, the Environmental Protection Agency paid \$200,000 to KKI, affiliated with Hopkins, to measure the amount of lead in the blood of healthy children living in lead-contaminated housing.¹⁵⁹ The researchers performed the study on children because they are particularly susceptible to lead poisoning, and they recruited families with small children to

live in selected lead-contaminated houses.¹⁶⁰ Although the parents gave their written surrogate *654 consent to the experiment, the court was troubled that financial incentives, such as food coupons, may have driven the consent.¹⁶¹ The court held that “children should not have been used for the purpose of measuring how much lead they would accumulate in their blood while living in partially abated houses to which they were recruited initially or encouraged to remain, because of the study.”¹⁶²

Grimes is controversial, both because commentators consider it more restrictive than the federal regulations and because it assigns different levels of permissibility to therapeutic and non-therapeutic research.¹⁶³ Nevertheless, cases such as Grimes and T.D. show that support for a prohibition against non-therapeutic research involving children is within the bounds of legal reality. The UNESCO Declaration should serve as inspiration to reexamine the ethics of submitting children to experimentation that offers them no benefit.

VII. Conclusion

International human rights law is the appropriate context for ongoing discussions regarding experimentation on children. UNESCO has contended that “modern bioethics is indisputably grounded in the values enshrined in the Universal Declaration of Human Rights and the human rights treaties that have followed it.”¹⁶⁴ Any exploitation or instrumentalization of children is a denial of human rights and as such concerns the entire international community; accordingly, the community should address these violations through an international convention on bioethics. The necessity for this international discussion is increasing, as more biomedical experiments span several states and as tissue collections, DNA samples, and genetic data involved in medical research flow across national borders.¹⁶⁵ The December 2005 IBC conference in Tokyo was a propitious start to such discussion and highlighted informed consent as an area in need of further elaboration.¹⁶⁶ Of particular relevance in future dialogues will be different cultural perspectives on the role of the individual in “consent” and the relationship between the individual and the *655 public interest.¹⁶⁷ Respect for cultural pluralism, however, should not permit researchers to use children in scientific experiments with no direct health benefit, particularly since, by the very nature of “experiment,” no researcher can know the attendant risks with any certainty.

Footnotes

- a1 J.D. Candidate, University of Michigan Law School, 2006; B.A., summa cum laude, Indiana University. I am very grateful to Professor Joseph Vining for his generous time and helpful comments on this Note, as well as to Brandon Reavis, Anat Grosfeld, Adrian Leipsic, and my parents for their editing and input. Mistakes and omissions are mine.
- 1 Immanuel Kant, *Ethical Philosophy* 1, 36 (James W. Ellington trans., Hackett Publ'g Co. 1983) (1785).
- 2 See 2 Trials of War Criminals Before the Nuerenberg [sic] Military Tribunals under Control Council Law No. 10 181-82 (U.S. Gov't Printing Office 1950) (containing full text of what has come to be known as the Nuremberg Code), available at <http://www.nihtraining.com/ohsrsite/guidelines/nuremberg.html> (last visited Mar. 18, 2006).
- 3 Convention on the Rights of the Child art. 36, G.A. Res. 44/25, U.N. Doc. A/RES/44/25 (Nov. 20, 1989), available at <http://www.unhchr.ch/html/menu3/b/k2crc.htm>.
- 4 U.N. Educ., Sci., & Cultural Org. [UNESCO], Universal Declaration on Bioethics and Human Rights, General Conference of UNESCO, 33rd sess. (Oct. 19, 2005), available at http://portal.unesco.org/shs/en/file_download.php/46133e1f4691e4c6e57566763d474a4dBioethic_EN.pdf [hereinafter Declaration]. See UNESCO, Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics, U.N. Doc. SHS/EST/02/CIB-9/5 (rev.3) (June 13, 2003), available at http://portal.unesco.org/shs/en/file_download.php/3880b5df8e0530134614da8d65c39d6aFinrep_UIB_en.pdf [hereinafter Report of the IBC]; Intersections of

Medical Ethics and International Human Rights Workshop (Austl. Sept. 2-4, 2004), at [http:// law.anu.edu.au/nissl/ethics.bg.pdf](http://law.anu.edu.au/nissl/ethics.bg.pdf) (recognizing the possibility of a subsequent international convention on bioethics).

5 Koïchiro Matsuura, Dir.-Gen., UNESCO, Address at the twelfth session of the IBC, Tokyo, Japan, U.N. Doc. DG/2005/201 (Dec. 15, 2005), at [http:// unesdoc.unesco.org/images/0014/001428/142832e.pdf](http://unesdoc.unesco.org/images/0014/001428/142832e.pdf).

6 The Declaration could evolve into customary international law, which is binding on states, as did the Universal Declaration of Human Rights. See T.A. Faunce, Will International Human Rights Subsume Medical Ethics? Intersections in the UNESCO Universal Bioethics Declaration, 31 J. Med. Ethics 173-78 (2005).

7 Declaration, *supra* note 4, art. 2(a).

8 List of Participants, twelfth session of the IBC, Tokyo, Japan, Dec. 15-17, 2005, at http://portal.unesco.org/shs/en/file_download.php/4e6c6bce3e98ac1dc52bf92cb7433537Particip_12+IBC.pdf. The participants at this conference, the twelfth session of the UNESCO IBC, came from thirty countries: Argentina, Australia, Canada, the Democratic Republic of Congo, Estonia, France, Germany, Hungary, India, Israel, Italy, Jamaica, Japan, Jordan, Lithuania, Mexico, Morocco, New Zealand, the Netherlands, Nigeria, Pakistan, the Philippines, Portugal, Spain, Syria, Turkey, Uganda, Uruguay, Venezuela, and Vietnam. The participants included research fellows, professors of medicine, philosophy and natural sciences, chairpersons of national bioethics committees, and members of various ethics councils. *Id.* Also participating were twelve guest speakers and twenty-five observers from member states, permanent missions of observation, and national commissions for UNESCO (from the Holy See, Angola, Argentina, Austria, Belgium, Brunei Darussalam, Colombia, France, Germany, Iran, Kazakhstan, Kuwait, Mexico, Mongolia, the Philippines, the Republic of Korea, Saudi Arabia, Thailand, the United States, and Zimbabwe). *Id.* Representatives from UN organizations and international intergovernmental and nongovernmental organizations participated: the Food and Agriculture Organization of the United Nations (FAO), the United Nations University, the International Centre for Genetic Engineering and Biotechnology (ICGEB), the World Federation of Teachers' Unions (WFTU), the International Federation of University Women (IFUW), the International Council of Jewish Women, and the Human Genome Organisation (HUGO). *Id.* About 128 professors, lawyers, scientists, and bioethics experts from Japan, the host country, participated. *Id.* Finally, fourteen "other observers" were present-- academics from Australia, France, Hong Kong, Japan, Kuwait, Poland, the United Kingdom, and the United States. *Id.*

9 Report of the IBC, *supra* note 4, P2.

10 UNESCO Bioethics website, http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html.

11 The United States withdrew from UNESCO in 1984 and the United Kingdom in 1986, both countries complaining of extensive mismanagement, excessive budget growth and increased politicization. Allyn L. Taylor, Globalization and Biotechnology: UNESCO and an International Strategy to Advance Human Rights and Public Health, 25 Am. J.L. & Med. 479, 525 (1999). The United Kingdom rejoined UNESCO in 1997 and the United States in 2003. *Id.* See also UNESCO Europe and North America website, [http:// portal.unesco.org/geography/en/ev.php-URL_ID=2317&URL_DO=DO_TOPIC&URL_SECTION=201.html](http://portal.unesco.org/geography/en/ev.php-URL_ID=2317&URL_DO=DO_TOPIC&URL_SECTION=201.html) (listing current European and North American members of UNESCO).

12 See Taylor, *supra* note 11, at 527; See also Noëlle Lenoir, Comment, Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level, 30 Colum. Hum. Rts. L. Rev. 537, 559 (1999).

13 UNESCO, First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics, Explanatory Memorandum on the Elaboration of the Preliminary Draft Declaration on Universal Norms on Bioethics, P3, U.N. Doc. SHS/EST/05/CONF.203/4 (Feb. 21, 2005), available at <http://unesdoc.unesco.org/images/0013/001390/139024e.pdf> [hereinafter Explanatory Memorandum].

14 *Id.* at PP4, 6. See Universal Declaration on the Human Genome and Human Rights, UNESCO, 29th sess., 26th plen. mtg. (Nov. 11, 1997), available at http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html; International Declaration on Human Genetic Data, UNESCO, 32d sess., 20th plen. mtg. (Oct. 16, 2003), available at [http:// www.academy.ac.il/bioethics/english/documents/Human_Genetic_Data.pdf](http://www.academy.ac.il/bioethics/english/documents/Human_Genetic_Data.pdf).

15 Explanatory Memorandum, *supra* note 13, P6.

- 16 IBC website, http://portal.unesco.org/shs/en/ev.php-URL_ID=1879&URL_DO=DO_TOPIC&URL_SECTION=201.html.
- 17 Id.
- 18 Id.
- 19 Explanatory Memorandum, *supra* note 13, P7.
- 20 Id. P11. A similar approach was taken in Resolution 2003/69 on Human Rights and Bioethics of the United Nations Commission on Human Rights of 25 April 2003. Commission on Human Rights Res. 2003/69, U.N. Doc. E/CN.4/2003/L.11/Add.7 (April 25, 2003).
- 21 UNESCO, Different Stages in the Elaboration of the Universal Declaration on Bioethics and Human Rights, at http://portal.unesco.org/shs/en/ev.php-URL_ID=3850&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited Mar. 17, 2006) [hereinafter Different Stages].
- 22 Of the questionnaires returned, eleven were from Africa, eight from Asia and the Pacific, ten from Arab states, 21 from Europe and North America, ten from Central and Eastern Europe, six from Latin America and the Caribbean, and one from Permanent Observers. PowerPoint: Towards a Declaration on Universal Norms on Bioethics, Progress Report (UNESCO Jan. 2005), at [http://portal.unesco.org/shs/en/file_download.php/50523d754289e00aad6d16990d576e22Bioethic+Declaration\(jan.2005\).ppt](http://portal.unesco.org/shs/en/file_download.php/50523d754289e00aad6d16990d576e22Bioethic+Declaration(jan.2005).ppt) [hereinafter Towards a Declaration].
- 23 The intergovernmental organizations were the Food and Agricultural Organization of the United Nations (FAO), the World Intellectual Property Organization (WIPO), the United Nations University (UNU), the Arab League Educational Cultural and Scientific Organization (ALECSO), the Organization for Economic Cooperation and Development (OECD), the Council of Europe (CoE), and the European Commission. The international nongovernmental organizations were the World Medical Association (WMA), the Human Genome Organization (HUGO), the International Council for Science (ICSU), Disabled Peoples' International (DPI), and the International Association of Bioethics (IAB). Id. The national bioethics committees were those from Japan, New Zealand, Korea, Tunisia, Egypt, France, Portugal, the United States, the United Kingdom, Côte d'Ivoire, the Republic of Congo, Russian, Croatia, Mexico, and the Dominican Republic. Id.
- 24 Different Stages, *supra* note 21.
- 25 Id. The participants at the two meetings of the UN Inter-Agency Committee on Bioethics were the FAO, UNESCO, UNU, WHO, WIPO, ALECSO, the European Commission, the CoE, the OECD, and the World Trade Organization (WTO). Towards a Declaration, *supra* note 22.
- 26 Intergovernmental Bioethics Committee (IGBC) website, at http://portal.unesco.org/shs/en/ev.php-URL_ID=1878&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited Mar. 17, 2006). The member states of the IGBC are currently Cameroon, Canada, the People's Republic of China, Costa Rica, Croatia, Cuba, the Czech Republic, Egypt, France, Germany, India, Italy, Japan, Kazakhstan, Kenya, Mauritania, Mexico, Mozambique, the Netherlands, Nigeria, Pakistan, Peru, Poland, Saudi Arabia, Senegal, Slovakia, Thailand, Tunisia, Uganda, the United Kingdom, Tanzania, the United States, Uruguay, Venezuela, and Zambia. Id.
- 27 Id.
- 28 Id.
- 29 IBC website, *supra* note 16; IGBC website, *supra* note 26.
- 30 IBC website, *supra* note 16; IGBC website, *supra* note 26.
- 31 These consultations took place at the Hague, Hamedan, Vilnius, Ankara, Buenos Aires, Seoul, Mexico City, Jakarta, Lisbon, and Moscow. Towards a Declaration, *supra* note 22.
- 32 Id.

- 33 These contributions included 31 from UNESCO member states and the Permanent Observer, four from intergovernmental organizations, 14 from nongovernmental organizations, 14 from national bioethics committees, and 12 in a personal capacity. *Id.*
- 34 Different Stages, *supra* note 21.
- 35 UNESCO, Summary of the Informal Meeting with Permanent Delegations Organized by the Chairperson of the Intergovernmental Meeting of Experts (Category II) Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics (May 17, 2005), at http://portal.unesco.org/shs/en/file_download.php/95bb11eb8045b7e384d7e8e2d0bddba3Summary-informal+meeting_en.pdf [hereinafter Informal Meeting].
- 36 Different Stages, *supra* note 21.
- 37 *Id.*
- 38 *Id.*
- 39 See, e.g., Report of the IBC, *supra* note 4, P39.
- 40 *Id.* P43.
- 41 Declaration, *supra* note 4, art. 1.
- 42 *Id.* art. 2.
- 43 *Id.* arts. 3-17.
- 44 *Id.* art. 27.
- 45 *Id.*
- 46 *Id.* arts. 18-20.
- 47 *Id.* art. 21.
- 48 *Id.* art. 25. See also Explanatory Memorandum, *supra* note 13, P115 (“The IBC provides the only global expert forum for in-depth general, multidisciplinary bioethical reflection by exposing the issues at stake. It does not make binding rulings on specific bioethical issues.”).
- 49 UNESCO, Global Ethics Observatory (GEO) website, at http://portal.unesco.org/shs/en/ev.php-URL_ID=6200&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited Mar. 17, 2006).
- 50 Explanatory Memorandum, *supra* note 13, P29.
- 51 Declaration, *supra* note 4, art. 6(2).
- 52 *Id.* The Explanatory Memorandum explains that the doctrine of informed consent is “largely a creation of court decisions” in which the right of individual self-determination has been the basis. Explanatory Memorandum, *supra* note 13, P63.
- 53 See Markus Schott, Medical Research on Humans: Regulation in Switzerland, the European Union, and the United States, 60 Food & Drug L.J. 45, 73 (2005).
- 54 Declaration, *supra* note 4, art. 7.
- 55 Explanatory Memorandum, *supra* note 13, P69.
- 56 Declaration, *supra* note 4, art. 7(a).
- 57 *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 812 n.2 (Md. 2001).

- 58 Declaration, supra note 4, art. 7(b).
- 59 The Declaration does not define “minimal risk” or “minimal burden.” Id.
- 60 Id.
- 61 The trial was known as *United States v. Karl Brandt*. Twenty were doctors, and all but one of them held positions in the Third Reich. See Paul M. McNeill, *The Ethics and Politics of Human Experimentation* 17, 22 (1993).
- 62 Id.
- 63 Id.
- 64 Nuremberg Code, supra note 2, at 181-82. See also Jay Katz, *Experimentation with Human Beings: The Authority of the Investigator, Subject, Professions, and State in the Human Experimentation Process* 305-06 (1980).
- 65 Nuremberg Code, supra note 2, P1.
- 66 Id. For an exegesis of these requirements, see Ruth R. Faden & Tom L. Beauchamp, *A History and Theory of Informed Consent* 151, 155 (1986).
- 67 See Schott, supra note 53, at 47.
- 68 See id.
- 69 George J. Annas, *The Nuremberg Code in U.S. Courts: Ethics versus Expediency*, in *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* 201, 204 (George J. Annas & Michael A. Grodin eds., 1992).
- 70 World Medical Association [WMA], *Declaration of Helsinki, Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects*, 18th WMA Gen'l Assembly, Helsinki, Fin., June 1964, available at <http://www.wma.net/e/policy/b3.htm> [hereinafter *Helsinki Declaration*]. The Helsinki Declaration has been revised five times: in 1975, 1983, 1989, 1996 and 2000, and notes of clarification were added in 2002 and 2004. Id.
- 71 Id.
- 72 See David N. Weisstub et al., *Establishing the Boundaries of Ethically Permissible Research with Vulnerable Populations*, in *Research on Human Subjects: Ethics, Law and Social Policy* 355, 374 (David N. Weisstub ed., 1998).
- 73 Helsinki Declaration, supra note 70, P28.
- 74 Id. P22.
- 75 Id. P24.
- 76 Id. P25.
- 77 Annas, supra note 69, at 205. Annas juxtaposes the reaction to the Helsinki Declaration by Henry Beecher, who welcomed the Helsinki Declaration's “correction” of the Nuremberg Code, to the reaction of Jay Katz, who admonished physicians not to place “too much reliance on codes of ethics,” which are “painfully vague.” Id. at 206.
- 78 Schott, supra note 53, at 49. For example, the U.S. Food and Drug Administration's policy on consent drew extensively from the Helsinki Declaration. See Faden & Beauchamp, supra note 66, at 157.
- 79 *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Council for Int'l Organizations of Med. Sci., Geneva 2002), available at http://www.cioms.ch/frame_guidelines_nov_2002.htm [hereinafter *International Ethical Guidelines*]. The Guidelines were revised in 2002. Id. For an analysis of the International Ethical Guidelines, see Sev S. Fluss, *The Regulation of Human Experimentation: Historical and Contemporary Perspectives*, in *Research on Human Subjects*, supra note 72, at 222, 229.

- 80 See Schott, *supra* note 53, at 51.
- 81 *Id.*
- 82 David N. Weisstub et al., *Biomedical Experimentation with Children: Balancing the Need for Protective Measures with the Need to Respect Children's Developing Ability to Make Significant Life Decisions for Themselves*, in *Research on Human Subjects: Ethics, Law and Social Policy*, *supra* note 72, at 380, 387 (citing International Ethical Guidelines, *supra* note 79, at 20).
- 83 The Council of Europe (CoE) should not be confused with the Council of the European Union. See CoE website, <http://www.coe.int>; Council of Europe List of Member States, at http://www.coe.int/T/E/Com/About_Coe/Member_states/default.asp. To become a member of the European Union, a state must accede to two important treaties drawn up by the CoE: the European Court of Human Rights and the European Committee for the Prevention of Torture. See European Court of Human Rights, *Historical Background*, at http://europa.eu.int/comm/external_relations/coe/index.htm (discussing the relationship between the EU and CoE).
- 84 Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Apr. 4, 1997, E.T.S. No. 164 (CoE), available at <http://conventions.coe.int/Treaty/en/Treaties/Word/164.doc> [hereinafter CoE Convention]. Three Additional Protocols to the Convention have been signed, pertaining respectively to the cloning of human beings, organ transplantation, and biomedical research. See Additional Protocol with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, Jan. 12, 1998, E.T.S. No. 186; Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin, Jan. 24, 2002, ETS No. 186 (not yet entered into force); Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research, opened for signature Jan. 1, 2005, E.T.S. No. 195, available at http://www.coe.int/T/E/Legal_Affairs/Legal_co-operation/Bioethics/Activities/Biomedical_research/195%20Protocole%CCC20recherche%CCC20biomedicale%CCC#%e.pdf.
- 85 The countries that have ratified the Convention are Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Georgia, Greece, Hungary, Iceland, Lithuania, Moldova, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, and Turkey. Council of Europe website, [http://conventions.coe.int/Treaty/Commun/ChercheSig.asp? NT =164&CM=8&DF=23/11/2005&CL=ENG](http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=23/11/2005&CL=ENG).
- 86 CoE Convention, *supra* note 84, art. 17(2).
- 87 *Id.* art. 27.
- 88 Declaration, *supra* note 4, art. 7(b).
- 89 Universal Declaration on the Human Genome and Human Rights, *supra* note 14.
- 90 Taylor, *supra* note 11, at 509.
- 91 Universal Declaration on the Human Genome and Human Rights, *supra* note 14, art. 5.
- 92 *Id.*
- 93 See Taylor, *supra* note 11, at 510.
- 94 *Id.*
- 95 Explanatory Memorandum, *supra* note 13, P15. Although beyond the scope of this Note, the U.S. federal regulations on research involving children are also consistent with the Declaration's requirements of surrogate consent and minimal risk for research without any benefit for the child subject. See 45 C.F.R. §§46.404-407.
- 96 Faden & Beauchamp, *supra* note 66, at 160.
- 97 Katz, *supra* note 64, at 523.

- 98 See Intersections of Medical Ethics, supra note 4 (citing Tom L. Beauchamp & James F. Childress, Principles of Biomedical Ethics 120 (4th ed., 1994)).
- 99 See Taylor, supra note 11, at 491 n.98 (citing Louis Henkin, The Age of Rights 4 (1991)).
- 100 Id. (citing Beauchamp & Childress, supra note 98, at 120-21).
- 101 See Schott, supra note 53, at 73.
- 102 See id.
- 103 Explanatory Memorandum, supra note 13, P40.
- 104 Declaration, supra note 4, art. 3(2). This principle is derived from article 2 of the Council of Europe Convention on Human Rights and Biomedicine, which states that “[t]he interests and welfare of the human being shall prevail over the sole interest of society or science.” See Explanatory Memorandum, supra note 13, P41.
- 105 See Faden & Beauchamp, supra note 66, at 156 (explaining the definitions of “therapeutic” and “non-therapeutic” as used in the Helsinki Declaration).
- 106 “Exploitation” means “[t]he act of taking advantage of something; esp., the act of taking unjust advantage of another for one's own benefit.” Black's Law Dictionary 475 (7th ed. abridged 2000).
- 107 Convention on the Rights of the Child, supra note 3, art. 36.
- 108 McNeill, supra note 61, at 17 (quoting R. Gillespie, Research on Human Subjects: An Historical Overview, 1988 Conf. Proc. Monash Univ. Centre for Hum. Bioethics 3-19).
- 109 Id.
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- 112 Id. at 17-18.
- 113 Faden & Beauchamp, supra note 66, at 163.
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- 119 Id. at 188.
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- 127 Id.
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- 130 Leonard H. Glantz, Research with Children, 24 Am. J.L. & Med. 213, 238 (1998) (citing Daniel S. Pine et al., Neuroendocrine Response to Fenfluramine Challenge in Boys: Association with Aggressive Behavior and Adverse Rearing, 54 Archives Gen. Psychiatry 839, 840 (1997)).
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- 144 Katz, *supra* note 64, at 959.
- 145 Id.
- 146 Id.
- 147 Id.
- 148 See Lainie Friedman Ross, Children as Research Subjects: A Proposal to Revise the Current Federal Regulations Using a Moral Framework, 8 Stan. L. & Pol'y Rev. 159, 164 (1997) (citing William A. Silverman, The Myth of Informed Consent in Daily Practice and in Clinical Trials, 15 J. Med. Ethics 6, 6-11 (1989)); S.C. Harth et al., The Psychological Profile of Parents Who Volunteer Their Children for Clinical Research: A Controlled Study, 18 J. Med. Ethics 86, 86-93 (1992).
- 149 Ross, *supra* note 148, at 164.
- 150 Cinead R. Kubiak, Note, Conflicting Interests & Conflicting Laws: Re-aligning the Purpose and Practice of Research Ethics Committees, 30 Brook. J. Int'l L. 759, 763 (2005).

- 151 Ross, *supra* note 148, at 163.
- 152 However, at least one IRB member must come from a non-scientific profession. See Kubiak, *supra* note 150, at 789.
- 153 See *id.* (citing Peter Williams, Success in Spite of Failure: Why IRBs Falter in Reviewing Risks and Benefits, 6 IRB: Rev. Hum. Subjects Res. 1, 1-4 (1984)); James A. F. Stoner, A Comparison of Individual and Group Decisions Involving Risk 58 (1961) (unpublished master's thesis, School of Industrial Management, Massachusetts Institutes of Technology) (concluding on the basis of experimentation results that individuals choose riskier courses of action when they reach their decisions as members of group).
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- 160 *Id.* at 812, 823.
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- 162 *Id.* at 848.
- 163 See Kopelman, *supra* note 158, at 41.
- 164 Explanatory Memorandum, *supra* note 13, P34.
- 165 Report of the IBC, *supra* note 4, P14.
- 166 See UNESCO, Abstracts or Texts of the Presentations of Speakers, 12th session of the IBC, Tokyo, Japan, Dec. 15-17, 2005, U.N. Doc. SHS/EST/CIB-12/05/CONF.509/INF.2, available at http://portal.unesco.org/shs/en/file_download.php/9d73eaabc609b418862d31ddd6a1cd19Abstract.
- 167 See, e.g., Tomoaki Tsuchida, UNESCO Declarations in the Field of Bioethics and Cultural Diversity, in Abstracts or Texts, *supra* note 166; Michel Revel, UNESCO Universal Declaration on Bioethics and Human Rights: Why There Is a Need To Take Cultural Diversity into Account, in *id.*; Tadafumi Kato, Informed Consent: Current Status in Clinical and Research Settings in Japan, in *id.*; Renzong Qiu, Cultural Diversity in Bioethics, in *id.*; Satoko Tatsui, Bioethics and Japan, in *id.*; Leonardo De Castro, Providing an Asian Character to the Globalization of Bioethics, in *id.*; S. Qasim Mehdi, Bioethical Concerns in a Muslim Country--Pakistan, in *id.*

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