UNITED STATES DISTRICT COURTWESTERN DISTRICT OF WASHINGTONAT SEATTLE

WILLIAM LEE WRIGHT, et al.,	:	**NO. C01-5217 (RSL)PLAINTIFF**
Plaintiffs,		**RESPONSE TO HUTCHINSON DEFENDANTS' MOTION FOR**
	:	**JUDGMENT ON THE PLEADIN**
v.		**PLAINTIFFS' CAUSES OF ACT**
	:	**THROUGH FOUR**
THE FRED HUTCHINSON CANCER RESEARCH CENTER, et al.,	:	
Defendants.	:	
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I. INTRODUCTION

The defendants' motion to dismiss asks this Court to find that the plaintiffs in this action can prove no set of facts that would support any claim under federal law. They do not challenge the sufficiency of the evidence nor the accuracy of plaintiffs' allegations. The plaintiffs have alleged that defendants committed intentional acts that deprived them of the true facts about the experimental treatment performed upon them for non-therapeutic purposes and resulted in their deaths. As set forth below, there is ample authority in American history and

federal case law to support plaintiffs' claims based on international standards set forth in the Nuremburg Code and the Declaration of Helsinki, which provide a basis for substantive rights under the Fourteenth Amendment. There is also ample judicial authority for plaintiffs' claims for the deprivation of bodily integrity and procedural due process under the Fourteenth Amendment. The regulatory standards applicable to the defendants are enforceable in their own right and through 42 U.S.C. § 1983 and the Assurance Agreements by which they are bound. Thus, the defendants are wrong on the law and their motion must be denied.

Plaintiffs are the estates and survivors of patients who participated in Protocol 126 (sometimes referred to as "the experiment"), a clinical trial involving T-cell depleted bone morrow transplants at the Fred Hutchinson Cancer Research Center ("Hutchinson Center") between 1981 and 1993. The allegations are that the defendants designed and conducted an unethical human research experiment in which, among other things, the risks far outweighed any benefits, the researchers had serious undisclosed conflicts of interests, the participants did not receive accurate and complete information material to informed consent, and the participants actually though wrongly believed it was in their best therapeutic interest to participate. By defendants' own admission, the experiment proved to be an abject failure resulting in the death and acute physical harm of virtually all the subjects. This lawsuit seeks judgment against the defendants for their actions and inactions.

The Hutchinson defendants have brought this Motion, seeking the dismissal of the first four counts of plaintiffs' Second Amended Complaint. The defendants have not challenged the sufficiency of evidence supporting these claims. Their sole argument in this motion is that the plaintiffs cannot prove any

set of facts that could support a cognizable federal claim in this case.

II. STATEMENT OF FACTS

As applies to this Motion, the Hutchinson Center is a medical facility that conducts medical therapy and research for cancer patients. Defendant Dr. E. Donnall Thomas is the co-founder and clinical director; defendant Dr. John A. Hansen at all times relevant was the head of a tissue-typing lab and later clinical director; defendant Dr. Paul J. Martin at all times relevant was a staff oncologist; and defendant Dr. Robert Day at all times relevant was the Director. In November 1980, Genetic Systems Corporation ("Genetic Systems") was formed by David Blech. Genetic Systems recruited physicians who treat cancer patients in exchange for a position on the board of Genetic Systems and stock in the company.

In December 1980, defendants Hansen, Thomas and Martin submitted Protocol 126 to the Institutional Review Board ("IRB"). The purported goal of Protocol 126 was to prevent an immune-system reaction known as graft-versus-host disease ("GVHD") which occurs in approximately 50% of recipients of bone marrow transplants from tissue-matched siblings. In January 1981, one month after defendants Hansen, Thomas and Martin submitted Protocol 126 to the IRB, Genetic Systems provided defendant Hansen 250,000 shares of its stock and an $18,000 consulting fee, defendant Thomas, 100,000 shares of stock and a $3,000 a year board position, and provided defendant Martin 10,000 shares of Genetic Systems stock.

Under Protocol 126, defendants proposed to use "monoclonal antibodies" to remove the "T-cells" from the donor's bone marrow prior to transplantation, on the assumption that these

cells contributed to a complication known as "graft-versus-host disease," or GVHD. Defendants knew, however, that T-cells were necessary to engraftment of the donor's marrow. See deposition transcript of Paul Martin, attached as Exhibit "A." T-cell depletion in bone marrow transplants actually increased the risk of graft failure or graft rejection. Defendants at all times understood that the experiment needed to be designed in accordance with the ethical standards governing human research and that, among other things, this involved weighing the risks to the subjects against the potential benefits.

In January 1981, the Institution Review Board ("IRB") at the Hutchinson Center rejected Protocol 126 because the increased risk of graft failure and cancer relapses did not outweigh the potential benefit of decreasing the incidence of GVHD. While this calculus never changed, and indeed was ultimately affirmed numerous times over the course of the next decade, defendants proceeded to conduct this experiment on unwitting subjects who came to the Hutchinson Center for one reason and one reason alone: to get well. In March 1981, Genetic Systems signed a 20 year deal with Hutchinson Center for commercial rights to 37 substances, including three to be tested in Protocol 126. In exchange for this agreement, Hutchinson Center received money and a royalty agreement while an affiliated foundation received stock in Genetic Systems. In April 1981, defendant Hansen resubmitted Protocol 126, which was approved. In December of 1981, defendant Martin sought and obtained approval of a revised Protocol 126 by adding agents that greatly increased the killing power of the monoclonal antibodies used in the experiment.

The informed consent form that the participants signed prior to formal participation in Protocol 126 minimized the risk of graft failure and made it sound as if a second bone marrow transplant could be done without difficulty if the first one

failed. The defendants knew, but did not advise the participants, that the salvage rate from second bone marrow transplants was between 5 percent and 10 percent. In addition, the informed consent form did not disclose that the Hutchinson defendants possessed a direct financial interest in Protocol 126.

In March 1983, the Hutchinson Center adopted a new conflict of interest policy whereby scientists were prohibited from participating in any research involving the Hutchinson Center in which the member had a financial interest. Despite this revised policy, defendants Hansen, Thomas and Martin continued to participate in Protocol 126. In April 1983, the interests of the individual defendants in Genetic Systems was as follows: Thomas - $916,000; Hansen - $2,000,000; Martin - $91,000; and the Hutchinson Center - $458,000.

In April 1983, the IRB imposed a two death by graft rejection stopping criteria for the experiment, understanding that a substantially increased risk of graft failure, normally one percent, would outweigh any potential benefit to the subject and render the experiment unethical. To get around this new stopping criteria, however, defendants simply added successive decimal points each time two graft failures would occur.

During the Spring of 1983, the IRB approved renewing the experiment though the informed consent form failed to disclose the risks of new cancers, relapse and graft failure. Nor did the informed consent form reveal that the Hutchinson defendants had a direct financial interest in the outcome of Protocol 126. In September 1983, the IRB asked for clarification on the animal tests, human risks and financial interests involved in Protocol 126. In response to this request, defendant Thomas denied any conflict of interest, refused the IRB's request for separate tests on antibodies, and warned the IRB not to impede research. In May of 1984, Nancy Haldeman left the IRB

administrator position stating the Hutchinson Center did not want independent oversight.

In January 1984, defendant Hansen began a one year leave from the Hutchinson Center to become medical director for Genetic Systems. Over the next several years, despite concerns over the financial interests of the researchers and Protocol 126 in general, the Hutchinson Center allowed Protocol 126 to continue. Additionally, the IRB approved the next phase of the experiment but suggested that it should go through outside review. Thereafter, defendant Day refused outside review of Protocol 126. In March 1984, defendant Martin failed to notify IRB or medical examiner of treatment-caused deaths as required by law.In January 1985, the IRB approved Protocol 126.2 for three months, excluding good-prognosis patients. The consent form still failed to mention the known risks of participating in the experiment. In April 1985, defendants Martin, Hansen and Thomas applied for Protocol 126.3, combining T-cell depletion with other chemicals. The IRB again asked for outside review.

In October 1985, Genetic Systems was bought out by Bristol-Myers for $294 million, or $10.50 per share, making the original interest of Defendant Thomas worth $1.05 million, FHCRC $502,000, and defendant Martin $105,000. Defendant, Hansen, who had sold some shares, held stock worth $1.8 million.In April 1988, defendant Martin presented a paper saying T-cell depletion in certain leukemia patients led to 100 percent relapse rate vs. expected 25 percent. This of course was never disclosed to the participants in Protocol 126. In 1991, ten years after the start of Protocol 126, defendant Martin proposed Protocol 126.7. The consent form for Protocol 126.7 finally stated: "There is a chance that the donor marrow will fail to produce new blood cells because of rejection or other problems. In this situation, there is a high chance of infections,

bleeding and death." Presently, the value of defendant Thomas' original stock is about $5 million, the foundation's $2.5 million, defendant Martin's $525,000 and defendant Hansen's shares are worth $9 million.

Some eighty of eighty-five patients are dead from graft failures and/or leukemic relapse attributable to the treatment.

The Hutchinson defendants now move to dismiss plaintiffs' causes of action seeking damages for violations of the Constitutions of the United States, 21 C.F.R. § 210, 211/21 C.F.R. § 601, 610/45, and for failing to follow the ethical principals in the Belmont Report and the requirements of 45 C.F.R. § 46. The entire motion rests on the contention that plaintiffs have no right, under any circumstances, to sue under these authorities. The defendants' motion should be denied.

III. LEGAL ARGUMENT

A. STANDARD OF REVIEWDefendants move to dismiss Counts One through Four of the Second Amended Complaint pursuant to Federal Rule of Civil Procedure 12(c). The parties agree that the standard to be followed pursuant to Rule 12(c) is the same standard as Rule 12(b)(6). In reviewing a Rule 12(b)(6) motion, a court accepts the allegations in the complaint as true and views them in the light most favorable to the non-moving party; a court, thus, does not weigh potential evidence. Regence Blueshield v. Philip Morris, Inc., 40 F.Supp.2d 1179, 1181 (W.D. Wash. 1999). To that end, a motion predicated on Rule 12(b)(6) shall not be granted unless it "appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Levine v. Diamanthuset, Inc., 950 F.2d 1478, 1482 (9th Cir, 1991) (citation omitted).**B. DEFENDANTS IMPROPERLY RELY UPON AN UNPUBLISHED OPINION**As an initial matter, plaintiffs submit that all references by defendants to unpublished

opinions, specifically Robertson v. McGee, No. 01-CV-60-C (N.D. Okla. Jan. 28, 2002), a case also involving plaintiffs' counsel, Alan Milstein, should be disregarded. Despite the clear rules of this Circuit, defendants have boldly sought to rely upon a matter that is unpublished, out of jurisdiction, and on appeal. Defendants have compounded this error by attaching the Robertson case to their brief.

The Ninth Circuit has held that counsel may not rely upon unpublished decisions for the precedential value that defendants seek to attach to the Robertson decision. In Hart v. Massanari, 266 F.3d 1155 (9th Cir. 2001), the issue was whether counsel should have been disciplined for violating Ninth Circuit Rule 36-3, which provides that "[u]npublished dispositions and orders of this Court are not binding precedent . . . [and generally] may not be cited to or by the courts of this circuit . . . "Id. at 1159. The respondent in Hart raised the defense that the Circuit's rule was unconstitutional. The Court went through a detailed analysis of the development and application of establishing case precedent before holding that its rule prohibiting citation to unpublished decisions did not violate the constitutional article governing the judiciary. Id. at 1180.

In addition, the Court discussed why an opinion in one circuit is not binding on other courts throughout the country:[A]n opinion of our court is binding within our circuit, not elsewhere in the country. The courts of appeals, and even the lower courts of other circuits, may decline to follow the rule we announce-- and often do. This ability to develop different interpretations of the law among the circuits is considered a strength of our system. It allows experimentation with different approaches to the same legal problem, so that when the Supreme Court eventually reviews the issue it has the benefit of "percolation" within the lower courts.Id. at 1172-73.

The Court also explained the meaning and value of a non-precedential opinion:That a case is decided without a precedential opinion does not mean it is not fully considered, or that the disposition does not reflect a reasoned analysis of the issues presented. What it does mean is that the disposition is not written in a way that will be fully intelligible to those unfamiliar with the case, and the rule of law is not announced in a way that makes it suitable for governing future cases . . . An unpublished disposition is, more or less, a letter from the court to parties familiar with the facts, announcing the results and the essential rationale of the court's decision.

Hart, supra, 266 F.3d at 1177-78. In addition, should a court permit these non-precedential opinions to be cited, "zealous counsel would be tempted to seize upon superficial similarities between their clients' cases and unpublished dispositions." Id. at 1178.

Thus, the Robertson decision, a non-precedential opinion generated by a district court in a different circuit, cited throughout defendants' brief and attached to their motion package, must be disregarded. Had the Court in the Robertson matter expected or wanted its opinion to be relied upon by others it would have published it. It was in clear error for defendants' counsel to rely upon and attach the Robertson decision.

C. THE RIGHTS TO BODILY INTEGRITY AND TO BE TREATED WITH DIGNITY ARE PROTECTED WITHIN THE FOURTEENTH AMENDMENT TO THE UNTIED STATES CONSTITUTION

Defendants argue that plaintiffs' first cause of action, breach of the right to bodily integrity and the right to be treated with dignity, should be dismissed solely because "there is no private

right of action under the Nuremberg Code or the Declaration of Helsinki." This argument misses the point. Plaintiffs do not claim a private right of action under either the Nuremberg Code, which is a decision by three United States judges sitting as an international tribunal, or the Helsinki Declaration, which is simply a recommended standard of conduct adopted by the World Medical Association. Instead, plaintiffs claim rights under the Fourteenth Amendment to the United States Constitution; plaintiffs offer the Nuremberg Code and the Declaration of Helsinki merely as evidence of this Nation's - and indeed the World's - recognition that such rights are fundamental human rights essential to an ordered society. Both history and an emerging body of law suggest that plaintiffs should succeed on these claims.

The constitutional right to bodily integrity is a long standing right. In addition to seeking redress for the violation of the right to bodily integrity, the plaintiffs seek recognition of a right that is equally important. What is at stake in this litigation is whether individuals have a Constitutional right to human dignity so as not to be the subjects of an unethical human experiment. Such a right, reflected in the Nuremberg Code and in the federal regulations known as the Common Rule, is a fundamental right of all citizens of the world and, thus, must be a right of the citizens of the United States, a Constitutional right.

The Fourteenth Amendment provides that no State shall "deprive any person of life, liberty, or property, without due process of law." This clause "guarantees more than fair process, and the 'liberty' it protects includes more than the absence of physical restraint." Washington v. Glucksberg, 521 U.S. 702, 719 (1997). Rights are protected under the Due Process Clause of the Fourteenth Amendment if they are "so rooted in the tradition and conscience of our people as to be

ranked as fundamental" or if such rights reflect "basic values implicit in the concept of ordered liberty" such that "neither liberty nor justice would exist if they were sacrificed." See Moore v. City of East Cleveland Ohio, 431 U.S. 494, 503 (1977); Griswold v. Connecticut, 381 U.S. 479, 500 (1965); Palko v. Connecticut, 302 U.S. 319, 325 (1937); Snyder v. Massachusetts, 291 U.S. 97, 105 (1934).

The right to bodily integrity has long been recognized as a fundamental right protected by the Constitution. See Albright v. Oliver, 510 U.S. 266 (1994) (due process accorded to matters involving marriage, family, procreation and the right to bodily integrity); Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992), (Constitutional liberty interest includes right to bodily integrity, a right to control one's person); Schmerber v. California, 384 U.S. 757 (1966) (integrity of an individual's person is cherished value of our society); Union Pacific R. Co. v. Botsford, 141 U.S. 250 (1891) (no right held more sacred or more carefully guarded than right of every individual to be in possession and control of his own person, free from restraint or interference of others). Courts have particularly recognized such Constitutional autonomy rights in the medical context. See, e.g., Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1990) (Constitution grants competent person right to refuse lifesaving hydration and nutrition); Roe v Wade, 410 U.S. 113 (1973) (women have Constitutional right to control decision on whether to obtain an abortion); Griswold v. Connecticut, 381 U.S. 479 (1965) (restriction on citizens from receiving contraceptives from their physician an unconstitutional intrusion); Rochin v. California, 342 U.S. 165 (1952) (forcible stomach pumping of accused violates due process and is conduct which: "shocks the conscience"); Skinner v. State of Oklahoma, 316 U.S. 535 (1942) (sterilization performed without consent deprives individual of basic liberty). As Justice

Cardoza stated in Schloendorff v. The Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92, 93 (1914), a case against a surgeon for performing an operation without consent: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." 211 N.Y. at 129-130.

Thus, this Court should easily find that the right at issue here, the right to be free from unethical human experimentation, is within the right to bodily integrity. Such a right has similarly already been recognized under the Constitution and defendants do not appear to dispute this. Accordingly, there can be no dispute that plaintiff's federal constitutional claims remain before this Court.

Defendants appear to object only to plaintiffs' claim that there exists an independent right to human dignity. This is, and has already been considered, a distinct fundamental right of all human beings. To best understand the nature of this right, it is important to understand both the historical context in which the Nuremberg Code arose and the post-Nuremberg controversies involving human subject protection. That understanding is necessary because an examination of "our Nation's history, legal traditions and practices" is critical in determining the scope of the right to liberty under the Due Process Clause. Washington v. Glucksberg, 521 U.S. 702 (1997); Collins v. Harker Heights, 503 U.S. 115, 125 (1992); Cruzan, supra, at 269-70; Moore, supra, at 503.After the Nazi holocaust, a series of twelve unprecedented war crimes trials took place at the Palace of Justice in Nuremberg, Germany. In the first trial, later the subject of numerous books and movies, the allies designated four judges from the United States, Great Britain, the Soviet Union, and France to sit and render judgement under international law on the leaders of the Third Reich. Thereafter, the United States proceeded with the other

prosecutions including with what became known as the "Doctors Trial," whose verdict included what is now known as the "Nuremberg Code." See Jay Katz, "The Nuremberg Code and the Nuremberg Trial," JAMA 1996; 276:1662-1666, a copy of which is attached as Exhibit "I."

The Doctors Trial, captioned United States v. Karl Brandt et al., was conducted by three United States judges. The trial began on December 9, 1946, under the authority of the United States Military pursuant to United States rules of procedure with United States lawyers as prosecutors. Karl Brandt, Hitler's personal physician, and twenty two other medical doctors were charged with war crimes, membership in criminal organizations, and crimes against humanity. See "From the Indictment," United States Holocaust Memorial Museum archives, reprinted at www.ushmm.org/research/doctors/persons.htm, a copy of which is attached as Exhibit "J." The first two charges concerned acts intended to aid the Third Reich's military aims; the third charged the physicians with acts undertaken under the guise of human experimentation either in the reckless pursuit of scientific knowledge or for sadistic torture. The experiments included studies on the tolerance of human beings to adverse conditions such as high altitudes, freezing temperatures and ingestion of sea water, tests involving the inoculation of prisoners with infectious diseases, pathogens and new vaccines, and gruesome physiological studies involving mutilations and transplants. See "The Brutalities of Nazi Physicians," JAMA, 1946; 132: 714-715, Editorial, a copy of which is attached as Exhibit "K."

Telford Taylor's opening statement for the prosecution underscores the point that the wrongs at issue in the Doctors Trial were breaches of the fundamental rights of all human beings under American jurisprudential principles. Mr. Taylor

stated:

The charges against these defendants are brought in the name of the United States of America. They are being tried by a court of American judges. The responsibilities thus imposed upon the representatives of the United States, prosecutors, and judges alike, are grave and unusual. . . The mere punishment of the defendants, or even of thousands of others equally guilty, can never redress the terrible injuries which the Nazis visited on these unfortunate people. For them it is far more important that these incredible events be established by clear and public proof so that no one can ever doubt that they were fact and not fable; and that this Court as the agent of the United States and as the voice of humanity, stamp these acts, and the ideas which engendered them, as barbarous and criminal.

Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law, Vol. I, No. 10, Washington D.C.: U.S. Government Printing Office; 1946-1949, reprinted at www.ushmm.org/research/doctors/telford.htm, a copy of which is attached as Exhibit "L."

A principal defense, as articulated by Dr. Brandt's counsel, the eminent jurist Robert Servatius of Cologne, was that the scientific and medical community at large and particularly in the United States had long been conducting human experiments on prisoners, vulnerable populations and uninformed subjects. Sadly, this charge was quite accurate, though certainly never to the extreme as practiced by the Nazis.

After 139 court sessions, 62 witnesses, and 901 written exhibits, Chief Judge Walter B. Beals, who was the Chief Justice of the Supreme Court of the State of Washington, announced the

verdict of the court. Sixteen of the defendants were convicted of war crimes against humanity and seven were condemned to death. Though nothing else was required, the court did far more, perhaps because of the troubling defense testimony with respect to unethical scientific and medical experiments occurring outside of the Third Reich. The court held:

The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other means of study. All agree, however, that certain basic principals must be observed in order to satisfy moral and legal concepts:

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 interventions of any elements 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. 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 reasonably 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 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 . . .

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

5. No experiment should be conducted where there is a priori reason to believe that death or disabling injury will occur. . .

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 experiments.

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 . . .

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end . . .

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he 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., reprinted at www.ushmm.org/research/doctors/nuremberg_code.htm, a copy of which is attached as Exhibit "M."

These ten points constitute what is now known as the Nuremberg Code. They were not promulgated as new legislation to be applied retroactively to the defendants then in the dock. They were an articulation of what these United States judges believed "all agree" were the fundamental rights of every human being. See Affidavit prepared for the case of Michael Grodin, M.D., a leading authority on the Nuremberg Code and one of plaintiffs' bioethics experts. A copy of his Affidavit and C.V. is attached as Exhibit "R." The Code set forth two equally important requirements of ethical human experimentation, both of which are at issue in this case. The first is the requirement of voluntary consent of the subjects after being informed of all material information about the experiment. The second, often overlooked but no less significant, is that such experiments must comport to certain ethical and scientific standards even if subjects have given their informed consent to participate. The Code did not just look backward at the events that gave rise to the Doctors Trial but looked forward to postwar research on human beings. As stated by Dr. Leo Alexander, one of the prosecution's key expert witnesses and the man many credit as the author of the Code:

[The Nuremburg Code] is a useful measure by which to prevent in less blatant settings the consequences of more subtle degrees of contempt for the rights and dignity of certain classes of human beings, such as mental defectives, people presumably dying from incurable illnesses, and other people

disenfranchised, such as prisoners or other inarticulate public charges whose rights might be easily disregarded for the apparently compelling reason of an urgent purpose.

Michael Grodin, "Historical Origins of the Nuremberg Code," in Annas and Grodin, The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation (1992) at p. 139, a copy of which is attached as Exhibit "N."

The World Medical Association, which includes representatives of the American Medical Association, was founded in 1947 soon after the Doctors Trial. In 1954, the Eighth General Assembly of the World Medical Association adopted a resolution on human experimentation based largely on the Nuremberg Code. The resolution contained the basic principles that "it is the duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject." After several revisions, this document now known as the Declaration of Helsinki was adopted by the 18th World Medical Assembly in Helsinki in 1964. It was revised again in 1975 to include a requirement for ethical review committees, such as Institutional Review Boards and adopted most recently by the 52nd General Assembly of the World Medical Association in Edinburgh Scotland in October 2000.

In the fifty years after Nuremberg, outrage over a series of public scandals involving human experiments in the United States have reaffirmed this Nation's commitment to human subject protection and the right to basic human dignity. The first two public scandals were revealed in a landmark article by Harvard physician and Medical School Professor Henry Beecher in the New England Journal of Medicine. See H. K. Beecher, Ethics and Clinical Research, New England Journal of Medicine, Vol. 274 (June 16, 1966) , pp. 1354-60, a copy of which is attached as Exhibit "O." One occurred at New York's

Sloan Kettering Institute for Cancer Research where a researcher working on the immune system's ability to fight cancer convinced the director of the Jewish Chronic Disease Hospital in Brooklyn to allow him to inject unwitting patients with live cancer cells. The second was the Willowbrook study, in which researchers at an institution for mentally disabled children sought to develop a hepatitis vaccine by studying children whom they had deliberately infected with isolated strains of the virus. In the conclusion of Dr. Beecher's article, he cautioned that no research should be conducted without the informed consent of the subject and that the risks in any experiment must be commensurate with the benefits.

It was the third scandal, with racial overtones all too reminiscent of Nazi atrocities, that generated federal action to regulate human subject research. The infamous Tuskegee Syphilis Study conducted by physicians of the U.S. Public Health Service was halted in 1972, nearly 40 years after it began while 200 African-American subjects with syphilis were allowed to remain untreated despite the availability of therapeutic measures. In 1973, the Ad Hoc Advisory Panel issued its Final Report of Tuskegee Syphilis Study, concluding "society can no longer afford to leave the balancing of individual rights against scientific progress to the scientific community." See Final Report, Department of Health Education and Welfare (Washington, D.C.: G.P.O. 1973), a copy of which is attached as Exhibit "P."

Public concern over the rights of research subjects have increased within the decade subsequent to the passage of the Common Rule, published in 1991, detailing conditions required for obtaining informed consent. See Part C, infra. Particularly within the last few years media reports detailed the tragic consequences of failed human experiments, including the one at issue here.

One question for this Court is, in light of this history, whether the principles of the Nuremberg Code have any present day applicability to American law and the rights of American citizens or whether they are simply wartime relics applicable only to understanding the Nazi horrors. Given that the Code emerged from the judgment of United States judges in a United States military tribunal, if any country is bound by the legal precepts of the Nuremberg Code, it is the United States. As George Annas, one of the leading authorities on the Nuremberg Code, has opined,

The most complete and authoritative statement of the law of informed consent to human experimentation is the Nuremberg Code... This Code is part of international common law and may be applied in both civil and criminal cases covered by state, federal and municipal courts in the United States.George J. Annas, et al., Informed Consent to Human Experimentation: The Subject's Dilemma 21 at 1 (1997). A number of evolving opinions support this view.

The first opinion to suggest that the Nuremberg Code has a place in American jurisprudence is the dissent in the Kentucky case of Strunk v. Strunk, 445 S.W. 2D 145 (Court of Appeals of Kentucky, 1969), in which the court by a vote of four to three authorized the removal of a kidney from a mentally retarded institutionalized adult for transplantation into his ailing mentally sound brother. In an eloquent dissent, Justice Samuel Steinfeld wrote:

Apparently because of my indelible recollection of a government which, to the everlasting shame of its citizens, embarked on a program of genocide and experimentation with human bodies, I have been more troubled in reaching a decision in this case than in any other. My sympathies and emotions are torn between a compassion to aid an ailing young

man and a duty to fully protect unfortunate members of society.... Regretfully, I must say, no."445 S.W.2d at 149-51.

In Whitlock v. Duke University, 637 F. Supp. 1463 (M.D.N.C. 1986), aff'd, 829 F. 2d 1340 (4th Cir. 1987), a subject in a non-therapeutic, deep-diving experiment sustained severe brain damage. In dismissing the action because of a finding that the plaintiff had consented to participate in the experiment with full knowledge of the risks, the court stated that the Nuremberg Code provided persuasive guidance on the standard of care in the context of human experimentation. The court stated:

The United States Military Tribunal at Nuremberg adopted the Nuremberg Code as a proper statement of the law of informed consent in connection with the trials of German scientists for human experimentation after World War II.Id. at 1471.One year later, the United States Supreme Court considered the case of James B. Stanley, a Master Sergeant who had been surreptitiously dosed with LSD as part of a mind control experiment conducted by the United States Army. United States v. Stanley, 483 U.S. 669 (1987). Mr. Stanley became aware that he had been a guinea pig in such an experiment when he received a letter almost 20 years later soliciting his cooperation in a study of the long-term effects on such "volunteers." The Supreme Court in a narrow 5 to 4 ruling reaffirmed the decision dismissing the plaintiff's complaint under the Feres Doctrine which holds that a serviceman can not sue the government for putting him in harm's way. In so holding, the Court impliedly acknowledged that Stanley would have had a constitutional claim, if not for the Feres Doctrine and Stanley's status as a serviceman during the experiment.

In dissent, Justice Brennan noted the importance of placing the

government's conduct in historical context:

The medical trials at Nuremberg in 1947 deeply impressed upon the world that experimentation with unknowing human subjects is morally and legally unacceptable. The United States Military Tribunal established the Nuremberg Code as a standard against which to judge German scientists who experimented with human subjects. Its first principle was: the voluntary consent of the human subject is absolutely essential.

Id. at 687. Justice Brennan then concluded that "the United States Military developed the Code which applies to all citizens--soldiers as well as civilians." Id.Justice Brennan characterized the government's experimentation on an unknown human subject as "an intentional Constitutional tort" and ended his opinion with a phrase that would thereafter be associated with the right to be free from unethical experimentation: "Soldiers ought not be asked to defend a Constitution indifferent to their essential human dignity." Id.

Justice O'Connor, also dissenting, stated: "No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case." Id. at 709-10. Justice O'Connor noted that the United States Military played an instrumental role "in the criminal prosecution of Nazi officials who experimented with human subjects during the Second World War... and the standards of the Nuremberg Military Tribunal used to judge the behavior of the defendants stated that the 'voluntary consent of a human subject is absolutely essential... to satisfy moral, ethical and legal concepts'." Accordingly, Justice O'Connor reasoned:

If this principle is violated the very least that society can do is to see that the victims are compensated, as best they can be, by

the perpetrators. I am prepared to say that our Constitution's promise of due process of law guarantees this much.Id. at 711.

In re Cincinnati Radiation Litigation, 874 F. Supp. 796 (S.D. Ohio), is the first case to expressly hold that Nuremberg may be applied in the courts of the United States. Plaintiffs who had been the unknowing subjects in experiments on radiation exposure brought suit against investigators and institutions involved in the study. In rejecting a motion for summary judgment, the court held that such claims were cognizable under the Due Process Clause of the United States Constitution.

In a section titled, "The Nuremberg Code," the court examined the history of the Doctors Trial, stating:

The judges appointed by President Truman to hear the medical case were all American judges and lawyers. The Nuremberg tribunal was asked to determine culpability . . . under "the principles of the laws of nations as a result from the usages established among civilized people, from the laws of humanity, and from the dictates of public conscience. . . Throughout the trial, the question of what were or should be the universal standards for justifying human experimentation recurred. "The lack of a universal principle for carrying out human experimentation was the central issue pressed by the defendant physicians throughout their testimony."

Id. quoting, United States of America v. Karl Brandt, et al., I Trials of War Criminals, Vo., II at 181 (1909).After quoting the first principle of the Nuremberg Code, the court concluded: "The Nuremberg Code is part of the law of humanity. It may be applied in both civil and criminal cases by the federal courts in the United States." The court thus held:

If the Constitution has not clearly established a right under which these clients may attempt to prove their case, then a gaping hole in that document has been exposed. The subject of experimentation who has not volunteered is merely an object. The plaintiffs in this case must be afforded at least the opportunity to present their case.Id. at 822.

The next case to invoke Nuremberg was Stadt v. University of Rochester, 921 F.Supp. 1023 (W.D.N.Y. 1996). In this case, plaintiff brought an action under the Federal Tort Claims Act claiming she had been the subject of testing by physicians who had injected her with plutonium without her informed consent. In rejecting a motion that the Constitutional claims should be dismissed, the court stated: "This case does not involve the right to refuse medical treatment, but instead the right to be free from non-consensual experimentation on one's body . . . the right to bodily integrity . . . a right which has been recognized throughout this nation's history." Id. at 1027. In support, the court reviewed the long line of cases holding that the right to bodily integrity, which would include the right to be free from unethical human experimentation, was a fundamental right under the United States Constitution. Id. at 1027-28, citing Albright v. Oliver, 510 U.S. 266 (1994); Schmerber v. California, 384 U.S. 757 (1966); Skinner v. State of Oklahoma, 316 U.S. 535 (1942); Union Pacific R. Co. v. Botsford, 141 U.S. 250 (1891). The court thus held: "The Constitution and, more specifically, the due process clause of the Fifth Amendment, clearly established the right to be free from non-consensual government experimentation on one's body." 921 F. Supp. at 1027-28.

The next case and the one most similar to the factual issues here is Heinrich v. Sweet, 62 F. Supp. 2d 282 (D. Mass., 1999), where family members brought an action based on allegations that various government doctors conspired to conduct

extensive, unproven, and dangerous medical experimentation on 140 terminally ill patients without their informed consent. The court stated that the issues presented must be understood in their historical context and then proceeded to describe the background of the Doctors Trial and the Nuremberg Code. The court then adopted the reasoning and holding of In re Cincinnati Radiation Litigation that a breach of the principles of the Nuremberg Code by a government actor would violate the Due Process Clause of the United States Constitution. In language particularly relevant here, the court stated: "Similar conduct that "shocks the conscience" includes the use of false promises of therapeutic hope to terminally ill patients in order to lure them into becoming human subjects . . . for the benefit of curious scientists rather than the health of test subjects." 62 F. Supp. 2d at 320.

The culmination of this body of emerging law is Grimes v. Kennedy Krieger Institute, Inc., 366 Md. 29 (2001). A research institution affiliated with Johns Hopkins University created a research program to determine the effectiveness of lead paint abatement procedures. Certain homes were selected to receive only partial lead abatement modifications. The research institute encouraged and, in one situation, required, the landlords of the homes to rent the premises to families with young children. The children were examined and tested to determine whether, and to what extent, their blood became contaminated with levels of lead dust in the home. Id. at 36-37.

Based upon a previous research program, the researchers were aware that lead dust remained and/or returned to abated homes. It was therefore anticipated that the human subjects of the study, the children, could accumulate lead in their blood. This would assist the researchers in determining the extent that the partial abatement methods succeeded. Id. at 38.

Neither the children nor their parents were advised of the risks of the study. "There was no complete and clear explanation in the consent agreement signed by the parents of the children that the research to be conducted was designed, at least in significant part, to measure the success of the abatement procedures by measuring the extent to which the children's blood was being contaminated." Id. at 38.

At some point, the plaintiffs, two of the children in the study and their mothers, filed lawsuits against, amongst others, the researchers. The Circuit Court, Maryland's trial court, granted summary judgment in favor of the research institution, finding no negligence against the research institute because it did not owe a duty to the children or their guardians.

In a strongly worded opinion, the Court of Appeals of Maryland, the State's highest court, vacated and remanded the trial court's decision. The Court held that the trial court's decision that summary judgment was appropriate and that the researchers in that case did not have the duty to warn the participants of known potential dangers was in error.

In reaching its decision, the court analyzed the Nuremberg Code, which the Court stated was "the result of legal thought and legal principles, as opposed to medical or scientific principles, and thus should be the preferred standard for assessing the legality of scientific research on human subjects. Under it, duties to research subjects arise" Id. at 74. The court further held:

Additionally, the Nuremberg Code, intended to be applied internationally, and never expressly rejected in this country, inherently and implicitly, speaks strongly to the existence of special relationships imposing ethical duties on researchers

who conduct nontherapeutic experiments on human subjects. The Nuremberg Code specifically requires researchers to make known to human subjects of research "all inconveniences and hazards reasonably to be expected, and the effects upon his health or person which may possibly come from his participation in the experiment." (Emphasis added.) The breach of obligations imposed on researchers by the Nuremberg Code, might well support actions sounding in negligence such as those at issue here. We reiterate as well that, given the facts and circumstances of both of these cases, there were, at the very least, genuine disputes of material facts concerning the relationship and duties of the parties, and compliance with the regulations.

Id. at 98-99. The court reiterated that the Nuremberg Code may be applied in both civil and criminal courts throughout the United States. Id. at 74.As noted by the court, the first tenet of the Nuremberg Code's ten points is that voluntary consent by the human subject "is absolutely essential." Grimes, supra, 366 Md. at FN 31. Even prior to the issue of consent, the court concluded, it is the obligation of the researcher to appraise the "scientific merits and the acceptability of risks." Id. at 79 (citation omitted).

The court further explained that the fact that the subject signed a consent form does not affirm that the research is justified. The court stated, "Researchers cannot ever be permitted to completely immunize themselves by reliance on consents, especially when the information furnished to the subject, or the party consenting, is incomplete in a material respect." Grimes, supra, 366 Md. at 101. To that end, the court held that "[a] human subject is entitled to all material information." and that without having provided full material information, a researcher has not obtained "informed' consent. Id. at 90. However, the researcher's duty to the participant is

independent of obtaining consent. Id. at 101.

In determining that there was not proper consent in the matter before it, the Grimes Court reaffirmed the right to human dignity by citing a recent law review article: The court stated, "The question is not so much whether we can afford to honor our commitment to human dignity, free from subterfuges . . . but whether we can afford not to, or whether we ought to." Id. at 113 (citation omitted).

As these cases and history make clear, and as "all agree" in the words of the Nuremberg judges, the right to essential human dignity (as well as the right to bodily integrity) in the context of medical experimentation as expressed in the Nuremberg Code is a fundamental right rooted in the conscience and history of the people of the world, in general, and of the United States, in particular. It is a right reflecting basic human values essential to any "concept of ordered liberty" and, if it is sacrificed, neither liberty nor justice can exist. It is, thus, a right guaranteed by the Fourteenth Amendment to the United States Constitution and its violation will give rise to liability under 42 § U.S.C. 1983.

Defendants do not submit any case law in opposition to these claims. Rather, they argue that the Nuremberg Code and the Declaration of Helsinki are not treaties and do not provide a private right of action. Defendants miss the point. The cause of action claimed by these plaintiffs is based not upon the doctrines themselves but upon the principles underlying the doctrines. The Nuremberg Code and the Declaration of Helsinki are simply the expressions of the right to bodily integrity and the right to human dignity. Also see, e.g., In re Cincinnati Radiation Litigation, 874 F.Supp. 796, 810-11 (S. D. Ohio 1995), "The right to be free of state-sponsored invasion of a person's bodily integrity is protected by the Fourteenth

Amendment guarantee of due process." The right to be treated with dignity is simply an extension of the right to bodily integrity.

D. THE PLAINTIFFS' FOURTH CAUSE OF ACTION SHOULD NOT BE DISMISSED

1. Plaintiffs Have Stated a Cause of Action for Substantive Due Process Violations.Plaintiffs claim that the defendants denied them the due process of law guaranteed by the Fourteenth Amendment by enrolling them in an unethical and ill-conceived medical experiment without their informed consent. Defendants' sole argument regarding this claim is that it simply does not exist.To the contrary, the federal courts have often recognized claims violations of due process resulting from nonconsensual medical treatment. Such was the case in White v. Napoleon, 897 F.2d 103, 113 (3rd Cir. 1990), in which the Third Circuit held:The Due Process clause of the Fourteenth Amendment substantively protects certain fundamental rights. Among these are the right to be free from unjustified intrusions into the body, Ingraham v. Wright, 430 U.S. 651, 673, 97 S.Ct. 1401, 1413, 51 L.Ed.2d 711 (1977), the related right to refuse unwanted medical treatment, Rennie v. Klein, 653 F.2d 836, 844 (3d Cir.1981), and, as we decide today, the right to sufficient information to intelligently exercise those rights.

Id. at 111. The court emphasized:

A prisoner's right to refuse treatment is useless without knowledge of the proposed treatment. Prisoners have a right to such information as is reasonably necessary to make an informed decision to accept or reject proposed treatment, as well as a reasonable explanation of the viable alternative treatments that can be made available in a prison setting.

Id. (emphasis added); see also Washington v. Harper, 494 U.S. 210, 229, 110 S.Ct. 1028 (1990) ("[t]he forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty"); Zinermon v. Burch, 494 U.S. 113, 110 S.Ct. 975 (1990); United States v. Stanley, supra; Riggins v. Nevada, 504 U.S. 127, 112 S.Ct. 1810 (1992) (holding that a prisoner's Fourteenth Amendment rights were violated when he was forced to ingest anti-psychotic drugs during his trial without the State demonstrating that the medication was medically appropriate and there were not less intrusive alternatives).

The constitutional right to informed consent is also expressly recognized in the context of experimental treatment. See Bibeau v. Pacific Northwest Research Foundation Inc., 188 F.3d 1105 (9th Cir. 1999); In re Cincinnati Radiation Litigation, 874 F.Supp. 796, 811 (1995); Craft v. Vanderbilt University, 18 F.Supp.2d 786 (1998); and Henrich v. Sweet, 62 F.Supp.2d 282 (D. Mass. 1999). Thus, the defendants' assertion that substantive due process rights do not apply in cases of informed consent involving medical treatment is false.

This constitutional right applies regardless of whether the experiment is therapeutic or non-therapeutic. Defendants cite no legal authority for their theory that the standards for non-therapeutic research experiments differ from those for therapeutic research experiments, and no court has so held. The sole case they cite, Whitlock v. Duke University, 637 F.Supp. 1463 (M.D.N.C. 1986), aff'd, 829 F. 2d 1340 (4th Cir. 1987), does not support this theory. In fact, it supports plaintiffs' claim that the defendants had a heightened duty, based on federal regulations and the Nuremberg Code, for obtaining informed consent. No Section 1983 claims were alleged in Whitlock. Instead, the federal court sitting in diversity jurisdiction was asked to determine whether an

alleged failure to obtain informed consent in a nontherapeutic experiment would be subject to North Carolina's statutory standard of care for health treatment, or whether a heightened standard would apply. After examining the Nuremberg Code as "persuasive guidance," the court concluded "that North Carolina would analyze informed consent in the nontherapeutic context consistent with 45 C.F.R. § 46.116(a)(2)."

Moreover, plaintiffs have alleged and found that Protocol 126 was conducted for non-therapeutic purposes. The plaintiffs contend that the purpose of the experiment was to further the scientific and personal ambitions of the defendants, not to provide the best known therapy to the plaintiffs. See Draheim's Motion for Partial Summary Judgment, filed 3/21/02. To the extent the distinction is pertinent to this motion, the defendants cannot ask this Court to determine as a factual matter whether this case involves "therapeutic" or "non-therapeutic" treatment, and the motion must be denied.2. Plaintiffs' Have Stated a Cause of Action For Violations of their Procedural Due Process Rights.

Similarly, in this case plaintiffs claim procedural due process violations resulting from (1) defendants' failure to provide plaintiffs with an opportunity to be heard prior to deprivation of their liberty interest in bodily integrity; (2) defendants' failure to abide by the procedural due process standards for human subject research defined by the federal regulations and Assurance Agreement applicable to Protocol 126; and (3) defendants' concealment of the true facts about the experiment.

As the U.S. Supreme Court stated in Cleveland Bd. of Educ. v. Loudermill, 470 U.S. 532, 546 105 S.Ct. 1487 (1985):An essential principle of due process is that a deprivation of life,

liberty, or property "be preceded by notice and opportunity for hearing appropriate to the nature of the case." We have described "the root requirement" of the Due Process Clause as being "that an individual be given an opportunity for a hearing before he is deprived of any significant property interest." (emphasis in original)(citations omitted).

Where explicit procedures govern the standards for informed consent, or where those procedures are inadequate under an Mathews v. Eldridge balancing test, the failure to properly obtain informed consent can constitute a violation of procedural due process rights. In Zinermon v. Burch, 110 S.Ct. 975, 494 U.S. 113 (1990), a patient who was voluntarily committed to a mental hospital asserted that the state actors who admitted him failed to properly apply the state statutes which would have provided him with a timely postdeprivation hearing. The patient claimed that he lacked the mental capacity to provide informed consent, and his admission to the hospital should have been treated as an involuntarily commitment. Due to State's failure to abide by the involuntary commitment procedures and provide a postdeprivation hearing, the patient claimed that he was deprived of his procedural and substantive due process rights. The trial court dismissed the case on a motion to dismiss on the pleadings. On certiorari, U.S. Supreme Court reversed, holding that, based on the facts alleged, the State's failure to implement informed consent procedures in place to protect the substantial liberty interests at stake, either pre-deprivation or post-deprivation, could constitute a violation of the patient's procedural due process rights.

In addition, the federal regulations and "Assurances" related to the policies and procedures for conducting experiments on human subjects exist in order to ensure that procedural due process rights in experimental research are protected. See

Section C supra. In Halikas v. University of Minnesota, 856 F.Supp. 1331 (D. Minn. 1994), these federal regulations and "Assurances" were recognized as "defin[ing] due process standards applicable to human subjects research." Id. at 1335.

In Halikas, after an IRB shut down a researcher's experiment based upon alleged violations of the informed consent requirements of 21 C.F.R. § 56.113, the researcher sued for a preliminary injunction to prevent the shutdown. The court denied his request, finding that "the IRB is in sufficient compliance with the procedures in the University of Minnesota General Assurance Agreement and the applicable federal regulations to satisfy the required procedural due process." Id. at 1136 (emphasis added). Here, plaintiffs' allegations that defendants' failure to abide by these identical standards give rise to a procedural due process cause of action under Section 1983.

The informed consent failures in this case (i.e. intentional withholding of information necessary to understand the proposed treatment and possible risks and benefit of the research protocols was withheld, intentional interference with the IRB review process, and the intentional continuation of financial conflicts of interest, despite prohibitions on such) resulted in a breakdown of the procedural due process protections intended to reduce the risk of erroneous deprivation. Here, the plaintiffs' procedural due process claims arise from defendants' failure to obtain informed consent, a direct violation of the federal regulations intended to protect human research subjects. The consequences of those were fatal -- 80 of 85 participants died prematurely as a result of defendants' actions.

Finally, procedural due process rights exist in the experimental research context where intentional withholding of information

regarding the true nature and purpose of the experimental treatments impaired the patients' rights to seek damages for substantive due process claims. Henrich v. Sweet, 62 F.Supp.2d 282 (D. Mass. 1999). In Heinrich, it was alleged that the defendants, including an amalgam of public and private researchers and institutions, failed to obtain informed consent of their cancer patients by concealing the true nature and purpose of the proposed treatments, which were primarily intended to research the effects of radiation exposure on humans. Many years after the experiments occurred, the patient and their survivors brought suit and alleged that their right of access to the court to had been violated through the defendants acts of withholding pertinent information. The Heinrich court held that the plaintiffs had stated a cause of action for violation of procedural due process as a result of the government's concealing information about the experiments, which, due to the loss of evidence over the passage of time, interfered with the plaintiffs' cause of action and "opportunity to be heard." See also In re Cincinnati Radiation Litig., 874 F.Supp. at 825 (finding that loss of witnesses due to concealing purpose of radiation experiments could amount of violation of procedural due process).

Procedural due process violations in this case occurred as a result of the defendants' failure to implement procedures which were designed to eliminate the risk of erroneous deprivation of substantive due process rights (and which were agreed to as a condition of obtaining authority to conduct research on human subjects). The informed consent process was inherently flawed by the defendants' intentional withholding of information necessary to evaluate the nature and purpose of the proposed treatment, and the risks involved.

3. Plaintiffs Have Sufficiently Pled a Section 1985 Cause of Action

Similarly, defendants' argument that plaintiffs have no right under 42 USC § 1985 should be rejected. Defendants deceptively seek to dismiss the entire Fourth Count of the plaintiffs' Second Amended Complaint pursuant to this statute, though plaintiffs' cause of action seeks damages under both Sections 1985 and 1983. Even if defendants were correct that Section 1985 does not apply, the Fourth Count of the pleading should not be dismissed in its entirety.In any event, defendants' contention should be rejected. At this stage of the litigation, defendants' contention that plaintiffs are not a proper "class" under the statute is not ripe. Taking plaintiffs' allegations as true, plaintiffs have set forth a valid cause of action under 42 U.S.C. § 1985.

4. Federal Regulations Can Give Rise to Rights Subject to Section 1983 Cause of Action.

The U.S. Supreme Court has held that, to the extent federal regulations secure a federal right guaranteed to an individual, they can form the basis of a Section 1983 claim. Wright v. City of Roanoke Redevelopment and Housing Authority, 479 U.S. 418, 430, 107 S.Ct. 766, 93 L.Ed.2d 781 (1987). The Ninth Circuit has upheld the following test for determining whether a particular regulation gives rise to a federal right.

First, Congress must have intended that the provision in question benefit the plaintiff. Second, the plaintiff must demonstrate that the right assertedly protected by the statute is not so "vague and amorphous" that its enforcement would strain judicial competence. Third, the statute must unambiguously impose a binding obligation on the States . . .

San Lazaro Association, Inc. v. Connell, 278 F.3d 932, 941 (2002). See also Williams v. Lane, 851 F.2d 867, 879-81 (7th Cir.1988), cert. denied, 488 U.S. 1047, 109 S.Ct. 879, 102

L.Ed.2d 1001 (1989) (holding that regulations requiring equal housing and program opportunities for inmates in protective custody can create liberty interest for purpose of a Section 1983 claim).

Thus, the court may find that certain regulations which are intended to benefit the plaintiff and which constitute a binding obligation on the state can constitute a right secured by federal law. In this case, plaintiffs have alleged, inter alia, that defendants failed to abide by the highly specific federal regulations and binding "Assurances" regarding informed consent in experimental research on human subjects, and that this failure deprived plaintiffs of a right secured to them under federal law that is subject to the protections of a Section 1983 action. As discussed below, application of the federal regulations at issue in this case to the Ninth Circuit test in San Lazaro demonstrates that plaintiffs have stated a Section 1983 cause of action. First, the human subject research regulations are undoubtedly intended to protect patients undergoing experimental treatments, whether therapeutic or non-therapeutic. Second, the requirements are not unreasonably vague or amorphous. Explicit steps for obtaining and maintaining records of patients' informed consent are set out in 45 C.F.R. Part 46. Third, the statutory requirements are set out not only in the federal regulations as mandatory obligations on all researchers conducting experimental research, but they are also repeated in "Assurance Agreements" as a condition of federal funding for that research. Under San Lazaro, plaintiffs are entitled to pursue Section 1983 damages for defendants' violations of the informed consent regulations and Assurances.

5. Section 1983 Remedies are Supplemental to, Not in Place of, State Law Remedies

The fact that state law remedies may be available is irrelevant to a Section 1983 claim. In Zimermon v. Burch, 494 U.S. 113, 110 S.Ct. 975, 982 (1990), the U.S. Supreme Court, in quoting Monroe v. Pape, 365 U.S. 167, 81 S.Ct. 473 (1961), stated: "It is no answer that the State ha a law which if enforced would give relief. The federal remedy is supplementary to the state remedy, and the latter need not be first invoked." As discussed at length in this brief, there is ample authority that substantive due process claims based upon the Fourteenth Amendment for violation of informed consent are well-established in U.S. jurisprudence. Defendants rely heavily on Collins v. City of Harker Heights, 503 U.S. 115, 112 S.Ct. 1061 (1992), however that case rejected only the argument that a municipality had a duty under the Constitution, to provide a safe workplace, for the purpose of a Section 1983 claim. It did not address informed consent. Federal courts are only reluctant to recognized certain Section 1983 claims that are not based on federal law, as explained by the D.C. Circuit as follows:[S]ection 1983 does not provide a remedy for any and all injuries inflicted by persons acting under color of state law. Rather, these cases draw a distinction between those rights secured by the Constitution or federal law and those secured only under state tort laws; section 1983 provides a remedy only for injuries to the former.Washington v. District of Columbia, 802 F.2d 1478, 1480 (D.C. Cir. 1986).

6. Defendants Are Not Entitled to Qualified Immunity

The defendants half-heartedly assert qualified immunity in defense of the constitutional claims against them. Private actors engaged in public functions generally do not enjoy qualified immunity. Richardson v. McKnight, 521 U.S. 399, 408-09, 117 S.Ct 2100 (1997); Wyatt v. Cole, 504 U.S. 158, 167-68, 112 S.Ct. 1827 (1992); Halvorsen v. Baird, 146 F.3d 680, 685 (9th Cir. 1998). The defendants have offered no basis for

qualified immunity in this case and it must be denied.

E. THERE IS AN IMPLIED PRIVATE CAUSE OF ACTION UNDER THE FEDERAL REGULATIONS CITED IN PLAINTIFFS' PLEADINGS

As the Amended Complaint indicates, plaintiffs also assert claims based on 21 C.F.R. § 210, 211 and 21 C.F.R. § 601, 610, which establish the law of the United States with respect to the manufacture and control of investigational biologics, and 45 C.F.R. Part 46, which establishes the law of the United States with respect to the protection of human research subjects.In 1974, Congress passed the National Research Act, which authorized the adoption and implementation of regulations to protect research subjects. In 1991, the regulations were integrated into the Common Rule for 17 departments and agencies, the most familiar of which is the Department of Heath and Human Services regulations at 45 C.F.R. Part 46, a copy of which is attached as Exhibit "S." The Common Rule is published in the Federal Register at 56 Fed. Reg. 28, 012 (June 18, 1991). These regulations, among other things, detail the conditions required for obtaining informed consent and the information that must be provided under those conditions, restrict experiments to those in which risks are minimized, require the equitable selection of research subjects and establish the requirement for institutional review boards to oversee research at every institution subject to the regulations.These regulations require:

Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subject to risk.. . .Risks to subjects are reasonable in relation to anticipated benefits . . .. . .Selection of subjects is equitable.. . .Informed consent will be sought from each prospective subject or the subject's legally authorized

representative, in accordance with, and to the extent required by § 46.116.. . .Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.. . .Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.. . .Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.. . .Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

These regulations also require institutions to appoint an IRB to review the design of any clinical trial protocol and to ensure that the conduct of any clinical trial at the institution is consistent with the requirements of the regulations. Defendants violated these and several other provisions of the federal regulations.Defendants contend that plaintiffs do not have a cause of action under the Code of Federal Regulations, as there is no private right of action provided under the sections defendants violated and that Titles 21 and 45 create enforcement rights for the FDA.The regulations for which plaintiffs bring causes of action are silent as to whether a claimant may assert a private cause of action. Thus, for plaintiffs to be able to assert a private cause of action, Congress or an administrative agency must implicitly intended to have individuals use them to litigate. 24 Hour Fuel Oil Corp v. Long Island Rail Road Company, 903 F.Supp. 393, 397 (E.D.N.Y. 1995). In Cort v. Ash, 422 U.S. 66, 78, 95 S.Ct. 2080, 45 L.Ed.2d 26 (1975), the United States Supreme Court set forth a four part test to determine the availability of an implied private cause of action:

(1) whether the plaintiff is one of the class for whose benefit the statute was enacted;

(2) whether there is any indication of legislative intent, explicit or implicit, to create or deny such a remedy;

(3) whether the private right of action would be consistent with or frustrate the purposes of the legislative scheme; and

(4) whether the cause of action is traditionally relegated to state law remedies, so that it would be inappropriate to infer a cause of action based solely on federal law.The primary factor in this analysis is whether there is any indication, one way or another, of legislative intent. Olmsted v. Pruco Life Insurance Company of New Jersey, 134 F.Supp.2d 508, 512 (E.D.N.Y. 2000).

A review of the Cort factors demonstrate that there is an implied private cause of action under 45 C.F.R. Part 46, the federal regulations concerning human experimentation. First, plaintiffs are obviously a beneficiary of the regulations. As set forth above, the history of the regulations has been concerned with the rights of human subjects. It is these individuals for whose benefit the regulations were enacted. As the Memorandum titled "Review of Federal policy for the Protection of Human Subjects" indicates, 45 C.F.R.. § 46 provides that review by the IRB for all research protocols involving human subjects to ensure that "(1) risks are minimized and reasonable in relation to anticipated benefits; (2) there is informed consent; and (3) the rights and welfare of the subjects are maintained." A true and correct copy of the February 17, 1994 Memorandum is attached hereto as Exhibit " ." This section is designed to protect substantive rights, not simply procedural ones. Stated differently, this is not a statute focusing on spending directives or conditions for government

grants. See Rapid Transit Advocates v. Southern California Rapid Transit Dist., 752 F.2d 373, 377 (9th Cir. 1985).

Second, there is no legislative history expressing an intent to deny individuals subjected to unlawful human experimentation the ability to seek redress. Had a bar to private actions been contemplated Congress would have so stated. The only logical presumption based upon the legislative history set forth above is that Congress intended for individuals to seek relief under a series of regulations designed solely to protect them.Third, for reasons similar to what has just been asserted, the purpose of the regulations is to ensure that unlawful human experimentation does not occur. To allow a patient the right to be made whole, to seek a remedy for the physical, mental and emotional damage from the experimentation advances the goals of the regulations.

Finally, the protection of human subjects to which 45 C.F.R. § 46 applies is a unique federal cause of action. That there are state causes of action applicable to defendants' conduct does not negate the viability of a federal cause of action. As stated In re Cincinnati Radiation Litigation, 874 F.Supp. 796, 817 (S.D.Ohio 1995), a case with facts similar to those in this matter,"[t]he distinction between this case and an ordinary tort case is not one of degree, but rather, of kind. Government actors in cases such as this violate a different kind of duty from that owed by a private tort defendant." Thus, a cause of action for damages from unlawful human experimentation based upon regulations prohibiting this conduct would not interfere with state law claims, especially considering that there is no state statute specifically barring defendants' conduct.

Whitlock v. Duke University, supra, 637 F.Supp. 1463 (M.D.N.C. 1986) is instructive. Whitlock concerned a subject in a non-therapeutic, deep-diving experiment who sustained

severe brain damage. The plaintiffs asserted several causes of action, including damages for breach of 45 C.F.R. § 46. While the court dismissed the action after finding that the plaintiff consented to participate in the experiment with full knowledge of the risks, the court relied upon 45 C.F.R.. § 46.116 in reaching its determination. The court did not opine whether a private cause of action exists under this section.

In addition, plaintiffs do not seek a private cause of action under the FDCA and have never sought such relief. While the defendants have violated the provisions of the FDCA and 21 C.F.R. Part 312, the plaintiffs claims are for violations of 45 C.F.R. Part 46, which is not stated as under the authority of the Food and Drug Administration, unlike the provisions of the FDCA.

None of the cases defendants cite are set forth for anything other than boilerplate language, that there is no private cause of action under the Food, Drug and Cosmetic Act. However, this same argument was rejected in Platzer v. Sloan-Kettering Institute for Cancer Research, 787 F.Supp. 360, 364 (S.D.N.Y. 1992), aff'd 983 F.2d 1086 (2d Cir.), cert. den., 507 US 1006, 113 S.Ct. 1648, where the court held that one case cited by defendants, Merrell Dow Pharmaceuticals, 478 US 804 (1986):

did not involve a direct implied right of action, but rather involved a state law action which required interpretation of a federal statute. The importance in this distinction can not be overemphasized. The Supreme Court stated, "This case does not pose a [direct] federal question . . . respondents do not allege that federal law creates any of the causes of action that they have asserted.

As such, its holding was limited to state law claims alleging violations of federal statutes. As the plaintiffs claim in this

matter are predicated on federal claims, e.g., the Code of Federal Regulations, defendants' reliance on Merrell Dow Pharmaceuticals and the other cases is misplaced, in addition to being moot.

F. PLAINTIFFS ARE THIRD-PARTY BENEFICIARIES TO THE ASSURANCE AGREEMENTS, WHICH CONTAIN THE PROVISIONS OF THE BELMONT REPORT

In the 1970's Congress appointed a federal commission to examine the system for protecting human research subjects. The National Commission for the Protection of Research Subjects in Biomedical and Behavioral Research was charged with identifying the basic ethical principles underlying research on human subjects. In 1979, it issued "The Belmont Report," a document all research institutions promise in an Assurance Agreement to uphold in all research studies in order to be eligible for certain grant monies. After acknowledging the influence of the Nuremberg Code, the Belmont Report sets forth three principles to guide human subject research: the first is respect for persons, which demands that researchers fully inform their subjects of all material information about the study and only then obtain their voluntary consent; the second is beneficence, which prohibits any experiment where the risks are too great or are outweighed by the benefits; and the third is justice, which requires equitable selection of research subjects. Belmont Report, DHEW Pub. No. (05) 78-0012. (Washington D.C.: G.P.O.), a copy of which is attached as Exhibit " ."

Plaintiffs are clearly third-party beneficiaries to the assurance agreements between defendants and the government, as the purpose of these agreements are for the protection of the human research subjects participating in clinical trial, such as Protocol 126. An objective test is used to determine whether a

third-party beneficiary contract exists. Postlewait Constr., Inc. v. Great American Ins. Companies, 106 Wn.2d 96, 99 (1986). If performance necessarily and directly benefits the third-party a beneficiary contract exists. Id. It is the participants of every human clinical research study that are protected by the provisions of the Belmont Report. Otherwise, there is no purpose to the Assurance Agreements. Accordingly, defendants' argument should be rejected.

IV. CONCLUSION

For the foregoing reasons, defendants' Motion to Dismiss should be denied in its entirety.DATED this 16th day of April, 2002.

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