Human Research Subject Protections for National Security Experiments

(This is a revised version of a paper originally submitted to Professor John Sims in partial fulfillment of the requirements for his course in National Security Law at the University of the Pacific, McGeorge School of Law, in the Fall Semester 2005.)

Note: This paper reflects the opinion of Cheryl Welsh, not Mind Justice.

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About Professor Sims

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Professor Sims clerked for Judge Frank M. Coffin (Chief Judge, U.S. Court of Appeals for the First Circuit). For 11 years, he was an attorney for the Public Citizen Litigation Group, a public interest law firm in Washington, D.C. founded by consumer advocate Ralph Nader. Professor Sims handled a wide range of complex cases at all levels of the state and federal courts, including the Supreme Court of the United States. He was in several significant constitutional cases including *INS v. Chadha* and *Snepp v. United States*. Professor Sims is a founding co-editor-in-chief of the *Journal of National Security Law & Policy*, a faculty-edited, peer-reviewed law journal that is published by Pacific/McGeorge with the participation of national security experts from across the country.

Introduction

It was a great honor for me to have this paper graded by Professor Sims. I knew of Sims in the often-cited 1985 US Supreme Court case, *CIA v. Sims*, a freedom of information lawsuit. The Court held that institutions and individuals who performed research on a project [Project MKULTRA], financed by the CIA, were "intelligence sources" and, therefore, the [CIA] Director was authorized to withhold their identities, to protect intelligence sources and methods from unauthorized disclosure. This paper will discuss the widespread deference to national security as illustrated in the unanimous holding in *CIA v. Sims*. As will be shown below, this deference is also a powerful factor in human subject legal protections for secret government experiments, including the MKULTRA and radiation experiments. National security law

provides a valid and reliable framework in which to analyze human research subject protections for national security experiments.

A core question raised in this paper is that a very powerful cold war culture easily thwarts human subject protections advocates who fail to act on their consensus. The CIA's infamous mind control experiments and the illegal radiation experiments on humans were condoned as essential for national security, at the very top levels of the government. The second core question raised in this paper is that a scandal involving classified experiments under the current system of federal regulations has not occurred, but as will be shown, the legal weaknesses of the system are apparent. The legal weaknesses are long-standing in spite of scandal-provoked efforts to remedy them. The weaknesses of the current system of federal regulations are not caused by flaws in the legal system itself. The weaknesses can be shown to be caused in part, by a very powerful but silent cold war culture based on the belief that human experiments are the only feasible means to achieve essential national security goals. This culture overwhelms the majority consensus of advocates for human subject protections whose rhetoric is well-accepted but who fail to act in any meaningful way. The widely-held belief that secret experiments couldn't happen again does not take into account this paradox. As a result, protections for human research subjects in national security experiments have failed and are likely to continue to fail to prevent major scandals without alternative approaches. A 1994 congressional hearing reported that "nearly half a million Americans were subjected to some kind of cold war era tests," often without being informed and without their consent. In addition, experimentation law is well grounded in constitutional and international law. It is an under-reported fact that two major reports on human rights and torture in the U.S. recently listed illegal radiation experiments. Many more facts are documented below. Therefore, human research subject protections should be a high priority and are just as significant as current issues of torture and illegal wiretapping.

Human Research Subject Protections for National Security Experiments

This paper addresses the legal and underlying historical factors that have led to the current status of US law on human research subject protections for national security experiments. A framework of national security law and presidential powers is used and provides a new perspective. Human research subject protections for secret experiments represents a small part of experimentation law although it has a well-established grounding in constitutional and international law. The secret CIA experiments to develop mind control weapons in the 1950s-1970s led to congressionally-imposed federal regulations and presidential executive orders so that illegal experiments on unwitting human subjects would never happen again. Military radiation experiments for the development of the atomic bomb led to executive memorandums ordering federal and intelligence agencies to implement regulations to prevent illegal and unethical secret experiments conducted without the consent of the human research subject. By examining the judicial, executive and legislative response to the two major scandals, strategies and proposals for preventing future illegal experiments for national security are more likely to succeed. So far, experimentation law has not included an analysis using current theories of national security law and presidential powers.

This paper specifically addresses why federal legislation has never been enacted and why the current executive memorandums and executive orders do not protect human subjects of national security experiments. Proposed remedies include enacting a federal statue to provide an effective legal protections for human research subjects of national security experiments. Some presidential scholars have recently studied executive orders and the historical and legal basis of presidential powers.[1] The history of executive orders for human experimentation can be applied to the study of presidential powers. Because human experimentation for national security experiments is an intelligence matter, the history and framework of national security law also provides an explanation for the long record of failed human subject protections.

First, experts on secret experiments and the law dating back to World War II discuss the major issues including: the cold war CIA experiments that were knowingly conducted outside the bounds of the law; the scientific-military culture of secrecy; the excessive control of all scientific information connected to weapons; and the propaganda and scientific deception surrounding the unethical and illegal radiation experiments. The importance of the cold war culture is that experts are now reporting a great increase of secrecy, new weapons, scientific propaganda and deception, and government actions above the law; all to protect national security.

The fifty year clash between the acknowledged validity of human subject legal protections and the perceived needs of national security is described by many experimentation law experts and they report utilitarian national security interests continue to trump human subject protections. As will be shown, this is carried out by means of: condoning illegal experiments at the very top levels of government; by the executive branch in failing to implement effective protections for human research subjects; by the historically-based acquiescence of Congress to presidential initiative in national security issues and thereby failing to pass effective legislation to protect human research subjects; by the acceptance at top levels of the government of a culture of scientific propaganda and deception including government cover stories; and the classifying of illegal government actions, ordered and implemented by top levels of the government for national security purposes. This pattern was in place for CIA mind control experiments, for radiation experiments and continues today, experts report.

This paper will address the judicial, legislative and executive response to human subject protections and the finding that the system of law works as well as in similar intelligence matters. As will be shown, the legal approach to solving this issue is dependent on a political question; the continuing cold war culture that allows the government to work outside of the law and to go unpunished.

The first section identifies and defines the problem of human subjects protections for national security experiments. The next section presents a history of experimentation law beginning with

the Nuremberg Code and the well-grounded basis for human subject protections in international and constitutional law. Next, the judicial branch response to illegal human experiments is followed with sections on the failed attempts of the executive and legislative branches of government to address human subjects protections as seen in several 1990-2005 government reports on experimentation. This section includes an analysis of the shared powers between the executive and legislative branches over national security issues within the framework of national security law and presidential powers. The final section covers the argument for a federal statute and other possible remedies.

The problem: a serious lack of human subject protections for national security experiments and a continuing cold war mentality

Past military and CIA experiments with toxic chemicals and for behavior modification were headline news in the 1970s. Congressional hearings uncovered illegal and extensive government programs including the CIA's now infamous MKULTRA mind control experiments. At the 1977 hearing on *Project MKULTRA: The CIA's Program of Research in Behavior Modification*, Senator Daniel Inouye reassured many when he stated that "we are reviewing past events in order to better understand what statutes and other guidelines might be necessary to prevent the recurrence of such abuses in the future."[2] Legislation in 1978 established a *President's Commission For the Study of Ethical Problems in Medicine, and Biomedical and Behavioral Research* and in 1981, federal regulations were strengthened.[3] President Ford signed an executive order banning intelligence agencies from conducting human experiments without the consent of the research subject and the order referred to the 1976 Department of Health, Education and Welfare (DHEW) Regulations (45 CFR 46) Protections for Human Subjects as the standard of human subject protections to be applied by the CIA and intelligence agencies.[4] A March 26,1977 CIA memorandum on *Guidelines for Human Subject Research* implemented the policy: "pursuant to Section 102 of the National Security Act of 1947, Executive Order 11905 and National Security Council Intelligence Directives, a policy is hereby established for the

protection of human subjects of research activities conducted or funded by the Central Intelligence Agency."

Executive orders are described as:

> a form of "presidential legislation" or "executive lawmaking," in the sense that they provide the president with the ability to make general policy with broad applicability akin to public law. For over a century the Supreme Court has held that executive orders, when based upon legitimate constitutional or statutory grants of power to the president, are equivalent to laws.[5]

Today, most executive orders waive the right to sue or enforce the order. Without legal enforcement, a law is relatively meaningless. Enforcement of executive orders is almost impossible:

> [T]he ability of private citizens to pursue claims through the courts. Claimants can, of course, challenge the validity of executive orders on the grounds that they exceed the president's constitutional or statutory authority. Additionally, as a general rule the courts have jurisdiction in disputes arising over executive orders issued pursuant to delegated statutory authority, or those directed at nongovernmental parties. In practice, however, it is almost impossible for private claimants to allege violations of an executive order itself or seek damages as a remedy for violations against another private party. Recent court rulings are consistent on this point, holding that executive orders do not generally permit citizens to insist on judicial enforcement of the orders' requirements.[6]

The 1977 *MKULTRA* hearing explained how the executive branch consulted with Congress about human subject protections. Senator Kennedy stated:

> Two years ago, when these abuses were first revealed, I introduced legislation, with Senator Schweiker and Senator Javits, designed to minimize the potential for any similar abuses in the future. That legislation expanded the jurisdiction of the National Commission on Human Subjects of Biomedical and Behavioral

> Research to cover all federally funded research involving human subjects. The research initially was just directed toward HEW activities, but this legislation covered DOD as well as CIA. . . . The CIA supported that legislation in 1975, and it passed the Senate unanimously last year. I believe it is needed in order to assure all our people that they will have the degree of protection in human experimentation that they deserve and have every right to expect.[7]

Kennedy's legislation did not pass and President Ford's executive order for intelligence agencies preempted Kennedy's legislative attempts, as the national security law and presidential powers framework would predict. "In a pattern at the core of executive institutional power, presidents have moved to fill in the gaps in authorizing legislation with their own interpretations, outflank congressional efforts to impose more substantive restrictions, and maintain the initiative in important policy areas."[8]

Congressional and executive efforts to prevent MKULTRA from happening again did not address the underlying problem- that the CIA had knowingly operated beyond the statutes preventing domestic activities by the CIA and constitutional law. Experimentation without the consent of the human research subject is a violation of the U.S. Constitution, specifically: the Fourth Amendment proscription against unreasonable searches and seizures (including seizing a person's body), the Fifth Amendment's proscription against depriving one of life, liberty or property without due process, and the Eight Amendment's prohibition against the infliction of cruel and unusual punishment.[9] A 1963 CIA inspector general's report on MKULTRA acknowledged the illegalities. "Some [of these] activities raise questions of legality implicit in the original charter. [The charter is congressionally approved]. . . . A final phase [of some of these projects] places the rights and interests of US citizens in jeopardy."[10] Law professor Alan Scheflin examined thousands of declassified CIA documents and concluded, "There are dozens of CIA memos that attest to the illegal and unethical nature of its work. . . . It is difficult not to conclude that the CIA is above the law and unhampered by Congress, the American public or the occupant of the Oval Office of the White House. "[11]

Another of many clear examples of the CIA operating above the law and with the implicit approval of the executive branch was reported in a 2002 *San Jose Mercury News* article:

> New files from a UC Davis history professor showed White House officials had intentionally withheld details of Frank Olson's death from the family.[Olson was the CIA scientist who allegedly jumped to his death from a hotel room in 1953 after being surreptitiously given LSD by the CIA.] They included a memo from Dick Cheney,[now vice president] a White House assistant at the time, to Donald Rumsfeld, [now secretary of defense] the chief of staff, on July 11, 1975, one day after the Olsons first held a news conference. The memo warned that a lawsuit could involve "the possibility that it might be necessary to disclose highly classified national-security information in connection with any court suit or legislative hearings on a private bill." The documents also include memos written by White House Counsel Roderick Hills to the president that were routed through Cheney and other officials. . . . As a result, Hills urged settling the case out of court.

Cheney and Rumsfeld completely ignored the illegality of giving Olson LSD without his consent as part of extensive illegal CIA LSD experiments. They did not volunteer to turn over this information to the Department of Justice for prosecution, for example. Instead the recommendation by White House Counsel was to keep the information classified while citing national security concerns.[12]

The strengthened federal regulations as a result of the MKULTRA scandal were not in effect until the mid-1970s. The unethical and illegal radiation experiments, publicly revealed in 1990s front page news occurred from the 1940s through the early 1970s. President Clinton appointed the Advisory Committee on Human Radiation Experiments (ACHRE) and its 1995 report said the federal government was "blameworthy for not having had policies and practices in place to protect the rights and interests of human subjects" in several thousand experiments.[13] The *ACHRE* report recommended strengthening federal regulations: "The Advisory Committee

recommends . . . the adoption of a federal policy requiring the informed consent of all human subjects of classified research and that this requirement not be subject to exemption or waiver. In all cases, potential subjects should be informed of the identity of the sponsoring federal agency and that the project involves classified information."[14]

The *ACHRE* report went further and addressed some of the underlying problems of secret experiments:

> It also is possible that a prohibition on classified human subjects research would be circumvented through redefinition of activities or disregarded outright. . . . The Advisory Committee believes, however, that the classification of human subject research ought properly to be a rare event and that the subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections. The Advisory Committee does not believe that continuing with the current federal policy governing the protection of human subjects, which does not provide any special safeguards or procedures for classified research is adequate. In the current political context, classified human subjects research occurs relatively rarely. Existing policy may prove an inadequate safeguard of individual rights and welfare, however, if in the future national security crises occur that generate a perceived need for classified research. The convergence of elements of secrecy, urgent national purposes, and the essential vulnerability of research subjects, owing to differentials in information and power between those conducting research and those serving as subjects, could again lead to abuses of individual rights and, upon subsequent revelation, the erosion of public distrust in government.[15]

And yet there have been no effective changes in the law since the 1995 *ACHRE* report. Federal regulations and the executive order for classified research have remained unchanged. A 1997 Clinton presidential *Memorandum on Protections for Human Subjects of Classified*

Research was addressed to government agencies under the current federal regulations for human experiments.[16] The memorandum was adopted only by the Department of Defense, there are no effective mechanisms to implement the memorandum and it was not adopted by intelligence agencies.[17] The memorandum stated: "All agencies that may conduct or support classified research . . . shall jointly propose to prohibit waiver of informed consent for classified research. . . . Agencies shall, within 1 year,. . . promulgate final rules on the protection of classified research."[18] This was not done. The memorandum continued: "Beginning one year after the date of this memorandum, no agency shall conduct or support classified human research without having proposed or promulgated [federal rules on experimentation] . . . , including the changes set forth in this memorandum . . . "[19] As one expert pointed out, there are no rules or mechanisms for oversight and accountability, or for how classified research is to be reviewed and conducted. In practice, this memorandum was a weak and ineffective legal document.

As critical as the *ACHRE* report was of secret government experiments, many others have expressed stronger concerns and have identified other root causes of the continuing problem of human subject protections. Pulitzer prize-winning reporter Eileen Welsome testified before a 1994 congressional hearing, *Radiation Testing on Humans* about the difficulties she encountered with the Atomic Energy Commission (AEC) in uncovering her story on eighteen Americans injected with plutonium between 1945 and 1947 in radiation experiments.[20] Her news accounts led to the public exposure of radiation experiments in the early 1990s.[21] In her 1999 book, *Plutonium Files*, *America's Secret Medical Experiments in the Cold War*, Welsome described that *ACHRE* "conclusions are weak and fail to come to terms with many of the controversial studies."[22] Welsome explained the cold war culture surrounding radiation experiments is largely overlooked or ignored. An excerpt of Welsome's book describes this culture, and as will be shown below, this culture is continuing in new weapons programs today:

> Many scientists couldn't accept the idea that they or their peers had committed any wrongs. They maintained their belief that the ends they had pursued justified the means they used, expressed little or no remorse for the experimental subjects,

> and continued to bash . . . the media for blowing the controversy out of proportion. . . . A few of the experiments increased scientific understanding and led to new diagnostic tools, while others were of questionable scientific value . . . [There was a] pervasive deception that the doctors, scientists, and military officials routinely engaged in even before the first bomb had been detonated. General Leslie Groves [head of the Manhattan Project to build the first atomic bomb] lied egregiously when he testified to Congress in 1945 about radiation effects of the bomb. "A pleasant way to die," he said-fully aware of . . . [what happened to the Japanese victims and in a fatal laboratory accident.] Stafford Warren [director of the Manhattan Project's Medical Section] downplayed the fatalities and lingering deaths in Japan. . . . During the war, the bomb makers believed that lawsuits would jeopardize the secrecy of the project. After the war they worried that lawsuits would jeopardize the continued development of nuclear weapons . . . The weaponeers recognized that they would have to allay the public's fear of atomic weapons in order to keep the [US plutonium] production plants operating . . . This meant an aggressive propaganda campaign about the "friendly atom" and the suppression of all potentially negative stories about health hazard related to atomic energy . . . AEC officials routinely suppressed information about environmental contamination caused by weapons plants . . . The fact is, the Manhattan Project veterans and their proteges controlled virtually all the information. They sat on the boards that set radiation standards, consulted at meetings where further human experimentation was discussed, investigated nuclear accidents, and served as expert witnesses in radiation injury cases.[23]

This cold war culture was and is instrumental in overshadowing the ethics of human subject protections as held by professionals in the 1950s and today. For example, a 1996 *Journal of the American Medical Association* (*JAMA*) reported the reaction of the medical community to the 1995 ACHRE report with calls for more voluntary reforms and weak sanctions:

> "Today, consensus exists that duties to obtain informed consent apply to all human subjects, whether healthy or sick, regardless of the risk or potential for medical benefit from participation in the research and regardless of the nature of sponsorship or funding (e.g. federal, military, or private). Based on a finding of serious deficiencies in the current system of protections for human subjects, recommendations include accountability and sanctions for ethics violations.[24]

Ten years after the *JAMA* article, no laws are in place to implement the consensus for a duty to obtain informed consent in human experiments. The core question raised in this paper is that the very powerful and silent cold war culture described by Welsome easily thwarts human subject protections advocates. The widely-held belief that secret experiments couldn't happen again does not take into account the paradox that this majority fails to act on their very vocal consensus for informed consent in experiments.

The testimony of Columbia University Professor John Rothman, at a 1994 hearing on *Cold War Human Subject Experimentation* further explains by illustrating how a very calculated government policy incorporates the unspoken but widespread belief of the need for illegal human experiments as essential to national security. This policy is well-funded with defense dollars and government action; thereby easily overpowering the consensus of professional communities who are offer rhetoric but no serious action for protecting human subjects:

> If the ethics of experimentation were so clearly established, why did American investigators so frequently violate them? Well, I think the essence of the answer is the war effort, first in 1940 to 1945, then the cold war effort after 1945, fostered what we might call highly utilitarian judgments. Investigators made the calculus that the national interest outweighed individual rights, that the exigencies of the cold war justified violations of known ethical practices. . . . I was most impressed this morning with the questioning that went on about the chain of command. Who was it that allowed or finally passed off on the experiment? How did it work its way through? Was it simply, well that is a fine idea, let's go out and do it? Was

there anything approximate meriting chain of command? Was there anything approximating signoff? . . . And if we are going to set up various kinds of corrective measures, I think that knowledge is absolutely essential.[25]

There are indications that today, the intelligence agencies and industrial-military complex are repeating the cold war deception and patterns described by Welsome. Human rights experts describe "new" weapons of mass destruction, after the atomic bomb that have also been classified for decades, involve top government officials and scientists, and reports of government actions beyond legal limits. Coupled with the continued secrecy and growth of national security, these factors are a valid challenge to the view that future illegal experiments won't happen again. A 2002 *Richmond Times-Dispatch* described the increased secrecy surrounding experiments:

> "It borders on the scandalous that we still don't have rules in place that would at least begin to protect the people who are in those trials," cautioned Jonathan D. Moreno, director of the Center for Biomedical Ethics at the University of Virginia. . . . Moreno pointed to a December news report that President Bush had given the secretary of health and human services [HHS] the authority to classify the information as secret. Moreno said that could allow the Defense Department or CIA to undertake secret human experiments with the HHS.[26]

In his 1999 *New York Times* reviewed book, *Undue Risk, Secret State Experiments on Humans*, Moreno wrote that national security concerns will outweigh human subject protections:

> Today and ever since the end of the World War II, the universal sensitivity about human experiments is coupled with the fact that they are probably unavoidable in the real world of national security. Textbook theories, laboratory experiments, and computer and animal models can only go so far. At some point, when information is needed about how human beings will react to new forms of weaponry, human experiments will have to continue in this business. In a

> dangerous world one might well argue that it would be irresponsible for us not to do so.[27]

Dr. Moreno warned of today's new weapons and the inevitability of unethical classified government experiments:

> In the next century, as in the past, military medical research involving human subjects will be dictated by the limits of information available from other sources. Because a new generation of weapons is being developed that are intended to incapacitate rather than kill an enemy, computer simulations and animal models can only go so far. Among the next generation of weapons is one that may involve a different sort of radiation than that emitted by atomic fission: microwaves. Electromagnetic waves may be used to disrupt an enemy soldier's central nervous system, to cause epileptic seizures.[28]

In 2005, military intelligence, secrecy expert and *Washington Post* columnist William Arkin described the illegalities beneath national security secrecy: "As I have learned . . . most genuine secrets ironically remain secret. . . . Yet Abu Ghraib is like every other national security surprise: We cannot know who the players are or what they are up to until after disaster strikes." Arkin listed "other national security surprise" including "domestic spying operations, illegal weapons developments, and human experimentation."[29]

Most national security issues are resolved politically: the issue of secret experiments seems to be in need of a political as well as a legal remedy, as seen in these larger issues that directly affect human subject protections for national security experiments. The two newspaper articles to follow are examples of Welsome's cold war culture continuing in current weapons programs, characterized by a lack of accountability and oversight. This briefly explains some of the factors that need to be addressed in human subject protections today in order to change the past failures of human subject protections. A 2005 *Washington Post* article described extreme secrecy surrounding new weapons and possible illegal acts.

> Further, Granite Shadow posits domestic military operations, including intelligence collection and surveillance, unique rules of engagement regarding the use of lethal force, the use of experimental non-lethal weapons, and federal and military control of incident locations that are highly controversial and might border on the illegal. Both plans seem to live behind a veil of extraordinary secrecy because military forces operating under them have already been given a series of "special authorities" by the President and the secretary of defense. These special authorities include, presumably, military roles in civilian law enforcement and abrogation of State's powers in a declared or perceived emergency. [30]

A 2005 *New York Times* article reported a lack of legislative and executive oversight and accountability for new weapons programs:

> Republican members of Congress say there are signs that the Defense Department may be carrying out new intelligence activities through programs intended to escape oversight from Congress and the new director of national intelligence. . . . The lawmakers said they believed that some intelligence activities, involving possible propaganda efforts and highly technological initiatives, might be masked as so-called special access programs, the details of which are highly classified. The report said the committee believed that "individual services may have intelligence or intelligence-related programs such as science and technology projects or information operations programs related to defense intelligence that are embedded in other service budget line items, precluding sufficient visibility for program oversight." "Information operations" is a military term used to describe activities including electronic warfare, psychological operations and counterpropaganda initiatives.[31]

As will be further detailed below, experts on past experimentation scandals cite this largely political information as definitive, yet repeatedly ignored when addressing human subject protections. Could human experiments similar to past national security scandals happen today?

Most people, including Steven Aftergood of the Federation of American Scientists Secrecy Project think the possibility is almost zero.[32] The new analysis in this paper will challenge this widely-held view. The argument can be made that it's a scandal waiting to happen, although taking into account increased secrecy and technological advances, it remains to be seen how the next scandal may unfold.

The Nuremberg Code-cited by most legal experts but ineffective against the powerful medical, pharmaceutical and military lobbies

The Nuremberg Code is the "most complete and authoritative statement of the law of informed consent to human experimentation."[33] It is also "part of international common law and may be applied, in both civil and criminal cases, by state, federal and municipal courts in the United States."[34] But when applied to cold war national security and to the Gulf War, the Nuremberg Code has proven to be legally powerless. Law professor and expert on experimentation law for over twenty years, George Annas explained:

> "Even when the Nuremberg Code applies directly we have never taken it seriously. We say that the rights of the individual are outweighed by national security concerns. This has been true even where those concerns are unclear or unarticulated, as where the experiments are carried out in secret and produce death and permanent disability. . . . when medical progress has been invoked, ethics continues to take a backseat to expediency.[35]

The Nuremberg Code has its' beginnings in the Nuremberg Doctors' Trial in 1947. The trial of twenty German doctors, charged with war crimes and crimes against humanity focused on the infamous human experiments on unconsenting prisoners in the Nazi concentration camps during World War II. The judgment concludes with the ten point code of human experimentation ethics, the Nuremberg Code. The first rule is that the voluntary consent of the human subject is absolutely essential.[36]

The first rule of the Nuremberg Code is included in the current federal regulations on experiments. "The Common Rule" which is today adopted by eighteen federal agencies, are the

federal rules that cover both classified and unclassified experiments and include the cornerstone of human experimentation law, informed consent of the research subject.[37] While the Nuremberg Code has had far reaching effects, it was seen as "good code for barbarians but an unnecessary code for ordinary physicians."[38]

The Nuremberg Code became part of international common law, an indication of its importance. The prohibition against torture in Article 7 of the International Covenant on Civil and Political Rights, states that "no one shall be subject without his free consent to medical or scientific experimentation."[39] Most experts view the Nuremberg Code as a significant, yet symbolic document. The highly regarded law professor M. Cherif Bassiouni regards human experimentation as a serious violation "of fundamental human rights affecting life, physical integrity and personal liberty."[40,41] Bassiouni believes that a code of ethics does not go far enough, as the history of the Nuremberg Code has shown. Bassiouni described unlawful human experimentation as a crime against humanity and a crime under international law.[42] Bassiouni unsuccessfully proposed that the United Nations adopt a specific criminal *Covenant on Human Experimentation* in the 1980s.[43] He included the *Draft Convention for the Prevention and Suppression of Unlawful Human Experimentation* in his 1999 *International Criminal Law* casebook.[44]

Bassiouni has commented on the powerful influence of the pharmaceutical lobbies on international experimentation law proposals.

> In its work, the Sub-Commission adopted a resolution that would have authorized a Special Rapporteur to 'prepare a study on the current dimensions and problems arising from unlawful human experimentation.' The resolution was referred to the Commission on Human Rights for action or consideration. It seems, however, that no further steps were taken.[45]

Bassiouni believes one possible explanation is that representatives of certain countries feared such a convention would infringe on the practices of their pharmaceutical industries. Bassiouni's

decades-long work and endorsement of international experimentation law is a further indication of its acceptance.[46]

Annas explained the conflict between the Nuremberg Code and national security priorities in the 1950s and 60s:

> The wartime mentality expressed by the CIA and the Army to justify its LSD experiments, and the Army to justify its atomic bomb exposure experiments, is substantially identical to one of the major defenses presented by the Nazi physicians at Nuremberg. Remarkably, the Nuremberg Code appears to have had no effect on medical researchers even in the 1950s.[47]

The Nuremberg Code was cited by the Pentagon in the "Wilson Memorandum" signed by Secretary of Defense, Charles E. Wilson on February 26th, 1953.[48] The Armed Forces Medical Policy Council presented the memo which described a policy for human military experiments including "the principles and conditions laid down as a result of the Nuremberg trials."[49] But as Moreno described in his book on secret experiments, the military culture never accepted this policy and it was largely ignored until the 1960s, when public and military human experiment scandals forced changes in federal rules and regulations.[50] In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published ethical guidelines including some of the Nuremberg principles.[51] Moreno stated "These [Nuremberg] principles are still the touchstone for human research ethics in the United States, including that which is conducted by national security agencies."[52]

Experimentation law is firmly rooted in the constitution and international law

Two recent human rights reports describe the legal foundation of constitutional and international law for human experiments. The reporting requirements for the United States Department of State to the UN Human Rights Committee included a section on human experiments. A relatively under-reported but significant fact is that the illegal radiation experiments were cited as an example of noncompliance by the US government with the International Covenant on Civil and Political Rights (ICCPR). This fact illustrates the acceptance

of experimentation law by the international human rights community. This 1994 report stated that under Article 7 of the ICCPR, freedom from torture or cruel, inhuman, or degrading treatment or punishment: "The United States considers itself bound by Article 7 to the extent that 'cruel, inhuman or degrading treatment or punishment' means the cruel and unusual treatment or punishment prohibited by the Fifth, Eight and/or Fourteenth Amendments to the Constitution of the United States."[53] The report continued:

> Medical or Scientific Experimentation. Nonconsensual experimentation is illegal in the US. Specifically it would violate the Fourth Amendment proscription against unreasonable searches and seizures (including seizing a person's body), the Fifth Amendment's proscription against depriving one of life, liberty or property without due process, and the Eight Amendment's prohibition against the infliction of cruel and unusual punishment."[54]

The following human rights report, as with the above 1994 human rights report, included radiation experiments as a violation, not of the ICCPR but the Convention Against Torture (CAT) and further supports the grounding of experimentation law in international law.[55] Those working in international law are reporting illegal radiation experiments in reports on human rights abuse in the U.S., a further indication of the importance of experimentation law.

The following excerpt is from the 1998 report entitled *Torture in the United States* by the World Organization Again Torture, a coalition of human rights groups. The report explains why experimentation law applies to the ICCPR and CAT, as well.

> The prohibition against torture in Article 7 of ICCPR, stipulates that "no one shall be subject without his free consent to medical or scientific experimentation." This provision is not included in CAT, which focuses in Article 1 on pain inflicted for punishment or intimidation, or for any reason based on discrimination. However, it was the overwhelming consensus of our working group that human scientific experimentation conducted by the government without the knowledgeable consent of victims constitutes, by its very nature, a

type of punishment that fits within the CAT definition as constituting "severe pain and suffering" as described by CAT. There is no question that the human experiments conducted by the Nazis during World War II constituted torture, despite their alleged scientific purposes, because the dangers and inhumanity victims were subjected to evidenced an essential lack of concern for the well-being of the subjects that resulted in the unnecessary infliction of pain and suffering. Similar elements that constitute punishment under the meaning of the CAT definition are present whenever human beings are unknowingly subjected to scientific tests, especially when they involve potential severe or long-lasting health consequences, or the purposeful denial of appropriate medical care. This type of disdain for human subjects can not be viewed as anything other than the purposeful infliction of punishment, even if legitimate scientific goals are involved, and the intent to do harm may not be present. It is the lack of due care for the severe (though unexpected) consequences that produces the pain and suffering of the type prohibited by CAT. This is the reason why the ICCPR makes special mention of human scientific experimentation under its treatment of torture, and justifies its inclusion among the activities subject to review under Article 1 of CAT."[56]

Experimentation law and the judicial system

General principles and trends of national security law can be applied to judicial decisions relating to secret experiments and experimentation law. National security is allocated to the president as part of the constitutional mandate to "take care that the laws be faithfully executed."[57] A very general trend can be described as follows. Historically, the general trend is that the areas of national defense and foreign relations have been presidential territory while the judicial and congressional branches avoid these areas and acquiesce to the executive, although, the framers of the Constitution meant for the executive and legislative branches to have shared powers.[58] In practice there are shared powers between the three branches but the proportions

have changed over the years and are dependent on the topic.[59] National security powers of congress are described in Article I of the Constitution. No constitutional text on national security and the judiciary can be found but the judiciary has a role in deciding disputes among the two branches, congress and the executive. The court holdings in national defense and foreign affairs are generally narrow and few in number. The courts have failed to give authoritative answers on national security questions.[60]

There are range of constructions of the Constitution regarding national security because the text is not precise and it does not prescribe power over some important national security areas. The original understanding of the allocation of national security powers can't be found from the Constitution alone. Most national security issues are resolved in the political process.[61]

Human experimentation case law reflects historical national security trends and generalities. The few court rulings on issues raised by post cold war experiments fit the trend for national security issues: the rulings are narrow and leave many questions unanswered.

One 1987 Supreme Court case directly on point is *United States v. Stanley*.[62] This case is widely cited in experimentation law. The ruling has not been overturned although there have been some negative discussions in subsequent cases. "The technical point decided by this case was whether an active duty serviceman could sue the US government for money damages for injuries sustained as a result of experimentation that violated the Nuremberg Code."[63] James Stanley was unwittingly given LSD as part of the army's program to determine the effects of LSD on humans. Stanley suffered from "hallucinations and periods of incoherence and memory loss."[64] His marriage fell apart. "Stanley was denied compensation for injury by the army and sued under the Federal Tort Claims Act alleging negligence in the administration, supervision, and follow-up monitoring of the drug research program."[65] This is one of the few cases to cite the Nuremberg Code. Justice Scalia wrote the opinion of this 5-4 decision and denied Stanley's claim for recovery.

Justice Scalia held that a constitutional violation provides no justification for departing from the general rule that injuries that "arise out of or are in the course of activity incident to service" shall not give rise to a cause of action for money damages, the *Feres* doctrine.[66]

In her dissent, Justice O'Connor quoted the Nuremberg Code and stated;

> "[the conduct at issue in Stanley could not] "arise out of or in the course of activity incident to services" [because the conduct] "is so far beyond the bounds of human decency that as a matter of law it simply cannot be considered a part of the military mission." . . . No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case. . . . voluntary consent of the human subject is absolutely essential. . . to satisfy moral, ethical and legal concepts.[67]

Justice Scalia and O'Connor's positions are extremely polarized in an almost equally divided court decision and seems to be a continuation of the ongoing debate which began after World War II over whether to implement and put into practice, the principles of the Nuremberg Code.

Elizabeth Barrett fought court battles for years on behalf of her father, Harold Blauer, "who died after being injected, against his will, with a synthetic mescaline derivative supplied secretly by the US Army Chemical Corps in the early 1950s."[68] After Senate hearings, Barrett won a $702,044 judgment in May 1987. In 1988, after an eight year court battle, eight victims of CIA depatterning experiments in Canada won $750,000 settlement from the CIA, which admitted no guilt.[69]

In re Cincinnati Radiation Litigation was a 1995 federal case against thirteen researchers and their hospitals for 1960s nonconsensual radiation experiments on low income terminal cancer patients in Cincinnati, with Department of Defense funding. Judge Sandra Beckwith's holding cited the Nuremberg Code and stated, "The Code developed at Nuremberg had become "part of the law of humanity, even if it were not afforded precedential weight in the courts of the United States," it could not be "readily dismissed in this case."[70] Beckwith cited the 1953 Wilson Memorandum as one example of "a mirror of the Nuremberg Code."[71] She ruled that the

plaintiff's constitutional rights may have been violated when the defendants acted "beyond the bounds of the powers delegated to them" and the plaintiff's allegations overcame the defense of qualified immunity. After years of court battles and settlement negotiations, the parties settled out of court.[72]

This series of cases are not representative of the thousands of victims of government cold war experiments. It is a well-established fact that most victims of MKULTRA, the CIA mind control experiments have never been informed by the government about their involvement. "Internal memos and depositions taken from CIA officials . . . reveal that of the hundreds of experimental subjects used in MKULTRA, only fourteen were ever notified and only one was compensated-for $15,000."[73] This pattern of flagrant abuse has been called "inexcusable" and "just one example of the many broken promises" by legal authorities on the issue and the problem is continuing with radiation experiments.[74]

Typically, only a few cases survive this legal battle. James Turner, a lawyer in *Orlikow v CIA* case of brainwashing, stated, ". . . the courts and the agencies now have made it virtually impossible for a victim to succeed in a legal claim. Records are gone, key witnesses have died, people have moved; in the drug testing cases, people are damaged in other ways, which undermines their credibility."[75]

Remedies under The Federal Tort Claims Act (28 U.S.C. Section 2674) have been denied in actions involving discretionary power of government officials. Government sovereign immunity is retained based on discretion, "a public official's power or right to act in certain circumstances according to personal judgment and conscious."[76] Federal court cases have consistently held in cases of exposure to atomic radiation testing that it is with the government's discretion "whether to tell citizens about hazards of radiation exposure."[77]

The history of judicial opinions involving cold war national security experiments indicate that most victims never overcome the many legal hurdles such as the *Feres* Doctrine. Another roadblock, is the doctrine of judicial restraint, used by the Supreme Court in its elimination process of the many cases which come before it. The courts consider many national security

issues as political questions; questions best resolved by the executive or legislative branches.[78] The few judicial opinions on experimentation law and the lack of judicial remedies for a majority of illegal experiments reflects the deference to national security by the courts and also the influence of the national security and the cold war culture on society, rather than a failure of the legal doctrines.

Experimentation law and the executive branch

National security powers in relation to the presidency have been described as follows: "[T]he constitutional origin of the president's control over intelligence is ambiguous, determined more by tradition, executive initiative, and congressional acquiescence than by any explicit grounding in the law."[79] Similarly, the executive branch has predominated in classified experimentation law by implementing a series of presidential executive orders, beginning with executive orders issued as a result of the CIA MKULTRA secret experiments of the 1950s-70s to President Ronald Reagan's 1981 executive order (EO) 12,333 in effect today.[80] The executive orders on human experiments have not changed for the most part. EO 12,333 cites and follows the Code of Federal Regulations (CFR), Title 45 CFR Part 46, which are the current rules for protections of human subjects in both classified and unclassified experiments. In 1991, fifteen federal agencies codified the regulations and the CIA updated the regulations to the current executive order on experimentation. EO 12,333 still includes "Section 2.10 Human Experimentation. No agency within the Intelligence Community shall sponsor, contract for or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services. The subject's informed consent shall be documented as required by those guidelines."[81]

Informed consent of the research participants, institutional review board approval of research conditions and other human subject protections have been a part of the federal rules since 1974.[82] Significantly, the current regulations include CFR Part 46 section 46.101(i). This section allows for a waiver of any or all of the CFR regulations and for a statute or executive order to override the notification and publication requirements. Section 46.101(i) states: "Unless

otherwise required by law, Department or Agency heads may waive the applicability of some or all of the provisions of this policy . . .” This waiver of any of the federal regulations provisions effectively nullifies the regulations, allowing for a total lack of protections for human subjects of classified research at the discretion of Department or Agency heads and under total secrecy.

For the most part, the secret radiation experiments were conducted under a haphazard system endorsing the Nuremberg Code; before the system of federal regulations and the executive orders on human experiments were in place. In 1993, the radiation scandal was exposed. The experiments on human subjects attracted intense media interest. They were even called "an enormous scandal for science and government, greater than Watergate."[83] President Clinton appointed the ACHRE to investigate and make recommendations. ACHRE found that the national security establishment in the 1950s were well aware of the Nuremberg Code. For example, the ACHRE “could conclude with certainty that the AEC (Atomic Energy Commission) was aware of the potentially negative legal and public relations effects of publicity surrounding the plutonium injection [late 1940s experiments].”[84]

The 1950s debate over applying the Nuremberg Code to military experiments continued when Defense Department lawyer, Stephen S. Jackson reported that the Nuremberg Code principles would have to be used in their entirety because they “already had international judicial sanction.”[85] The ACHRE reported that highly classified discussions resulting in the promulgation of Secretary of Defense Wilson’s 1953 human subjects memo. The Nuremberg Code was seen as unrealistic by the Pentagon professional community, in light of national security concerns and was ignored in most cases.[86]

The *ACHRE Final Report* concluded that "with respect to classified research, the current requirement of informed consent is not absolute; if consent is waived, the research may proceed in ways that do not adequately protect the research subject."[87] President Clinton incorporated many of the ACHRE recommendations in his 1997 presidential memorandum, but the memorandum was only adopted by the Department of Defense. The Department of Health and Human Services (HHS) has not adopted the new regulations, and the CIA in turn has not adopted

the regulations, since intelligence agencies follows HHS regulations on human experiments, as directed by Executive Order 12,333.[88]

The second core question raised in this paper is that a scandal involving classified experiments under the current system of federal regulations has not occurred, but as will be shown, the legal weaknesses of the system are apparent. The legal weaknesses are long-standing in spite of scandal-provoked efforts to remedy them. The weaknesses of the current system of federal regulations are not caused by flaws in the legal system itself. The weaknesses can be shown to be caused by the very powerful but silent cold war culture described by Welsome, which easily thwarts the majority of advocates for human subject protections who fail to act on their consensus As a result, protections for human research subjects have failed to prevent major scandals.

The inherent weakness of executive memorandums and orders are that they are "subject to evasion, rescission, or modifications the commander in chief sees fit."[89] A 2003 *US News and World Report* article entitled *Keeping Secrets*: *The Bush Administration is doing the Public's Business Out of the Public Eye. Here's How-and Why*, provides an example:

> Bush's chief of staff, Andrew Card, directed federal agencies to freeze more than 300 pending regulations issued by the administration of President Bill Clinton. The regulations affected areas ranging from health and safety to the environment and industry. The delay, Card said, would "ensure that the president's appointee's have the opportunity to review any new or pending regulations."[90]

President Clinton's memorandum for classified experiments became a part of the above review. A recent example of a waiver of consent in an executive order on grounds of military expediency was signed on Sept. 30, 1999 by President Clinton. As shown above, the ACHRE had actually warned about the possibility of redefining a medical problem in order to avoid the consent requirement.

> A new executive order empowers the President to authorize "investigational" medicines for troops without their consent. The Clinton executive order sets down

> procedures for permitting drugs to be administered by the Department of Defense without consent, the conditions under which the practice will be allowed, and the approvals and reviews that must be obtained.[91]

Arthur L. Caplan, director of the Center for Bioethics at the University of Pennsylvania commented:

> "[O]ne way to make sure requests are rare (for untested drugs to be given to troops) and compliance is thorough is for some articulation of what a compensation policy might be if harm occurs. . . . That might be the best measure to ensure that requests are going to be infrequent to waive informed consent and that if they are granted that there's going to be serious tracking of what happens to people who don't get to give permission when something new is used." . . . but the fact is that when you're using new experimental innovations you are then creating an experiment.[92]

Presidential directives have differing levels of power as described here. President Clinton's memorandum on classified experiments was weaker than if he had made the memorandum an executive order:

> The major classes of presidential policy instruments such as executive orders, proclamations, memoranda, administrative directives, findings and determinations, and regulations. Of these, executive orders combine the highest levels of substance, discretion, and direct presidential involvement. . . . executive orders are a "more far reaching instrument for administrative legislations" and have more substantive effects. Presidential memoranda and directives more often address issues that are temporary or are used to instruct agency officials to take specified action in accordance with established regulatory or departmental processes.[93]

Another weakness of presidential directives for human experimentation protections: they are subject to the political leanings of the president in power at the time. A 1994 *Bulletin of Atomic Scientist*s article explained:

> Many people have wondered why these events [human radiation experiments] were not revealed earlier. But most of the facts of human experimentation were known. There have been a number of attempts to tell parts of the story. Local newspapers, such as the Knoxville Journal, told parts of it, as did national papers such as the Washington Post and the New York Times. Cong. Edward Markey of Massachusetts and his staff conducted an investigation into many of the human experiments and published their findings in 1986. At the time, Markey called on the Energy Department to find the victims, assess their health status, and compensate them. But none of the earlier revelations shook the conscience of the country the way Hazel O'Leary's announcement did. It was a propitious time and platform.[94]

President Reagan favored secrecy and national security and would not investigate radiation experiments in 1986 while President Clinton supported an investigation into the radiation experiments in the 1990s and even publicly apologized to some of the victims, a first for cold war experiment victims.[95] But President Clinton's waiver of informed consent for military expediency is just one example of national security priorities that continue to arise, one of many clear demonstrations that executive memorandums and orders on experimentation law, as in the past, continue to be ineffective. Clinton, as a lawyer could be considered disingenuous in his 1997 presidential memorandum on *Protections for Human Subjects of Classified Research*, as seen in the above described weaknesses of an executive memorandum, although he has done more for human subject protections than any president so far.

Experimentation law, national security law and congressional powers

A succinct analysis of national security as it relates to the separation of congressional and presidential powers and experimentation law for secret experiments, an intelligence matter, is described as follows.

> The Church Committee, organized in the mid-1970s to investigate intelligence activities, argued that intelligence should be governed by both Congress and the president with the same system of checks and balances that applied to any other policy area. . . . In practice, however, the constitutional elements of the debate have been displaced by a consistent pattern of congressional acquiescence and presidential preemption. Congress has typically ceded the ground to the president by enacting broad statutory delegations of power and by an inability to take the initiative on intelligence matters. In a pattern at the core of executive institutional power, presidents have moved to fill in the gaps in authorizing legislation with their own interpretations, outflank congressional efforts to impose more substantive restrictions, and maintain the initiative in important policy areas.[96]

This congressional/executive pattern of shared powers can be seen in the fact that no legislation on protections for human subjects of classified experiments has ever passed. The congressional hearings on MKULTRA in the 1970s led to executive orders, not legislation. Congress has passed legislation for three major programs to provide compensation to radiation victims who may have been harmed, but this only affects a small fraction of the victims. Compensation bills can be seen as a way to placate the current victims and as a result congress does not have as much pressure to make the fundamental changes to prevent illegal experiments again. *The Veteran's Dioxin and Radiation Compensation Act of 1988* "administers a program designed for veterans who were exposed to radiation with special provisions for those exposed at Hiroshima and Nagasaki and in atomic weapons tests.[97] Only 1,401 claims were approved out of 15,000 claims and in light of estimates of 200,000 soldiers exposed to nuclear bomb tests. The *Nuclear Claims Trust Fund* "was established under a 1986 agreement between the United States and the Marshall islands to compensate inhabitants of the islands exposed to radiation from US

weapons testing of 67 nuclear explosions between 1967 and 1958.[98] The *Radiation Exposure Compensation Act of 1990*, "established to provide compensation to uranium miners, persons living downwind from the Nevada Test site, and veterans and civilians who received radiation at the site of atmospheric weapons tests in Nevada and the Pacific."[99] But the legislation is too restrictive and "place too low a ceiling on the amount of compensation awarded."[100]

A 1994 *American Bar Association* article further explains the serious legal roadblocks to relief and that some enacted legislation protects contractors of atomic testing from potential liability, an indication of the clout of the defense industry and the relative weakness of human subject protections:

> *Radiation Exposure Compensation Act of 1990* (*42 U.S.C. Section 2210*) [provides a $100 million fund] allows payment of up to $75,000 but they cannot sue in court. Civilians dusted with radioactive fallout from Nevada testing who can show the onsets of specified terminal afflictions within a specified periods of time can receive up to $50,000 each under the *Radiation Compensation Act*. But they must forego all other litigation against government and private parties. Civilians in a university research project or unwittingly exposed after a nuclear blast face another obstacle. The so-called Warner Amendment (42 U.S.C. Section 2212) gives immunity to contractors involved in Nevada testing and also places limits on discovery. This statute lets the government take the place of contractors as the defendant in radiation claims. At that point, the tort-claims and *Feres* obstacles arise again. "The [radiation] cases I've worked on have been the worst PI [personal injury] cases I've ever heard," says one lawyer. The obstacles for potential plaintiffs is a virtual landslide of statutes and judicial opinions."[101]

Compensation bills have been passed by Congress in a handful of cases for compensation for damages to an individual by government experiments. In 1994, Democratic Rep. Leslie Byrne of Virginia sponsored a bill that sought $254,488 for Air Force officer Lloyd Gamble.[102] The Defense Department says in 1957, Gamble signed a "volunteer's participation agreement" and

was given LSD. Gamble was told that he "would receive a chemical compound, the effects of which would be similar to those experienced from being intoxicated by alcoholic beverages."[103] Gamble suffered blackouts, depression, anxiety and violent behavior. But the Justice Department claimed the statute of limitations had expired in his case and the Veterans Administration found "no evidence of permanent injury", thus denying his disability claim.[104] The Department of Defense opposed the Byrne bill, saying there was "insufficient factual basis" for compensation.[105] This is a typical experience.

The balance of power between Congress and the President clearly favors presidential powers regarding human experimentation law. No effective statute regulates classified human experiments even as two major scandals have occurred. The analysis of national security law and presidential power provides an explanation. "This pattern of presidential initiative and flexibility stands in sharp contrast to Congress's largely ineffective attempts to enact meaningful restrictions and oversight [in intelligence matters]."[106]

> "As Eisenhower did in the 1950s, though, Ford was able to deflect the move toward a legislative charter by establishing his own investigating body (the Rockefeller Commission) and issuing his intelligence executive order, . . . "The entire exercise," writes Frank Smist, "was an attempt by the administration to prevent legislative action that would permanently inscribe congressional oversight into law. " Carter continued this pattern of presidential preemption."[107]

A further problem as seen in both intelligence matters and human subject protections is that the executive branch does not follow the law. The CIA and radiation scientists conducted illegal experiments in spite of ethic codes and fundamental constitutional rights to the contrary, similar to the Iran-Contra scandal:

> In any case, the notification and finding provisions failed to prevent the abuses that emerged from the Iran-Contra scandal.. . . the history shows how easy it was for the president and those acting on his behalf to maneuver within the congressionally imposed boundaries on the conduct of covert intelligence

> operations (as well as to ignore those restrictions that proved burdensome). . . . What is clear is that the executive branch had no trouble circumventing the legislative proscriptions. . . . The struggle between Congress and the executive branch over the structure and organization of the intelligence community continues, as has the pattern of presidential dominance.[108]

The presidential appointed committee, ACHRE looked at the current status of protections in human radiation research and research generally. But interestingly, proposing model legislation was not a part of the mandate of the ACHRE. ACHRE "may recommend further policies, as needed, to ensure compliance with recommended ethical and scientific standards for human radiation experiments."[109] ACHRE did not recommend legislation. The ACHRE did inquire into the possibility of current illegal experiments. "We were advised that the only classified studies involving human subjects currently conducted by six federal agencies are a small number of projects sponsored by the DOD and the CIA."[110] But there are no current mechanisms to verify this and no reason to trust the information as accurate, based on the CIA and DOD's track record for cover stories, illegal actions and lying.

The radiation experiments scandal resulted in President Clinton's 1997 executive memorandum and presidential commissions and committees and while Congress proposed congressional legislation, none passed. The executive branch's historical interest in continuing national security experiments seems to be reflected in the presidential actions of preempting congress by appointing presidential panels and issuing executive directives. In this manner, the executive branch can retain their power over national security experimentation law and deflect stronger legislation and oversight by congress.

Recognizing that ethical rules and federal regulations are not enough, several government and influential organizations have called for legislation on human subject protections. And yet, this rhetoric is not followed by meaningful actions. In a 2002 *Boston Globe* article, Annas explains: "We need a lot more reform than the IOM (Institute of Medicine) seems to recognize. This is but

another voice crying in the wilderness. All their major recommendations have been made over and over again."[111] The *Boston Globe* article continued, "The release of the report (IOM report) comes as Congress this year has failed to come to an agreement on legislation to tighten protection in human experiments."[112]

A 2005 Congressional Research Service (CRS) report entitled, "*Federal Protection for Human Research Subjects* reported that "Congress has shown a keen interest in the Common Rule largely because of the federal government's long-standing investment in medical research, and its interest in research-subject safety. . . . legislation to revise the Common rule has been introduced in every Congress since 1997.[113] The National Bioethics Advisory Commission, a presidential commission formed in 1995 to advise the President, issued the report, *Ethical and Policy Issues in Research Involving Human Participants*.[114] The report stated, "This topic[human experiments] was one that led to the establishment of the [NBAC] Commission in 1995, after the report of the Advisory Committee on Human Radiation Experiments [ACHRE] made clear that oversight problems remained in conducting research with human beings."[115]

Both the 2001 NBAC and 2005 CRS reports fail to address classified experiments. And while the 2001 NBAC report provided a list of "ACHRE Recommendations Relevant to this Report," it does not mention the ACHRE's recommendations for classified research.[116] The report details other types of waivers of consent raised by the ACHRE but does not mention the waiver for classified research covered by the ACHRE. The factors described above match the presidential/congressional pattern for dealing with intelligence and national security issues, as predicted by the national security law and presidential powers framework: a deference by Congress of their shared powers to the President.

To summarize, in light of the immediacy of the scandal of recent classified radiation experiments: the 2001 NBAC is a Presidential Commission, not congressional; NBAC did make recommendations for legislation "for a unified, comprehensive federal policy" for human experiments; some of the NBAC proposed legislation were adopted into recent legislation but no bills have passed; NBAC made no mention that Clinton's 1997 memorandum was not adopted

by HHS, just adopted by the DOD; no mention of any new rules to implement ACHRE's recommendations for classified research; NBAC omitted information on the classified waiver while citing other waivers cited in the ACHRE report; the NBAC report only mentions the 1990s illegal radiation experiments scandal in passing and made no recommendations for its prevention from happening again, while at the same time, covered in depth, recent unclassified research scandals and recommended remedies.

Former Senator John Glenn of Ohio's 1997 proposed bill, *Human Research Subject Protection Act of 1997* promised to be the nation's first criminal sanctions for medical researchers who fail to obtain consent from people participating in experiments.[117] In his speech on the proposed legislation, Glenn stated:

> Specifically, the advisory committee recommended that informed consent of all human subjects of classified research be required, and that such requirement not be subject to waiver or exemption. Under current rule and executive order, it is possible to waive informed consent . . . for classified research. Title II of this legislation would prohibit the waiver of either informed consent . . . for classified research.[118]

Section 105 of the Glenn bill stated: "Any employee of a research facility that knowingly violates any provision of this act shall, on conviction thereof, shall be fined not more than $10,000, or imprisoned not more than 3 years, or both. Such violation shall be referred by the Secretary of the United States Department of Justice for prosecution."[119] The bill had little support, "languished", and did not pass.[120] A 1997 *New York Times* article provided some explanation for this:

> The [Glenn] bill also would create criminal penalties for violators -- a provision that has drawn criticism from the Pharmaceutical Research and Manufacturers Association of America, which often finances private research. "We believe in informed consent and our companies bend over backwards when we deal with

patients," said Mark Grayson, the group's spokesman. But criminal penalties were unwarranted, he said.[121]

Congressman Diane Degette of Colorado has proposed three bills on experimentation, a 2000,2002, and 2003 bill, with plans to introduce a 2004 bill, but none have passed.[122] The 2000 *Denver Post* reported on the pharmaceutical and medical lobby's influence on the 2000 bill.

> Although DeGette had lined up an impressive array of supporters, including the Association of Medical Colleges, Citizens for Responsible Care and Research and the American Diabetes Association, her "*Human Research Subject Protections Act of 2000*" did not have the immediate endorsement of either the drug industry or the American Medical Association, two major players on any health care legislation before Congress. Spokesmen for the AMA and the Pharmaceutical Research & Manufacturers of America said they had not studied the legislation. Jeff Truewhitt, the PRMA spokesman, called DeGette's legislation's goals "commendable" but added, "The devil is in the details."[123]

Degette's 2000 and 2003 bill included sections on classified experiments:

> Certain classified Human Subject Research
>
> Notwithstanding any other provision of law, Federal funds may not be expended for the conduct of classified human subject research if 1) the Institutional Review Board reviewing the proposal for the research pursuant to this section has under the Common Rule waived the requirement to obtain the informed consent of the human subjects in the research; or 2) the research is exempt from the requirement under the Common Rule that the proposal for the research be reviewed by such a Board.[124]

The 2004 *Annals of Internal Medicine* reported on Senator Kennedy's experimentation bill, the *Research Revitalization Act of 2002*, illustrating the political hurdles in passing experimentation legislation:

> However, like all previous efforts, the major hurdle has been passage; neither bill was enacted. . . and Senator Kennedy plans to reintroduce his bill in 2004. . . . With Senator Frist now the majority leader and Senator Kennedy now in the minority on the Health, Education, Labor, and Pensions Committee, legislation to protect human subjects seems to have a lower priority in the Senate.[125]

Legislative attempts so far have failed dismally and the national security law and presidential powers framework supports a prediction of a strong likelihood of future experimentation scandals. Presidents have preempted Congress's ineffective attempts at legislation on human subject protections with presidential commissions and committee reports. The presidential reports describe a government policy of strong support for human subject protections but are followed by weak, incomplete and unrealistic recommendations. Presidents have implemented human subject protections, including presidential memorandums that were never promulgated and executive orders that include clauses preventing lawsuits while allowing for waivers of the consent of human research subjects and secrecy. In this way, presidents can hamper legislative attempts while advocating rhetorical support for human subject protections. This consistent response by every president so far is intended to thwart meaningful legal human subject protections or remedies. In reality, by failing to effectively address the issue even after two major scandals, presidents continue to condone the belief in illegal experiments as essential to national security. The legislative acquiesence to the president's actions and national security concerns have effectively resulted in an absymal failure of government policy for human subject protections in national security experiments**.**

The need for a federal statute on human subject protections for national security experiments

The benefits of a statute rather than executive orders for human subject protections are as follows: Codifying human subject protections would ensure legal remedies not currently available for illegal classified experiments. A statute could provide for express legal rights to sue. Currently, the Common Rule does not expressly establish a private right of action for injured research subjects.[126] A statute, unlike executive orders, could not be repealed, rescinded, modified, or evaded with the next presidency.[127] A statute for enforcement of criminal penalties for researchers who fail to obtain consent would be more consistent than with the current variation of rules for the many federal agencies which have adopted the Common Rule. Past and current executive orders provide no compensation for victims or punishments for wrongdoing, which a congressional bill normally includes. A 1998 *Boston Globe* article reported the comments of two experts who for many years, have endorse sanctions:

> Some medical ethicists want such a panel to go even further, by having the authority to sanction researchers deemed to have acted unethically. "You have to have real live penalties for violating the rights of subjects -- like fines and jail," said George Annas, . . . , who plans on drafting legislation to create a board able to impose sanctions. Dr. Jay Katz, a Yale University professor emeritus of Law, Medicine, and Psychiatry who was the first to call for such a national board, agreed: "If you don't have any teeth in the regulations, that creates problems."[128]

The risk that the executive branch may bypass the law and ignore a statute for experimentation law should also be considered in any future legislative efforts. The pattern of bypassing the law is not unusual in intelligence matters as shown above. The MKULTRA and radiation experiments were implemented at the highest levels of government and were known at the time to be illegal. Experimentation law experts have recommended legislation and criminal penalties. After two major scandals, the legislative and executive branches have not implemented meaningful protections or addressed criminal penalties. There was no evidence of presidential support for any legislation for human subject protections during the last fifty years, even though, as almost all legal experts would agree, legislation would provide much better protection for

research subjects. A major experimentation scandal after strengthened regulations were put into place, has not occurred but government reports and experimentation law experts have called for legislative reforms for the subsequent unclassified experimentation abuses that have occurred. After fifty years of ineffective ethics codes and regulations, the need for a federal statute continues to increase.

Experimentation law-alternative approaches

The Nuremberg Code and the judicial, congressional and executive branches have been no match for the overwhelming cultural acceptance of the crisis of post cold war experiments. Much more ground work, which began with the Nuremberg Code may be the only practical alternative.

One approach is to educate the public about national security law and the lack of human subject protections. As described above, everyone can agree on this: human experimentation without voluntary consent is a clear violation of the U.S. Constitution and international human rights treaties, specifically the ICCPR and the CAT. Unconstitutional acts are not acceptable, even for national security rationales enforced by an unspoken and powerful consensus. The history of experimentation law demonstrates that cultural acceptance of experimentation law may be a necessary step towards putting effective experimentation law into practice.

Education on the ethics of experimentation law could address the victim's individual rights, which have been ignored for the most part. The consensus that consent of the human research subject is necessary in human experiments has been constant and vocal but in reality most people, by their inaction, accept the necessity and inevitability of illegal human experiments for national security purposes. A strong alternative argument against this entrenched belief system can be made. The Nazi doctors argued that they did no wrong and admitted no guilt. US researchers for the CIA MKULTRA and military radiation experiments also did not apologize for their actions and felt that national security priorities necessitated sacrificing the evils of a few human experiments for the defense of the country. This has been the accepted argument put forth in post World War II experimentation scandals. But there is a strong alternative argument for

individual rights that is put forth less often. Is it worth giving up individual rights for national security concerns? The answer is clearly, no. National security rationales can be traced back to the Nuremberg Trials and can be challenged for their amoral logic. The modern history professor Ulf Schmidt wrote a 2004 book about the Nuremberg trials, the Nuremberg Code and modern ethics. He described the ethics of an alternative argument:

> Human research is-or should ultimately be- a dialogue between two equal subjects, and should remain so even if this exchange causes progress to be slowed along the way. Unless we see this dialogue as an essential part of the research process, and unless we are willing to pay a certain price for this dialogue to take place, medical ethics codes and other professional regulations amount to little more than lip-service. . . . Doctors need to acknowledge that moral codes are formulated by man and thus subject to change. At the same time, however, they should be constantly mindful that both medicine and society must always uphold certain universal principles, including respect for the inviolability of patient-citizens and the rights of the individual to self-determination.[129]

Balancing this ethical approach with national security will at the least, lead to progress. As the record of abuses in past experimentation scandals have revealed, some of the past experiments could have been improved in significant ways. An under-reported but successful military program of volunteer human subjects for biological experiments also offers an alternative to unethical and illegal national security experiments.[130] While intelligence agencies may still insist on tight security for some human experiments, the volunteer approach may alleviate the huge numbers of victims seen in past cold war experiments.

National security in past experimentation scandals has been iron-clad and allowed for serious abuses. A possible alternative that addresses secrecy surrounding national security experiments was described in a 2001 book, *Secrecy Wars*: *National Security, Privacy, and the Public's Right to Know*. The model of the Assassination Records Review Board was a "highly successful and novel experiment in public disclosure."131 This model may allow for continuing secrecy

requirements for national security while allowing for oversight, accountability and transparency in national security experiments. This is a possible mechanism to retain secrecy requirements while protecting human research subjects and could be adapted accordingly. A citizen panel appointed by the president was given full legal access to all agency records relating to the assassination of President Kennedy and 4.5 million documents were released. Professor Melanson recommends this model for areas in which:

1. There is a historic, long-running subject encompassing both old and new records over a period of many years or decades.
2. The topic is politically sensitive or contentious.
3. There is a large volume of records.
4. The regular disclosure process is not working, in terms of timeframe, reasonable release, or both (that is, too slow, too much secrecy).[132]

According to the book, this model could include the radiation exposure of US troops during atomic testing and experimental testing of unwitting human subjects by US military and intelligence agencies. The book describes the process in detail, including that the boards should have a fixed, four-year term and need a staff component of lawyers who are expert regarding disclosure laws and the secrecy system.[133]

The failures of past attempts to protect human subjects in national security experiments call for a more impartial, balanced examination of the ethical, cultural and political factors and their influence on experimentation law. By understanding why the failures have occurred, more realistic approaches as described above may have a much better chance for progress. Now the government has argued that cold war national security and post 9-11 conditions require increased secrecy and the sacrifice of individual rights guaranteed by the Constitution. Before accepting this argument, many lessons can be learned from the history of cold war human experimentation law within a framework of national security law and presidential powers.

Endnotes

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> In the very unlikely event that any part of the U.S. government should attempt to develop or use any of this sort of stuff [electromagnetic weapons targeting the mind]against any American, or in any way other that through legal authorization and appropriation by the Congress, the relevant government officials would doubtless find their activities disclosed forthwith ... Conspiracy theorists always seem to me to forget that we have: (a) First Amendment,(b) two independent branches of the federal government outside the executive, and (c) a federal system.

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1130. Federal Policy (Common Rule) For the Protection of Human Subjects Legal Authority: 5 USC 301; 42 USC 289 CFR Citation: 45 CFR 46 Abstract: In compliance with the President's Memorandum of March 27, 1997,this interim final rule would amend the Federal Policy (common rule) for the Protection of Human Subjects to add a new section that applies only to classified research involving human subjects. The new section would modify the Federal Policy by: 1) prohibiting any executive branch agency from engaging in classified research involving human subjects unless the agency has adopted the Federal Policy and the interim final rule; 2) eliminating the availability of waiver of informed consent and expedited review for classified research involving human subjects; 3) enhancing the informed consent requirements and allowing for disclosure of classified information if necessary; and 4) changing the composition of the institutional review board (IRB) and establishing a process for individual IRB approvals of classified research.
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