



Informed Consent

What is it? Who Needs it? Who Gets it? Who Cares?



**A Natural Solutions Foundation White Paper
In Cooperation With the Institute for Health Research**

“Informed Consent is the defining issue of the 21st Century.” Gen. Stubblebine

**Preserve YOUR Informed Consent Rights:
<http://TinyURL.com/InformedConsentPetition>**

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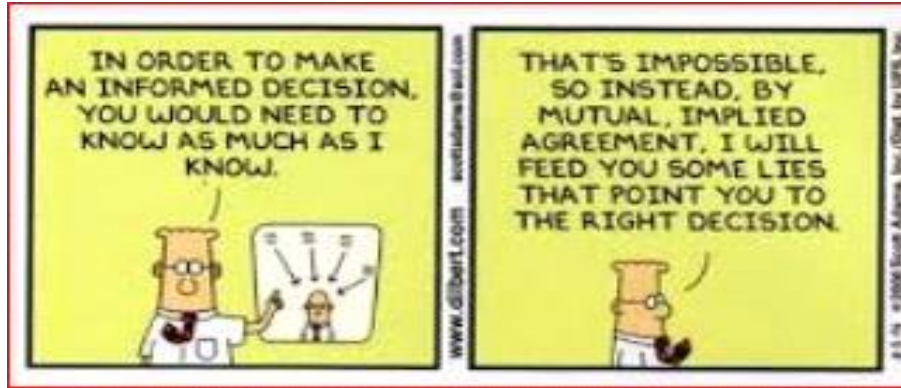
Abstract: International humanitarian law provides a clear standard for Informed Consent, succinctly stated in the Nuremberg Code.¹ Widely coordinated efforts by the political class to mandate vaccines, in such places as Australia and California, violate the fundamental human right of Informed Consent. The history of unlawful experimentation without Informed Consent in the United States and elsewhere requires remedial action by the

¹ “The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of 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. <http://www.hhs.gov/ohrp/archive/nurcode.html>



government agencies responsible for failing to prevent the violations. Natural Solutions Foundation, on June 11, 2015, filed a formal Petition with FDA, demanding establishment of regulations required to implement the right, including clear reference to the right in all FDA approved drug (including vaccine) package inserts.

INTRODUCTION



Informed Consent is, without doubt, your most basic, and most widely guaranteed, human right. Without it, anyone in power can do what they like to your body. You are a slave to their whim about what happens to you physically.

With your Informed Consent rights intact, you own your body and make decisions about what happens to it. You have, and must assert, your basic ownership over your physical body.

On July 10, 2015 the United States House of Representatives, in what was termed a “rare example of bipartisan agreement” adopted HR-6, the “21st Century (sic) Cure Act”² which, in relevant part, diminishes the Right to Informed Consent by permitting pharmaceutical companies to conduct medical experiments without Informed Consent if there is “minimal risk” to the procedure. The bill does not specify what constitutes “minimal risk” nor does it specify who determines what is “minimal risk.” If adopted into law, there is concern that the bill would allow mass public testing of new drugs, including spray vaccines, without Informed Consent, in clear violation of international standards.³

As guiding directors of the largest health freedom organization, the Trustees of the Natural Solutions Foundation have been thinking a great deal about the need for, the lack of, disseminating the history of Informed Consent and examining the current state of this basic right. Many know about Nuremberg at the end of World War II and the Doctors Trials, resulting in imprisonment and even capital punishment for a few guilty medical monsters. Fewer people also know the same laws that allowed the US to self-righteously punish some doctors for their crimes

² <https://www.congress.gov/congressional-report/114th-congress/house-report/190/1>

³ <http://www.campaignforliberty.org/ures-act-cure-liberty>



against humanity actually bind the US to engage in effective enforcement against crimes against humanity, including those associated with mandatory vaccinations, even when committed under color of State or Federal law. Mandatory vaccination laws, such as SB 277 in California violate both international norms and binding US law regarding Informed Consent.

That needs to change. Now. The United States government must accept its responsibilities under international law and acknowledge that it is bound by such law, having used it for its own purposes following World War II.

The Natural Solutions Foundation has challenged the Food and Drug Administration to do just that, with the formal Petition under the Administrative Procedures Act which we filed this past June.⁴ Details of the filing and a copy of the Petition may be found at <http://tinyurl.com/InformedConsentPetition>. When you visit the Informed Consent Petition site, take a moment to submit your own comments to the FDA and share it widely with your Circle of Influence.

To make that change, we have to take into account our own medical pioneers-cum-monsters, upon whom so much of medicine and medical [mal]practice rests today. We have to examine the climate of lies that support and reward these doctors and the companies and agencies that they serve for their consequence-free experimentation on us and on our children.⁵



VACCINATION AS EXPERIMENTATION

Vaccines are an experiment based in *pus* and deceit, devoid of real scientific support but rich in bought-and-paid-for propaganda masquerading as science. They are part of the misuse of humans by the medical 'profession' for its own ends and the ends of whichever tyrant *du jour* is at the helm at the moment.

Each and every vaccination administered to anyone is far more risky than a "crap shoot" where the odds can at least be calculated because the number of pips on the known number of sides of a die can be calculated. Not so with vaccine injury. Vaccination, an uninsurable risk, is, according to the US Supreme Court, "unavoidably unsafe"

⁴ Filed June 11, 2015 as Petition No. FDA-2015-P-2149

⁵ "...Phase 4 trials are conducted after a product is already approved and on the market to find out more about the treatment's long-term risks..." - <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm>



To make matters worse, according to crucial information shared by attorney Walter Kyle, the FDA has adamantly refused to allow the use of a simple, safe and non-invasive device which already has been approved by the FDA because it can *accurately predict which people are at risk for adverse vaccine reactions*. Clearly, such information would lead to reduced vaccination sales - an unacceptable outcome. It would also lead to fewer killed and maimed children and adults.⁶



MEDICAL MALFEASANCE

Human experimentation without regard to Informed Consent has a long and dishonorable history in the US and elsewhere. Vaccine experimentation on a grand, and increasingly coercive scale, fits right into this progression of shame and injury.

The medical profession has done shockingly little to distinguish itself as a protector of either human health or dignity over the many centuries of its existence since the founding of the first modern medical schools in Medieval Italy in the 13th Century and the resultant weeding out of economic competitors called “witches” in the subsequent entirely manufactured witchcraft hysteria which lasted until the 1700s.

Let’s start with Thimerosal. Eli Lilly was manufacturing and, more importantly, selling, a great many mercury-containing products back at the beginning of the 20th century. But their toxicity was drawing attention and Lilly sought help and protection of its market from its new friend, the John D Rockefeller JR innovation called the FDA.

The newly formed FDA was busily compiling a list of GRAS or Generally Regarded as Safe items and Lilly wanted its big seller, Thimerosal, on that list. They staged a brilliant demonstration of its safety in 1929 by injecting it into patients who were in meningitis coma and expected to die. All of the patients did, in fact, die.

Eli Lilly reported back to the FDA that Thimerosal, 49.5% mercury by weight, was safe and should be included on the Generally Regarded as Safe because although all 11 of the patients died they would have died from their disease anyhow so the mercury compound could be concluded [by them, and apparently by the FDA as well] to be (sic) “safe” for use in everyone. Yes, this is the quality of “science” that has continued to the present day where the CDC

⁶ See Walter Kyle Interview: <https://youtu.be/AluYaDCQW2c>



routinely approves vaccines based on the flimsiest crony-tainted pseudo-science, never conducting truly independent third-party testing.

We will see that “they would have died anyway” rationale used over and over again to legalize and legitimize toxic substances including vaccines.

The pundits of the profession rarely raise an eyebrow.

It is rather akin to “they would have gotten autism anyway. In fact, it is identical to that irrational rationale.

In modern times, the widely revered Jonas Salk, in association with Thomas Francis, a virologist at the University of Michigan, infected healthy patients at various mental institutions in Michigan with the influenza virus by spraying it directly into their nasal passages.

When they attempted to publish their results, Francis Payton Rous of the Rockefeller Institute and the editor of the *Journal of Experimental Medicine*, responded to them by saying,

"It may save you much trouble if you publish your paper... elsewhere than in the *Journal of Experimental Medicine*. The *Journal* is under constant scrutiny by the anti-vivisectionists who would not hesitate to play up the fact that you used for your tests human beings of a state institution. **That the tests were wholly justified goes without saying.**" [Emphasis added by the authors] The “using” of people without any reference to Informed Consent is the essence of the crime against humanity, as it would be defined a few years later, in the Nuremberg Code.

In the same year, 1941, the same editor rejected the publication of an article by Dr. William C Black in which a 12 month old baby “offered as a volunteer” (by *whom?*) was inoculated with herpes. The paper, however, was published in the *Journal of Pediatrics*.



VIVISECTION

Although the word is no longer used very often, the history of human experimentation and use of patients must include the word "vivisection" which means the use of living humans (later, animals) for medical experimentation purposes. Clearly, vivisection is done without Informed Consent.

Has the medical profession condoned and lauded unwilling human experimentation in our own culture, indeed, in the history of our own "advances"? Sadly, tragically, yes.

The history of the medical abuse or vivisection is rich and consistent in the selection of the vulnerable for its horrors: the poor, those in charity institutions, the hopelessly ill, the insane. Since no one speaks for them to safeguard them, they are ideal victims of both curiosity and cruelty.



Today, our equivalent of vivisection is still carried out largely on the young, the old and those in other vulnerable categories. The difference, however, is that legislation is rapidly being brought forward which makes us all into vivisection victims without the right of refusal, in violation of international norms.

Some examples of generally widely admired and regarded vivisection science:

William Beaumont is widely regarded as the Father of Gastric Physiology because he was the first human to see and study gastric function in the flesh. He took advantage of the fact that Alexis St. Martin had suffered a gunshot wound to the abdomen which created a gastric fistula (opening) allowing Beaumont to see the inside of St Martin's stomach.

It is not clear how hard Beaumont tried to close St. Martin's wound since he was fascinated by what he, alone of all medical scientists, was able to observe while it remained open. He took samples of St. Martin's gastric juices, suspended foods on a string in St. Martin's stomach to study their digestion and wrote vivid and enthusiastic reports, gaining knowledge and fame for himself.

St. Martin was considerably less enthusiastic, however, suffering excruciating pain for the rest of his life at the hands of his vivisectionist. History notes that St. Martin's discomfort was so great that Beaumont was "forced to pay him" for his continued compliance.

When Beaumont died, another doctor, T. G. Bunting, exhibited St. Martin from 1833 onward "carnival style" for his own personal financial gain.

In 1874 Dr. Roberts Bartholow was presented with a patient whose cancerous ulcer of the scalp had eroded into her brain. Mary Rafferty, who worked as a domestic servant, did not appear to the eminent Dr. Bartholow to need care: she appeared to him as a walking, living, breathing opportunity to learn how to map cortical functioning and trigger seizures in a human brain.

He continued to experiment upon her for his good and gain, rather than hers, for as long as she survived, which was not long.

In his own notes, he gleefully described her response to needles and electric currents he introduced into the available brain this way:

"When the needle entered the brain, she complained of acute pain in the neck. To develop more decided reactions, the strength of the current was increased. Her countenance exhibited great distress, and she began to cry. The left hand was extended as if in the act of taking hold of some object in front of her; the arm presently was agitated with clonic spasms; her eyes became fixed, with pupils widely dilated; lips were blue, and she frothed at the mouth; her breathing became stertorous; she lost consciousness and was violently convulsed. She then lapsed into a coma and died a few days later."

Bartholow was so enthusiastic about this experimentation that he conducted her autopsy himself, publishing his results which conveniently blamed her death on her cancer although he did note that there were very serious and negative changes along the track of the needles he introduced.



The American Medical Association did denounce his experiments on Mary as "incompatible with the spirit of our profession and our feelings of humanity" but this had no discernable impact on Bartholow's career or luster.

He went on to become an honored senior physician at the University of Pennsylvania and author of several highly regarded textbooks.

In the 1950s Saul Krugman, MD, saw a wonderful opportunity to use pediatric inmates living in the filthy, overcrowded and dehumanizing conditions of Willowbrook State School in Staten Island, NY, to carry out "research" that would kill at least 60 healthy children between the ages of 3-10.

Conditions at Willowbrook were so unhygienic that about half the children placed there developed hepatitis.

Krugman deceived the parents of his vivisection subjects through a fraudulent consent letter telling them that their children would be vaccinated against hepatitis or given a "new form of protection" against it.

They were not informed that Dr. Krugman and his medical associates planned to infect their children with intentionally contaminated extracts from the blood and feces of children who already had hepatitis or that their children would be exposed to this material either orally or by injection specifically to infect their children with the disease.

Neither the world nor Dr. Krugman learned anything from these experiments except how easy it is to misuse science and rationalize any form of inhumanity sought. In 1986, nearly 3 decades after these wanton pseudo-scientific "experiments" Dr. Krugman could still justify his actions, declaring "I am as convinced today as I was at the time that our experiments were ethical and justifiable."

He also favored investigators into his activities by saying that the children he infected did not then have hepatitis but that they would get it anyway so giving it to them was of no consequence. This parallels the idea that the meningitis victims would have died anyway, so Thimerosal is "safe" to inject into everyone.

In 1908, the diagnosis of tuberculosis was a major public health problem. Doctors at The University of Pennsylvania decided that "Human Material" in the form of orphans living at St. Vincent's Home for Orphans would make an excellent test bed for their work.

Instilling their infectious tuberculosis material under the skin, into the muscles and eyes of 160 healthy children under the age of 8, they reported on the intense agony caused by the introduction of the contamination into their eyes.

The nurses at St. Vincent's complained about the moaning of the children all night, as they tried to fall asleep "with their little hands pressed over their eyes."

The doctors published their data noting "great physical discomfort," which included itching, photophobia, and serious inflammation; some children suffered severe recurrent conjunctivitis, corneal ulceration, and scarring, with probable permanent loss of vision.



Scarlet fever and hoof and mouth disease absorbed the attention of Dr. Joseph Stickler who sought fame, even immortality and apparently was willing to use any means to achieve it, including children who were unfortunate enough to attract his attention by being healthy and not having either scarlet fever or hoof and mouth disease.

Stickler believed that bovine hoof and mouth disease infection would prevent scarlet fever in the same mistaken way that Jenner believed infection with cow pox would prevent small pox.

To demonstrate his theory, Stickler injected himself and several young children with pus from the lesions of infected cattle.

Next, to accomplish scarlet fever infection, he exposed the children to the soiled bedsheets of scarlet fever victims and forced them to breath in the soiled material by "holding pillows" [from the victims] over their faces "for some time".

Alternatively, he forced the children to inhale the breath of scarlet fever patients.

All of the children became ill from the injection of the bovine pus although none of them developed scarlet fever.

Despite this apparent success in "preventing" scarlet fever, his theory was later discredited and Sticker committed suicide.

IMPLIED "INFORMED CONSENT" IS NOT INFORMED CONSENT

What of patients already in a hospital or otherwise under medical supervision?

In 1914 respected Judge (later Supreme Court Justice) Cardoza held that doctors had a legal obligation to obtain Informed Consent prior to any surgery.⁷

The current flawed Doctrine of *Implied* Consent, however, dates directly back to the experiments of Dr. Udo Julius Wile at Pontiac State Hospital (Michigan) where, in 1915, in a search for spirochetes in the brains of patients with syphilis, Dr. Wile opened the skulls of paralyzed patients, trephining them with a dental drill. He and an assistant introduced a long thin needle to remove sections of the patients' brains without consent, informed or not, or notification to the patients or their relatives.

The ensuing uproar led other medical experts to issue clarification by making it clear **"admission to the hospital implied permission for any experiment deemed necessary by the physician."**

Vaccination and other medical procedures introduced at the peril of, and without the consent of, the patient, follow in this long line of barbaric assaults on patients for some other agenda than their own good.

Prisoners have been widely used in medical experiments of no benefit to them, supposedly as a means of offering "expiation" of their crimes.

⁷ Schloendorff v. Society of New York Hospital, 105 N.E. 92 (1914)



The reality is that because of the totally disparate and unequal balance of power between a prisoner and a jailer, the opportunity to meaningfully consent to any procedure is absent. Nonetheless, prisoners were used in 90% of Phase I drug research up to a change in the law in the 1970's.

Phase I drug trials are among the most dangerous types of drug trials and carry the greatest risk since previously untested substances are introduced into the subject's body at various doses with potentially disastrous consequences.

Morbid and irrational curiosity cloaked as medical research is easy to satisfy using prisoners. For one example of many, in 1920 Leo L Stanley, MD, removed the testicles of some prisoners at San Quentin Prison in California and implanted them in others. The results were predictably disastrous.

In the 1940's, 441 so called volunteer inmates were bitten by malaria infected mosquitos in Stateville Penitentiary (Joliet IL) to study the effectiveness of primaquine and other antimalarial drugs.

The abuse was so clear, and so well sanctioned under US law that the doctors accused of war crimes at the Doctor's Trial in Nuremberg cited this case in their defense!

While these experiments offer nothing positive, and may offer cataclysmically negative consequences for the subjects, there is little evidence that conducting abusive, vivisectionist or criminal experiments is harmful to the careers of the perpetrators.

For example, in 1963, Dr. Chester M Southam repeated an experiment previously carried out in 1952 on prisoners at Ohio State Prison. This time his unwilling and uninformed subjects were 22 elderly patients at the Jewish Chronic Disease Hospital in Brooklyn, New York who were injected with live cancer cells to "discover the secret of how healthy bodies fight the invasion of malignant cells".

A public uproar followed and the administration of the hospital attempted to cover the study up. Eventually the New York State medical licensing board placed Southam on one year probation. Two years later, the American Cancer Society honored him by electing Southam as its Vice President.

Military personnel and civilians fare no better when researchers seek data and even to this day, the Courts have ruled that military personnel have no option but to submit to vaccines and other "treatments" selected for them by the military. Of course, the new mandates for vaccines put all of us into the same category of uninformed and optionless subjects for any experiment deemed useful by whomever so deems it.

From 1963 to 1969 as part of Project Shipboard Hazard and Defense (SHAD), the U.S. Army performed tests which involved spraying several U.S. ships with various biological and chemical warfare agents, while thousands of U.S. military personnel were aboard the ships. The personnel [known in other contexts as "human beings"] were not notified of the tests and were not given any protective gear or clothing.

In these and other programs, chemicals tested on the U.S. military personnel included the nerve gases VX and Sarin, toxic chemicals such as zinc cadmium sulfide and sulfur dioxide as well as a variety of biological agents.



Dangerous vaccines like Vaccine A, the squalene containing anthrax vaccine, sickened and killed large numbers of Gulf War I vets to the stonewalling and lies of the US Government as it sought to keep the truth from them and their loved ones.

That same vaccine was “tested” on school children in St. Louis MO, an area in which anthrax is not even a remote threat.

In 1966, the U.S. Army released the supposedly harmless *Bacillus globigii* into the tunnels of the New York City subway system, as part of a field study called *A Study of the Vulnerability of Subway Passengers in New York City to Covert Attack with Biological Agents*.⁸ The Chicago subway system was also subject to a similar experiment by the Army.

BIO-WEAPONS TESTING ON CIVILIANS IN THE USA

The US has given itself virtually unlimited power to test biological, radiological, chemical or other types of weapons on the US population without notice to that population and continues to do so decade after decade.⁹

Whether civilian or military, the pace of unauthorized vivisectionist experimentation continues apace despite the supposedly protective laws. Vaccines seem to be outside of the legal restraints, for example, of informed consent and Institutional Review Board protection against uninformed experimentation or non-consenting experimentation, or both.

Cancer is a perfect medium for patient abuse: patients will agree to almost anything that a doctor proposes, including the irrational introduction of highly toxic chemicals and radiation. Patients are often unconscious for part of their time with the doctor and are trained to trust everything the doctor says, no matter how irrational it is.

Numerous cancer grafting experiments have occurred without the consent of the patient receiving the cancer implant. For example, while Dr. Nicholas Senn inoculated himself with cancerous material from one of his patients, Dr. Victor Cornil was less willing to risk his own health, preferring instead to implant a portion of a removed breast tumor from a patient into her healthy breast without informing her of either the procedure or of the results.

Dr. Cornil repeated the experiment on another patient. In both cases, the cancer proliferated in otherwise healthy tissue.

Multiple experiments have been done in which cancer was transplanted from one patient to another, generally in patients who were, at least to the doctors involved, "hopelessly ill" and therefore not expected to survive. The experiments, despite their clear inhumanity and violation of Informed Consent, were repeatedly defined as "harmless" since the patient's death was, in so far as the doctors were concerned, assured.

⁸ Blum, William (2006). *Rogue State: A Guide to the World's Only Superpower*. Zed Books. pp. 152–154.

⁹ <http://www.cbsnews.com/news/us-admits-bio-weapons-tests/>



The topic of unwitting human radiation experiments by the US government and its agencies is an enormous one. We know today, for example, that a very cursory examination reveals that premature infants were fed plutonium, prisoners had their testicles irradiated, children were given milk containing radioactive substances, conscientious objectors were fed radioactive food, the University of Iowa participated with the Atomic Energy Commission in giving pregnant women increasing amounts of radioactive materials to determine at what dose abortions would occur, healthy premature and normal infants were fed radioactive formula to see if there were differences in the way they reacted to the radioactive materials and more. And more. And more.

How much more? A LOT!

The University of Rochester injected radioactive material into dialysis patients to see how their kidneys would deal with it.

Mass General Hospital injected uranium into the brains of dying patients to see if they would stop dying (they did not) and numerous patients have surreptitiously been injected or otherwise contaminated with the indescribably deadly substance Plutonium "to see what would happen". Since Plutonium does not occur in nature, many researches have apparently been driven by an insatiable curiosity to find out what harm it does in the human body. It is clear that it does no good.

The cruelty has not been limited to simply contaminating and watching to see what happens.

Researchers directly funded by the US Army and the Atomic Energy Commission at the Medical College of Virginia, for example, experimented on poor, black severe burn victims in the 1950s without their knowledge or consent. They exposed them to additional burning, experimental antibiotic treatment, and injections of radioactive isotopes such as Phosphorus 32 in amounts so great that they exceeded by 50 times the amount deemed acceptable for healthy people. Burn victims could be expected to die at a higher rate just from the presence of so much phosphorus, without consideration of its radioactive status.

The tragic consequences? Disabled and dead involuntary experimental subjects.

During World War I, although removing the gall bladder was cataclysmic and dangerous surgery, soldiers were ordered to submit to that procedure upon pain of Court Martial to see whether its removal would render typhoid carriers safe to others. Even Typhoid Mary, incarcerated for life in a prison, refused the operation because of its known dangers.

Perhaps no other human experimentation in the US has received so much attention as the 40 year long syphilis experiments carried out at the Tuskegee Institute in Tuskegee AL.

The 400 poor black sharecropper "participants" were lured with promises of free transportation "healthcare", meals and burial costs to participate in what they had no idea was an observational study designed to watch them deteriorate and die, rather than assist them.

The collection of data began in 1932 and none of these men, their families or their communities were notified that by 1947 penicillin was widely available and was a highly effective treatment for the syphilis that would kill them under the satisfied observation of the medical "researchers" and their fully complicit staff.



Despite the fact that calls for protection of patients have been made since the early 19th century, no law existed to protect the rights humans in the US until 1974 and what we have now is woefully inadequate, as the current spate of vaccine mandates makes clear.

Well before 1974, the US conducted the Subsequent Nuremberg Trials, including the well-known "Doctor's Trial" which resulted in the execution of some of the worst offending doctors for their crimes against humanity.

This use of patient protection standards actually bound the US to precisely the same standards under the Geneva Convention which states that when war crimes are adjudicated and perpetrators punished, that can only be done under the same laws that apply to the people of the acting nation (in this case, the US).

Informed consent is an obligation of the United States, as it is an obligation of every nation in the world.

That includes vaccination and any other medical treatment. As cited above, the international standard requires true Informed Consent “without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion.”

Click here, <http://tinyurl.com/InformedConsent>, to make sure that your legislators understand clearly the magnitude of the group resistance to having those rights taken away to serve any other agenda than our own freedom and well-being as defined by the patient himself.

LEGAL BACKGROUND¹⁰:

“During the [Nuremberg Medical Trials](#), several of the Nazi doctors and scientists who were being tried for their human experiments cited past unethical studies performed in the United States in their defense, namely the [Chicago malaria experiments](#) conducted by Dr. [Joseph Goldberger](#).¹¹ Subsequent investigation led to a report by [Andrew Conway Ivy](#), who testified that the research was "an example of human experiments which were ideal because of their conformity with the highest ethical standards of human experimentation¹²." The trials contributed to the formation of the [Nuremberg Code](#) in an effort to prevent such abuses¹³ from ever occurring again.

Apparently, not everyone agrees with the objective of preventing such experimentation.

A secret AEC document dated April 17, 1947, titled *Medical Experiments in Humans* stated: "It is desired that no document be released which refers to experiments with humans that might have an adverse reaction on [public opinion](#) or result in legal suits. Documents covering such fieldwork should be classified Secret."

¹⁰ https://en.wikipedia.org/wiki/Unethical_human_experimentation_in_the_United_States

¹¹ [Germ War: The US Record – Alexander Cockburn, *Counterpunch*](#)

¹² Ed Edelson (April 28, 2008). "[Experimental Blood Substitutes Unsafe, Study Finds](#)". *ABC News*.

¹³ Weindling, Paul (Spring 2001). "[The Origins of Informed Consent - Nuremberg Code](#)", *Bulletin of the History of Medicine*



At the same time, the [Public Health Service](#) was instructed to tell citizens downwind from bomb tests that the increases in cancers were due to [neurosis](#), and that women with radiation sickness, hair loss, and burned skin were suffering from "housewife syndrome".

In 1964, the [World Medical Association](#) passed the [Declaration of Helsinki](#), a set of ethical principles for the medical community regarding human experimentation.

In 1966, the United States [National Institutes of Health](#) (NIH) Office for Protection of Research Subjects (OPRR) was created. It issued its *Policies for the Protection of Human Subjects*, which recommended establishing independent review bodies to oversee experiments. These were later called [institutional review boards](#).

In 1969, [Kentucky Court of Appeals](#) Judge [Samuel Steinfeld](#) dissented in *Strunk v. Strunk*, 445 S.W.2d 145. He made the first judicial suggestion that the [Nuremberg Code](#) should be applied to American [jurisprudence](#).

In 1974 the [National Research Act](#) established the National Commission for the Protection of Human Subjects. It mandated that the [Public Health Service](#) come up with regulations to protect the rights of human research subjects.

Project [MK-ULTRA](#) was first brought to wide public attention in 1975 by the [U.S. Congress](#), through investigations by the [Church Committee](#), and by a presidential commission known as the [Rockefeller Commission](#).

In 1975, the Department of Health, Education and Welfare (DHEW) created regulations which included the recommendations laid out in the NIH's 1966 *Policies for the Protection of Human Subjects*. [Title 45 of the Code of Federal Regulations](#), known as "The Common Rule," requires the appointment and use of institutional review boards (IRBs) in experiments using human subjects.

On April 18, 1979, prompted by an investigative journalist's public disclosure of the [Tuskegee syphilis experiments](#), the [United States Department of Health, Education, and Welfare](#) (later renamed to [Health and Human Services](#)) released a report entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, written by Dan Harms. It laid out many modern guidelines for ethical medical research.

In 1987 the [United States Supreme Court](#) ruled in *United States v. Stanley*, 483 U.S. 669, that a U.S. serviceman who was given [LSD](#) without his consent, as part of military experiments, could not sue the U.S. Army for damages.

Dissenting from the verdict in *U.S. v. Stanley*, Justice [Sandra Day O'Connor](#) stated:

“No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case. Indeed, as Justice Brennan observes, the United States played an instrumental role in the [criminal prosecution](#) of Nazi scientists who [experimented with human subjects](#) during the [Second World War](#), and the standards that the [Nuremberg Military Tribunals](#) developed to judge the behavior of the defendants stated that the 'voluntary consent of the human subject is absolutely essential ... to satisfy moral, ethical, and legal concepts.' 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.”

On January 15, 1994, President Bill Clinton formed the [Advisory Committee on Human Radiation Experiments](#) (ACHRE). This committee was created to investigate and report the use



of human beings as test subjects in experiments involving the effects of ionizing radiation in federally funded research. The committee attempted to determine the causes of the experiments and reasons that the proper oversight did not exist. It made several recommendations to help prevent future occurrences of similar events.¹⁴

As of 2007, not a single U.S. government researcher had been prosecuted for human experimentation. The preponderance of the victims of U.S. government experiments have not received compensation or, in many cases, acknowledgment of what was done to them.

CONCLUSION

As we concluded in the Petition pending before the FDA:

There can hardly be a more fundamental or central freedom issue than whether agents of government can force one to receive a medical treatment. That the treatment may be vaccination, which is not merely experimental and (sic) preventative but uninsurable and “unavoidably unsafe” gives greater emphasis to the unconscionable personal sacrifice the individual is mandated to make. Such a mandate is inconsistent with status as a free person, rather than a slave. No free society can tolerate any such imposition.”

The Foundation seeks public crowd-funding support for the Informed Consent Petition and expected litigation to enforce the fundamental human right of Informed Consent. You may support this effort at: <http://www.GoFundMe.com/FreeHealthSpeech>.

For more information:

- Hornblum Allen M.; Newman Judith Lynn; Dober Gregory J. (2013). [*Against Their Will: The Secret History of Medical Experimentation on Children in Cold War America*](#). Palgrave Macmillan.
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The screenshot shows the FDA website with the following content:

- Header: U.S. Department of Health and Human Services, U.S. Food and Drug Administration, Protecting and Promoting Your Health.
- Navigation: Home, Food, Drugs, Medical Devices, Radiation Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Tobacco Products.
- Breadcrumbs: Home > Drugs > Resources for You > Information for Consumers (Drugs)
- Section Header: **Inside Clinical Trials: Testing Medical Products in People**
- Text:

Done at hospitals and research centers around the country, clinical trials are conducted in phases. Phase 1 trials try to determine dosing, document how a drug is metabolized and excreted, and identify acute side effects. Usually, a small number of healthy volunteers (between 20 and 80) are used in Phase 1 trials.

Phase 2 trials include more participants (about 100-300) who have the disease or condition that the product potentially could treat. In Phase 2 trials, researchers seek to gather further safety data and preliminary evidence of the drug's beneficial effects (efficacy), and they develop and refine research methods for future trials with this drug. If the Phase 2 trials indicate that the drug may be effective--and the risks are considered acceptable, given the observed efficacy and the severity of the disease--the drug moves to Phase 3.

In Phase 3 trials, the drug is studied in a larger number of people with the disease (approximately 1,000-3,000). This phase further tests the product's effectiveness, monitors side effects and, in some cases, compares the product's effects to a standard treatment, if one is already available. As more and more participants are tested over longer periods of time, the less common side effects are more likely to be revealed.

Sometimes, Phase 4 trials are conducted after a product is already approved and on the market to find out more about the treatment's long-term risks, benefits, and optimal use, or to test the product in different populations of people, such as children.

Phase 2 and Phase 3 clinical trials generally involve a "control" standard. In many studies, one group of volunteers will be given an experimental or "test" drug or treatment, while the control group is given either a standard treatment for the illness or an inactive pill, liquid, or powder that has no treatment value (placebo). This control group provides a basis for comparison for assessing effects of the test treatment. In some studies, the control group will receive a placebo instead of an active drug or treatment. In other cases, it is considered unethical to use placebos, particularly if an effective treatment is available. Withholding treatment (even for a short time) would subject research participants to unreasonable risks.

Downloaded 30 June 2015: <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm>