To: The Presidential Commission for the Study of Bioethical Issues
From: G. Mason
Date: August 12, 2011
RE: Adequacy of 45 C.F.R. § 46 in Enforcing the Right to Informed Consent
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MEMORANDUM OF LAW

I. Question presented

Whether present safeguards contained in Federal Regulation 45 C.F.R. § 46 ("45 C.F.R. § 46" or "the Regulation") provide human research subjects with adequate protection of their right to informed consent.

II. Short answer

Present safeguards contained in 45 C.F.R. § 46 fail to provide human research subjects with adequate protection of their right to informed consent.

Ill. Introduction

Since the twentieth century, the right of human beings to be free from involuntary experimentation has been firmly established; a central tenet of this right is the mandate that researchers expressly obtain the informed consent of research study participants. Officials in the Presidential Commission for the Study of Bioethical Issues have made recent claims that 45 C.F.R. § 46, a section of the Code of Federal Regulations, adequately protect individuals from violation of their right to informed consent. This assertion, however, is incorrect.

45 C.F.R. § 46, in truth, provides no legitimate scheme, mechanism, or other means to enforce this purported right of human research subjects. Federal courts have repeatedly and consistently ruled that the Regulation establishes no private right of action that would enforce the rights identified and supposedly protected by 45 C.F.R. § 46. This means that a U.S. citizen who has been injured as a result of federally funded, non-consensual experimentation has no way to win if he or she decides to sue.

Involuntary research subjects are rarely informed that they are research study participants; are not given

details regarding experiments in which they have been forced to participate; and therefore lack access to evidence with which they could identify the individuals and agencies that have violated their right to informed consent. Federal agencies have abdicated responsibility for investigating the reports of involuntary research participants, some of whom allege non-consensual involvement in highly-advanced electronic experiments using technology typical of that employed by military and intelligence agencies. The Federal Bureau of Investigation has refused to investigate such claims; without a federal oversight authority, alleged involuntary research subjects rarely possess the means to obtain c edible evidence that could identify the specific entities involved. Even in the rare cases in which such proof is available, however, victims have no legal remedy.

In effect, due to the federal government's refusal to enact effective legislation, an involuntary human research subject has no apparent legal recourse. Federal law fails to provide subjects with compensation or redress for injuries resulting from forced experimentation; moreover, it does not enforce provisions for sanctioning or deterring those who willfully fail to follow the Regulation's dictates.

The record shows that this lapse constitutes not an oversight, but a deliberate failure. As a defendant in Stevens v. U.S., a case of involuntary human experimentation, the federal government argued successfully against compensation for the alleged victim, averring that the informed-consent provisions contained in 45 C.F.R § 46 are not laws, but merely "guidelines" -- which unscrupulous or careless experimenters are therefore free to ignore, with impunity, to the detriment of their human subjects.

Technical flaws contained in 45 C.F.R. § 46 preclude the Regulation from adequately protecting human research subjects, because:

(1) "Adequate" protection of a right must include an effective mechanism or method for enforcing that right, but 45 C.F.R. § 46 contains no express enforcement mechanism;

(2) Federal courts have repeatedly refused to recognize an implied enforcement mechanism in the Regulation;

(3) Federal courts have repeatedly refused to recognize an express or implied enforcement mechanism for 45 C.F.R. § 46 in other sources of federal law -- including the U.S. Constitution, federal statutes, federal regulations, international laws or treaties, and the Regulation's legislative history;

(4) In the absence of any such enforcement mechanism, courts have consistently refuse to recognize the right of human research subjects to prevail in lawsuits brought in federal courts;

(5) Although the Office for Human Research Protections (OHRP), as a part of the U.S. Department of Health and Human Services (DHHS), holds some responsibility for enforcing the Regulation, it has discretionary authority and consistently refuses to fulfill its duty of investigation and enforcement; [1]

(6) The Regulation contains no mechanism for requiring OHRP or other authority to federally enforce the rights of human subject research participants, whether judicially, administratively or otherwise; and

(7) 45 C.F.R. § 46 contains no provision for any other means whereby human research subjects may effectively enforce their right to informed consent.

Involuntary-experimentation lawsuits brought under 45 C.F.R. § 46 are consistently dismissed by courts due to deficiencies of the Regulation. This inability of involuntary participants in federally-funded experimentation to prevail in litigation further indicates that the Regulation provides grossly inadequate protection to human research subjects' right to informed consent.

This state of affairs directly contravenes both the express and the implied intent of the U.S. Congress. The Regulation's legislative history indicates that the Senate intended to create a scheme of enforcement providing full protection for the rights of experimental subjects, including a scheme of compensation for those whose right to informed consent had been violated. See S. Rep. No 93-381, Title XII (1973).

The failure of the legislature to enact laws protecting humans from involvement in involuntary experimentation, and the refusal of the federal courts to rectify this acknowledged lapse, freely permit willful violation of international laws and domestic regulations.

IV. Discussion

A. Authority for the right to informed consent.

45 C.F.R. § 46 was codified explicitly in response to the public disclosure of decades-long atrocities committed in the course of the Tuskegee experiments and other government-funded, involuntary human experimentation. (Regrettably, extensive discussion of the cultural events, legislative history, and legal authority underlying the right to informed consent lies beyond the scope of this brief memorandum.) The Regulation establishes requirements for informed consent. As noted by the court in Washington University v. Catalona, 45 C.F.R § 46 mandates that:

"Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective consent of the subject or the subject's legally authorized representative. "" Washington University v. Catalona, 437 F.Supp. 2d 985, 211 Ed. Law Rep. 283 (E.D. Mo. 2006). See also, e.g., Stevens v. United States, 2011 WL 1883010 (Fed.CI. 2011); Wright v. Fred Hutchinson Cancer Research Center, 269 F.Supp.2d 1286 (D.W.D. Wa. 2002); Whitlock v. Duke University, 637 F.Supp. 1463 (M.D. NC (1986»; Washington University v. Catalona, 437 F.Supp.2d 985,211 Ed. Law Rep. 283 (B.D. Mo. 2006); Abdullahi v. Pfizer, Inc., 2005 WL 1870811 (S.D.N.Y. 2005); White v. Paulsen, 997 F.Supp. 1380 (E.D.Wash. 1998); Ammend v. BioPort, Inc., 322 F.Supp.2d 848,872 (W.D.Mich.2004); Robertson ex reI. Robertson v. McGee, 2002 WL 535045 (N.D.Okla. 2002); Crane v. Mathews, 417 F.Supp. 532 (D.C.Ga. 1976); c.K. v. New Jersey Dept. of Health and Human Services, 92 F.3d 171 (3rd Cir. 1996).

Informed consent is a legislatively-established right. Drafted in the wake of World War II, the Nuremberg

Code, Declaration of Helsinki, and other international treaties and agreements explicitly forbid non-consensual human experimentation. In addition, the universally-acknowledged right to informed consent corresponds to numerous rights protected under the U.S. Constitution and state statutes, including due process, bodily integrity, privacy, assault, and battery. S. Rep. No 93-381, Title Xll (1973), which creates guidelines and a structure for a commission on human research protection, refers to informed consent as a "right." Moreover, the Bioethics Commission's very question as to whether 45 C.F.R. § 46 adequately protects the rights of human research subjects itself implies (1) the existence of a right and (2) the requirement for "adequate" enforcement of this right.

The right to informed consent cannot be credibly questioned. Nevertheless, a right is nominal, or for all intents and purposes even nonexistent, if it cannot be enforced. This is the unfortunate circumstance of the right to informed consent.

B. Federal courts have not recognized a private right of action pursuant to the Regulation. Though acknowledging the right to informed consent, federal courts have consistently refused to recognize a private right of action in 45 C.F.R. § 46. In the absence of a private right of action, victims of involuntary human experimentation may not seek relief in the federal courts for violations of their rights. Moreover, courts have refused to identify any other federal regulation, federal statute, clause or provision in the U.S. Constitution, or international law or treaty that would create a private right of action under the Regulation for victims of involuntary experimentation.

1. No private right of action exists in 45 C.F.R. § 46 or other federal regulations.

In Stevens v. United States, 2011 WL 1883010 (Fed.Cl. 2011), a formerly-incarcerated plaintiff claimed hat, while he was imprisoned, U.S. government employees victimized him via unauthorized experimentation.
[2] Stevens brought suit under 45 C.F.R. § 46 in the U.S. Court of Federal Claims. The court agreed with the federal government [3] that it lacked jurisdiction over the case because neither the Regulation nor any other relevant provision in the C.F.R. mandated payment of money damages by the United

States in cases of unauthorized experimentation, and Stevens had failed to identify a money-mandating source of law. The judge declined to find such an implied mandate in the Regulation.

Based on Jan's Helicopter Serv., Inc. v. FAA, 525 F.3d 1299, 1306 (Fed.Cir.2008) (quoting Fisher v. United States, 402 F.3d 1167, 1172 (Fed.Cir.2005», the court ruled that "the test for determining whether a statute or regulation can support jurisdiction in our court is whether it can be fairly interpreted as mandating compensation" (citations omitted). Neither the court nor the plaintiff, however, could identify such a federal statute or regulation, and the case was dismissed.

2. No federal statutes create a private right of action pursuant to 45 C.F.R § 46.

Plaintiffs in Wright v. Fred Hutchinson Cancer Research Center, 269 F.Supp.2d 1286 (D.W.D. Wa. 2002), were relatives of cancer patients who had died during the course of experimental treatment at the Fred Hutchinson Cancer Research Center (the "Hutch"). Plaintiffs claimed that medical personnel at the Hutch had failed to adequately inform their decedents of risks and other pertinent facts associated with the therapy.

Averring that this failure to thoroughly inform their decedents constituted a breach of the doctrine of informed consent, plaintiffs sued the Hutch and other individuals. Asserting claims for violation of 45 C.F.R. § 46 and other federal regulations, plaintiffs attempted to enforce these regulations through 42 U.S.C. §§ 1983 and 1985, alleging deprivations of the 14th Amendment's guarantees of procedural and substantive due process. [4]

The court concluded that, in order to obtain a remedy under § 1983, claimants "must assert the violation of a federal right, not merely a violation of federal law" (quoting Blessing v. Freestone, 520 U.S. 329, 340 (1997). The court determined that neither 45 C.F.R. § 46 nor other cited federal agency regulations established federally-protected rights; nor could they create rights giving rise to a private cause of action, if such rights were not created by an authorizing statute. Quoting Gonzaga Univ. v. Doe, 536 U.S. 273 (2002), and Alexander v. Sandoval, 532 U.S. 275, 286 (2001), the court observed that only Congress (i.e., not a

federal regulatory agency) could create rights enforceable under § 1983. Expressing reluctance to impute a specific legislative intent to enforce the rights of involuntary research subjects, the court declined to assume that such an intent existed in the Regulation or in any federal law, and determined that plaintiffs had failed to identify any federal statute serving as the basis for their asserted private right of action. The case was dismissed. [5]

The court in Robertson ex rel. Robertson v. McGee, 2002 WL 535045 (N.D.Okla. 2002), went even further than the Wright court, and stated: "Because there is no private right of action under the federal regulations in question, § 1983 cannot be used to create a private right of action which otherwise does not exist." Therefore, even plaintiffs who have participated in non-consensual experimentation may not rely on § 1983 for redress.

3. The U. S. Constitution does not create a private right of action pursuant to the Regulation. The Wright court similarly dispatched the plaintiffs' constitutional claims.

(a) Procedural due process

Though assuming that the decedents, as human research subjects, had been deprived of life and/or another constitutional right without due process of law, the court nevertheless insisted that the correct question for analysis was whether the Hutch's informed consent process was constitutionally adequate; in order to sustain a § 1983 action, a plaintiff must show that procedures provided by the state tend to deprive persons of constitutionally-protected rights without due process (citing Logan v. Zimmerman Brush Co., 455 U.S. 422 (1982». Noting that plaintiffs not challenged not the adequacy of the informed consent procedures in question, but objected rather to the defendants' failure to follow these procedures, the court concluded that the state's informed consent process was constitutionally sufficient. Plaintiffs' complaints regarding implementation of the procedures were deemed irrelevant, and their procedural due process claim therefore could not survive. [6]

(b) Substantive Due Process

According to Wright, legal precedent holds that a substantive due process constitutional violation has occurred where human research subjects were not informed that they were participating in experiments, and/or where the government conducted experiments knowing that the research had no therapeutic value. However, the court did not apply that rule here, because these research subjects had participated voluntarily and knew the research was experimental,[7] and the regimen was generally believed to be beneficial.

Nor would the court identify legal precedent equating lack of informed medical consent with a constitutional violation. Thus, concluded the judge, no "fundamental" right had been violated. The court further cautioned that it was opting for judicial restraint in any decision that could potentially expand substantive due process rights.

Determining that claimants' causes of action based on federal regulations and the U. S. Constitution had failed to establish the violation of any fundamental right, congressionally-mandated federal right, or private right of action, the district court dismissed the case.

4. International laws and treaties do not create a private right of action enforceable pursuant to 45 C.F.R. § 46.

The federal courts' position was further clarified in Washington University v. Catalona, 437 F.Supp.2d 985 (R.D. Mo. 2006), in which plaintiffs argued that Washington University's refusal to transfer research subjects' biological materials violated 45 C.F.R. § 46. As enforcement mechanisms for the Regulation, plaintiffs pointed to international laws including the Declaration of Helsinki and Nuremberg Code, which prohibit non-consensual human experimentation. But the court replied: "There is no private right of action for an alleged violation of international law for the protection of human research subjects based upon the Declaration of Helsinki and the Nuremberg Code (citations omitted)." Washington University at 211. As with Wright and Stevens, the court dismissed plaintiffs' case, partly on a determination that international laws did not create a private right of action in the U.S.[8]

Plaintiffs in Robertson ex reI. Robertson v. McGee fared no better. Asserting informed consent violations arising out of their participation in an experiment at the University of Oklahoma Health Science Center-Tulsa campus, plaintiffs sued under 45 C.F.R. § 46, the Nuremberg Code, the Declaration of Helsinki, 42 U.S.C. § 1983, and 28 U.S.C. § 1331.

Un surprisingly, the judge reiterated the precedent dictating that violating international laws such as the Nuremberg Code or the Declaration of Helsinki by ignoring the mandate of informed consent does not create a private right of action. Once again, due to the lack of protection provided to human research subjects under 45 C.F.R. § 46, the plaintiffs' case was dismissed.

V. Conclusion

The above discussion shows that 45 C.F.R. § 46 provides inadequate protection for human research subjects. The right to informed consent under 45 C.F.R. § 46 has failed to be enforced or protected by case law, federal regulations, federal statutes, the U. S. Constitution, and international law and treaties. Federal courts have refused to enforce informed consent under the Regulation. Moreover, entrusting involuntary federal research cases to the OHRP (apparently the only extra-judicial enforcement authority) has proven comparable to letting foxes guard the henhouse, as the OHRP regularly refuses to fulfill its duties of investigation and enforcement. This state of affairs violates the express and implied intent of the legislature, as well as, international law.

Because courts continue to defer to the Congress, the situation must be rectified by legislative means. It is time for Congress to initiate an investigation into this matter, and subsequently to enact legislation that will provide effective remedies for human victims of non-consensual federal experimentation. Otherwise, none can claim innocence upon the public revelation of another Holocaust.

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NOTES

[1] In cases of alleged non-consensual human experimentation, the OHRP's unwavering (yet illogical) procedure is to refuse to investigate unless involuntary research subjects can provide

complete details of the experiments in which they have participated. Such details -- including the names of the projects and . researchers, institutions involved, and duration of the experiments -- clearly lie beyond the reach of the vast majority of non-consensual government experimentees, who were never given this information by the government agencies conducting illicit research studies upon them. Further, these victims are barred from obtaining such classified data under the Freedom of Information Act.

[2] Plaintiff claimed that, in 1994, the U.S. Government surreptitiously implanted him with a transceiver. In response to a FOIA request, Stevens received a letter from the Department of Health and Human Services (DHHS) indicating that he "may have been involved in DHHS sponsored research."

[3] The government stated that the Regulation is intended not "to create rights in individuals, but rather to direct the actions of researchers."

[4] Plaintiffs argued that defendants, as state actors, had violated federal regulations and state and law by failing to obtain informed consent from decedents, amounting to a deprivation of due process. This position was based on an assumption that the Nuremberg Code and Declaration of Helsinki established that the rights violated were "fundamental" under the 14th Amendment's Due Process clause.

[5] According to the court, even if the federal agency regulations did create a federal right enforceable under § 1983, the regulations failed to meet certain applicable standards imposed by Cort v. Ash, 422 U.S. 66 (1975) and Gonzaga Univ. because (1) the regulations were not "phrased" or "focused" in terms of the individuals benefitted, and the courts are loath to presume Congress's intent to create a private right of action where statutes do not do so expressly; (2) the Regulation itself does not establish an individual right, because it is concerned only with "aggregate" acts and "material" violations by researchers, rather than with de minimis violations, and does not demonstrate attention to "the needs of any particular person"; (3) the federal regulations do not provide for private litigation, and therefore fail to demonstrate an intent to create private causes of action by individuals; and (4) the Regulation's legislative history (S. Rep. No 93-381, at 90 (1973)) shows that Congress had not implemented a statutory scheme that would provide human research subjects and their families with the means to recover damages for injuries resulting from their participation in human

subjects research.

[6] The court rejected the procedural due process claims because (1) defendants' violations were unforeseeable, (2) additional procedural safeguards would not have protected the decedents from violations, (3) defendants' failure to adhere to the principal of informed consent was not behavior authorized by the state, and (4) plaintiffs had recourse to remedy through the state.

[7] Pointing to 9th Circuit precedent (specifically, Bibeau v. Pacific Northwest Research Foundation, Inc., 188 F.3d 1105 (9th Cir. 1999», the court stated: "Knowledge that one is participating in a human subjects experiment, whether therapeutic or not, is a 'crucial' factor in determining whether a constitutional right is at stake. "

[8] Because the United States has never formally ratified or otherwise legislatively adopted these international agreements, courts have adjudged them to lack the force of domestic law. See, e.g., Abdullahi v. Pfizer, Inc., 2005 WL 1870811 (S.D.N. Y. 2005): "[T]he law of nations does not itself create a right of action because it does not require any particular reaction to violations of law, and therefore whether and how the United States reacts to such violations are domestic questions (citations omitted)"; Ammend v. BioPort, Inc., 322 F.Supp.2d 848, 872 (W.D.Mich.2004) ("No Supreme Court decision ... has adopted the Nuremberg Code as constitutional law"); White v. Paulsen, 997 F.Supp. 1380 (B.D.Wash. 1998): "Where Congress has not enacted authorizing legislation, a treaty gives rise to a private right of action only if it is "self-executing"; i.e., if it either expressly or impliedly creates a private right of action to enforce rights described in the treaty ... non-self-executing international agreements "are merely [] agreements !between the two nations and have no effect on domestic law absent additional governmental action"" (citations omitted). Although admitting that the courts hold authority to find an implied private right of action for international law violations, judges typically defend their refusal to imply remedies for plaintiffs by pointing to judicial restraint: "Whether a federal court should imply the existence of such a remedy in the context of a particular case is a different question. The implication of a private right of action does not necessarily flow from the identification of a potential violation of an important federal right. ... Rather ... , federal courts also must

consider whether there exist "special factors counseling hesitation in the absence of affirmative action by Congress." White v. Paulsen, 997 F.Supp. 1380 (B.D.Wash. 1998). See also Abdullahi *v,* Pfizer, Inc., 2005 WL 1870811 (S.D.N.Y. *2005).*

See: Bob S's comment: left for the Bioethics Committee blog that has not yet been published - please find at the end of this letter. *Top*

May 2, 2011

Open Letter To:

Presidential Commission for the Study of Bioethics

Amy Gutmann, Ph.D., Chairperson

Re: Non-consensual Human Subject Testing

I am a retired attomey who has been working as an activist with hundreds of US citizens who have been used as involuntary subjects of federal agency experiments. I am also one of those involuntary subjects.

I have submitted separately to the Commission testimonies from 17 victims of non-consensual experiments who have suffered and our continuing to suffer severe pain and permanent harm as the result of lengthy, highly advanced electronic experiments carried out on us without our consent and against our will by federal government agencies.

Because we understand that our submissions will be made public, we are not including identifying information on our statements. We have, however, provided you with contact information. We are more than willing to provide full identifying information to the Commission in investigating our complaints, and we are willing to make identifying information public if it serves a useful purpose.

I want to make it clear that I am not providing legal representation to any of these victims of illegal federal agency experiments. I am speaking on their behalf only as an activist, not as their attorney.

In this letter, I shall discuss the following points:

1. Federal agencies have engaged in nonconsensual human experimentation over the past 110 years and are continuing such experimentation today.

2. Experimenters within federal agencies are permitted to literally get away with murder since their crimes are protected as classified govemment secrets.

3. Present Federal Regulations and international standards provide no protection whatsoever to the victims of government experimenters since government secrecy barriers make it impossible for the victims of government experiments to obtain proof that Federal Regulations and international standards are being violated.

4. The Department of Health and Human Services, which has been given by Federal Regulations the responsibility for investigating complaints nonconsensual human experimentation by any federal agency has evaded its responsibility by using a ludicrous excuse for refusing to investigate complaints and for covering up the violations of Federal Regulations, which it has the duty to enforce.

5. Only government agencies have available for use the highly advanced technology that is being used for current experiments on involuntary subjects.

6. Responsibility of government agencies for the current advanced electronic technology experiments is established by the participation of federal agencies in covering up responsibility for these experiments.

7. Massive evidence proves beyond reasonable doubt that the FBI is actively participating in the cover-up of nonconsensual experiments that are torturing citizens.

8. Historically proven COINTELPRO operations of the FBI are now being combined with nonconsensual experimentation so that victims of the combined programs will seem to be paranoid and delusional when they tell the true story of their bizarre total experiences.

9. The COINTELPRO experiences of nearly all victims of present nonconsensual electronic experimentation are proof that the total program is being carried out by federal agencies.

10. The massive available evidence of highly advanced electronic technology experiments, causing extreme pain and suffering to hundreds of involuntary subjects, necessitate a report to President Obama concluding that present Federal Regulations and international standards do not adequately guard the health and well-being of participants in scientific studies supported by the Federal Govemment and that a thorough, independent investigation of this evidence is mandatory to determine which federal agencies are presently engaged in nonconsensual experimentation on US citizens so that the torture of this involuntary experimentation can be brought to an end.

11. Since the FBI and DHHS have both refused to meet their responsibility to investigate reports of violations of Federal Regulations and of the Geneva Convention and since the FBI has disqualified itself as an objective investigator of its own misconduct relating to these experiments, it is imperative for the Commission to recommend to the President the appointment of an Independent Prosecutor to determine specific responsibility within federal agencies for carrying out illegal experiments on hundreds of involuntary subjects.

DISCUSSION

1. Federal agencies have engaged in nonconsensual human experimentation over the past 110 years and are continuing such experimentation today.

The present investigation was ordered by President Obama in response to the discovery of government agency experiments conducted between 1946 and 1948 in which nearly 700 Guatemalan prisoners, soldiers and mental patients were intentionally infected with syphilis without their knowledge or consent, in an effort to test penicillin's effectiveness against the disease. This was only one small part of the long and sordid record of illegal and unethical programs of experimentation carried out over the past 110 years. An account of this shocking history may be found at:

htip:ffen.wikipedia.orgfwikifHuman experimentation in the United States

The President has asked the Commission to determine whether present Federal Regulations and international standards adequately guard the health and well-being of participants in scientific studies supported by the Federal Government. The answer to that question is that federal regulations and international standards may provide adequate protection to voluntarv participants in scientific studies supported by the Federal Government, but that they provide no protection whatsoever to hundreds of present involuntary participants in federal agency experiments.

The human subjects of the Guatemalan syphilis experiments were all involuntary participants. They did not know that they were being infected with syphilis. They certainly would not have volunteered to be the subjects of such experimentation, but they were given no choice. I will prove to you that the same thing is happening today to hundreds of US citizens who have been made the involuntary subjects of severely harmful government experiments using highly advanced electronic technology.

The present victims of government experiments did not volunteer to be participants in experiments. They were not informed that they had been selected as subjects of government electronic experiments. They were not informed about the risks of participating in the experiments. They did not give their consent to participation in the experiments. They would have refused to consent to the experiments if they had been asked. They have no possible way of ending their participation in the experiments unless the Commission recommends to the President procedures that will enable these involuntary participants to withdraw from experiments that they never consented to participate in.

2. Experimenters within federal agencies are permitted to literally get away with murder since their crimes are protected as classified government secrets.

Federal agencies have a 110 year record of engaging in secret, harmful, often deadly, nonconsensual human experimentation. Wikepedia summarizes the record in these words:

> "There have been numerous experiments performed on human test subjects in the United States that have been considered unethical, and were often performed

illegally, without the knowledge, consent, or informed consent of the test subjects.

Many types of experiments have been performed including the deliberate infection of people with deadly or debilitating diseases, exposure of people to *biological* and *chemical* weapons, human *radiation* experiments, injection of people with toxic and radioactive chemicals, surgical experiments, interrogation/torture experiments, tests involving mind-altering substances, and a wide variety of others. Many of these tests were performed on children and mentally disabled individuals. In many of the studies, a large portion of the subjects were poor racial minorities or prisoners. Often, subjects were sick or disabled people, whose doctors told them that they were receiving "medical treatment", but instead were used as the subjects of harmful and deadly experiments.

Many of these experiments were funded by the United States government, especially the Central Intelligence Agency, United States military and federal or military corporations. The human research programs were usually highly secretive, and in many cases information about them were not released until many years after the studies had been performed."

htlp:llen.wikipedia.org/wiki/Unethical human experimentation in the United States

Many of these secret federal agency experiments produced serious risks of death of the human subjects and many of the subjects did in fact die because of harm inflicted upon them by the government experimenters. The federal agency personnel who produced these deaths could have been prosecuted for murder if the facts could have been proven.

The crime of murder is defined by law as the unlawful killing of a human being with malice aforethought.

Malice aforethought exists if there is intent to inflict grievous bodily harm short of death. Malice aforethought also exists if there is reckless indifference to an unjustifiably high risk to human life.

Government experimenters who deliberately infect an uninformed, involuntary subject of their experiment with syphilis are inflicting grievous bodily harm short of death. They are also acting with reckless indifference to an unjustifiably high risk to human life, which may eventually result in death. They meet both these definitions of malice aforethought. Therefore, when death does occur as the result of the syphilis infection, the government scientists who produced the death are guilty of murder!

The same is true for a great many of the other government experiments on involuntary subjects over the past 110 years, and the same is true for the highly advanced electronic technology being carried out on hundreds of involuntary subjects today. None of the evil government experimenters who committed countless murders over the past 110 years could be prosecuted for their crimes.

Neither can any of the present government experimenters be prosecuted because the evidence needed to prove their guilt is shrouded behind the impenetrable government walls of secrecy. These government-funded criminals have been getting away with murder for 110 years. They are still doing so today.

The victims of non-consensual government experimentation cannot go to court to obtain a remedy. If they die, their heirs have no civil remedy available. Government secrecy barriers prevent them from accessing the evidence necessary to prove responsibility for harm. The evidence they need is classified and thus cannot be accessed through FOIA requests nor through discovery procedures during litigation.

If victims of non-consensual government experimentation or the heirs attempt to bring a legal action against government officials who are believed to be responsible for the for severe harm or death produced by nonconsensual experimentation, the government has the power to tell the court that the case must be dismissed because litigation of it will result in disclosure of "state secrets." Courts will then dismiss the case, relying only on this statement by government and without any need by government to prove to the court the truth of the assertion that litigation will disclose "state secrets." The "state secret" that the government does not want disclosed is the murder by government experimenters of involuntary subjects of their experiments.

It is thus easily possible for government scientists to get away with murder. Our government has given them a license to kill as well as to inflict prolonged physical torture upon anyone that they choose to be an involuntary subject of their experiments.

Whatever happened to the constitutional guarantee that government may not impose punishment upon citizens without due process of law? What happened to the guarantee that the government may not impose cruel and unusual punishment upon anyone? Those constitutional rights are now only an illusion. They have been superseded by government secrecy laws which authorize government torture and murder as long as it is done under the protective cloak of classified government secrets.

3. Present Federal Regulations and international standards provide no protection whatsoever to the victims of government experimenters since government secrecy barriers make it impossible for the victims of government experiments to obtain proof that Federal Regulations and international standards are being violated.

Now we come to the specific question that the Commission is responsible for investigating: Do present Federal Regulations and intemational standards adequately guard the health and well-being of participants in scientific studies supported by the Federal Government.

The Geneva Convention of 1949 prohibits human experimentation by government without obtaining advance, informed consent from the subjects of the experiments. The Geneva Convention is equivalent to law in the US.

Federal Regulations now also require that advance, informed consent must be obtained from human subjects of experiments authorized by the Federal Government. Federal Regulations are also equivalent to law.

However, no penalties are provided for violations of the Geneva Convention nor for violation of the Federal Regulations. For 110 years, govemment experimenters have totally disregarded laws against murder, which carry very severe penalties. So how could we expect them to comply with Federal Regulations or with international standards which provide no penalties for violation?

Of course there has been no compliance whatsoever by federal agencies with either the international standards set forth in the Geneva Convention nor with the Federal Regulations. Exhibit A describes the deadly. nonconsensual experiments that continued after the fourth Geneva Convention became binding on the US. The international standards prohibiting experiments on involuntary subjects were entirely ignored by federal agencies. Federal agency experiments on involuntary citizens are now being carried out on a massive scale, far in excess of anything that has occurred in previous US history.

4. The Department of Health and Human Services. which has been given by Federal Regulations the responsibility for investigating complaints that any federal agency is engaging in nonconsensual human experimentation has evaded its responsibility by using a ludicrous excuse for refusing to investigate complaints and for covering up the violations of Federal Regulations, which it has the duty to
enforce.

Present Federal Regulations require that every experiment involving human subjects must be registered with the Dept. of Health and Human Services (DHHS). DHHS has an office responsible for investigating complaints about experiments which fail to comply with the regulations. I realize that the Commission is operating as a part of DHHS. but I must tell you that DHHS has been covering up the truth about the federal agency experiments, which it has the responsibility to investigate or to arrange to have investigated.

I know exactly how DHHS handles complaints about nonconsensual experimentation. I have made one myself, and I know of other victims of nonconsensual federal agency experiments who have done the same. We present to DHHS a complaint that we are being used as involuntary subjects of federal agency experiments. We offer to provide evidence to prove our allegation. DHHS then sends us a form letter, saying that before it can investigate our complaints. it is necessary for us to identify the specific govemment experiment about which we are complaining.

DHHS is making the ludicrous assumption that if we are participants in a government experiment. then we must have been informed about which experiment we are participating in because this is required by Federal Regulations and all agencies are required to comply with Federal Regulations.

I wrote back to explain to a dimwitted bureaucrat that my complaint was that I had been made an involuntary participant in a govemment experiment and that this meant that I had not been given any information to identify the experiment I needed to have DHHS investigate to identify the experiment which was being carried out on me without informing me or obtaining my consent. The dimwitted bureaucrat wrote back, ignoring what I said, and repeating the same refusal to investigate a complaint that did not identify the specific experiment about which I was complaining.

It wasn't just my bad luck in encountering a dimwitted bureaucrat. Every other involuntary participant in government experiments who has sought investigation by DHHS has received the same form letter response. By this ludicrous method, DHHS has evaded its responsibility to investigate all complaints of nonconsensual experiments.

Imagine a city enacting an ordinance requiring that burglars must leave calling cards at the scene of their crimes so that they can be identified and arrested. When a burglary victim tries to report the crime to the police, the police ask to see the calling card left by the burglar. When the victim says that the burglar failed to leave a calling card, police tell the victim that there could not have been a burglary since burglars are now required by law to leave a calling card when they commit a burglary.

That is the kind of irrational response that the victims of nonconsensual experimentation are getting from DHHS when they try to report nonconsensual experiments being performed on them without being given an identification of the experiment in which they are involuntarily participating.

5. Only government agencies have available for use the highly advanced technology that is being used for current experiments on involuntary subjects.

The advanced electronic technology, which is being tested on hundreds of involuntary subjects is available to federal agencies. They are at the forefront in developing advanced technology through their contractors. The contractors supply the new technology only to government. The contracts prohibit them from furnishing the *technology* that they develop for government to independent outside sources from which it could be transmitted to other nations. We can thus conclude that the most advanced forms of electronic technology used for experimentation on involuntary subjects is available only to govemment agencies and to their contractors.

I do not have the technical expertise to say which kinds of experiments involve such advanced technology that it *could* only be available to government, but there is no doubt that a large amount of the technology would fall into this category. An analysis of the technology being used in the experiments should be done by experts who have the capability of determining which forms of technology are available only to govemment. This will establish the certainty that experiments using those forms of technology are being performed by a govemment agency.

It is highly unlikely that people outside govemrnent would be testing any of this technology on involuntary subjects. The risk for them would be too high. They do not have the protection of govemment secrecy.

The only safe way for government agencies to carry out these experiments is to do the experiments themselves. This is what they have always done in the past. There is a very high probability that the present experiments are being performed by federal agencies. We don't know which ones. It is likely that more than one govemment agency is responsible for conducting the present experiments. A thorough investigation will be necessary to determine precise responsibility within govemment agencies for these experiments.

6. Responsibility of government agencies for the current advanced electronic technology experiments is established by the participation of federal agencies in covering up responsibility for these experiments.

As discussed above, we know that DHHS is using absurd excuses to cover up nonconsensual experimentation by agencies and to evade its responsibility to investigate or see that the allegations are investigated. The way that DHHS handles such complaints violates the purpose and intent of the Federal regulations and of the Geneva Convention.

The other agency that has a clear responsibility to investigate is the FBI. It is the responsibility of the FBI to investigate violations of federal law. The Geneva Convention and Federal regulations requiring advance, informed consent by participants in federal agency experiments are equivalent to federal laws. The FBI has a responsibility to investigate the violation of these laws, but whenever the victims of nonconsensual experiments by federal agencies have asked the FBI for investigation of their experiences as involuntary test subjects, the FBI has flatly refused the requests without any explanation.

Why will neither DHHS nor the FBI meet their responsibility to investigate the reports by hundreds of people that they are being tortured in violation of the equivalent of Federal Regulations and also in violation of the Constitution? The FBI also has an obligation to investigate serious misuse by federal agencies of federal funds for engaging in the torture of citizens in violation of the law and the Constitution.

7. Massive evidence proves beyond reasonable doubt that the FBI is actively participating in the cover-up of nonconsensual experiments that are torturing citizens.

The FBI has not only refused to investigate these extremely serious allegations, but it has actively engaged in the cover-up of the experiments by carrying out covert COINTELPRO operations in conjunction with the experiments.

COINTELPRO operations are programs of crime and harassment developed under the leadership of infamous FBI Director J. Edgar Hoover for the purpose of combating and repressing political activists whose views Hoover considered "unacceptable." These unconstitutional operations by the FBI were investigated by congress in 1976-78 and again in 1989. Court cases and the work of investigative journalists revealed additional information about the massive program of illegal and unconstitutional covert warfare waged against innocent citizens by the FBI from 1956 to at least 1990.

I was targeted by the FBI in 1954 because of my activism against McCarthyism in college and because of my intention to enter the legal profession for the purpose of advancing and protecting constitutional rights. I can testify that these operations did not end for me in 1990. They have continued without interruption to the present day.

Examples of typical COINTELPRO operations are:

· Interception and tampering with mail in both directions. The Senate investigation of 1976-78 revealed that USPS had been giving the FBI illegal access to mail since 1940. Our experience establishes that the illegal access still continues.

· Access and thefts from safe deposit boxes at four banks on repeated occasions. Banks are supposed to permit access only when shown a search warrant, but in practice, they grant access whenever they are asked by the FBI.

· Ability to bypass any lock or security device on any home, office, or car without breaking in. Common thieves must physically break in, and they steal only things of value. Our burglars stole things of great personal value to us but mostly of little value to anyone else.

· Ability to obtain cooperation and participation by local police. Local police have always been a part of COINTELPRO. They cover it up and sometimes participate in it. The LAPD refused to take burglary reports, claiming that there could not be a burglary without a physical break-in. This is not true legally. Police misstated the law about this and other subjects to evade their responsibility to take reports. The LAPD openly harassed us for years. They followed us wherever we went until I wrote a letter to the Police Chief. That stopped the harassment, but they still refuse to take reports of COINTELPRO crimes.

· Ability to arrange for numerous local people to participate in elaborate harassment operations. The FBI maintains an army of people throughout the nation who work at full time at regular jobs but who are available at any time to carry out whatever special work assignments the FBI gives them to perform. The FBI calls these people "informants." The victims of harassment by these people call them "perps" (short for perpetrators).

Around 2000, I made contact with people on the Internet who were experiencing both COINTELPRO operations and electronic attacks. I had not previously been aware that I and my domestic partner had been experiencing electronic attacks, but now I realized that they had long been going on for us for years without our recognition.

I realized now that there had been a merger of two government programs. Electronic attacks had been added to COINTELPRO operations as an additional weapon to use against those such as myself who had been politically targeted. COINTELPRO harassment and crime operations had been added to government programs of experimentation such as the MKUL TRA mind control experiments of the CIA.

8. Historically proven COINTELPRO operations of the FBI are now being combined with nonconsensual experimentation so that victims of the combined programs will seem to be paranoid and delusional when they tell the true story of their bizarre total experiences.

The purpose of combining COINTELPRO with the experiments is to weaken, debilitate and confuse the subjects so severely that they would not be able to fight back and achieve a solution that had been achieved twice previously when COINTELPRO victims took proof of the truth of COINTELPRO operations to the public and created public pressure that forced congress to undertake the two COINTELPRO investigations.

COINTELPRO operations have evolved over the decades into harassment activities that are designed to seem utterly impossible and unbelievable so that anyone who hears reports of the truth will think that the victim must be utterly paranoid and delusional. When unbelievable COINTELPRO experiences are combined with unbelievable electronic experiments, the combined experiences of the victim are far beyond belief by all normal standards.

Even close friends and relatives of the victim do not believe the truth. If victims go to the police to seek investigation of the crimes being committed against them, the police, who know what is really happening, have a good excuse for treating truth as insanity.

Victims of these combined programs are being viciously tortured, but they have nowhere to turn for help. It is a horror beyond the imagination of someone who has not lived with these experiences. Some of the victims have committed suicide. Some have turned into vegetables. All of them have been hurt so deeply that they will never get over the pain even if the horror stopped tomorrow.

I am reluctant to try to tell the Commission truth that seems so unbelievable, but it is truth that I and hundreds of other victims of this combined program must live with day and night. We must try to make this unbelievable truth recognized and understood by the Commission.

We must try to make the Commission understand how COINTELPRO operations are being used by the FBI for the purpose of discrediting victims of the combined programs and giving local police an excuse for refusing to investigate any of the true horrors to which the victims of these programs are being constantly subjected.

The Commission is likely to receive submissions from other victims who do not understand their true situation and who use the wrong terminology to describe their experiences with COINTELPRO operations. Some of the victims who know nothing about FBI history believe that they are being persecuted by "local gangs." They describe true experiences with delusional terminology such as "gang stalking," "citizen stalking," "organized stalking groups," etc.

The Commission will no doubt do Internet research and find websites that use this delusional terminology. It's not because the people are mentally ill. They are describing real COINTELPRO experiences but misinterpreting what they see and using the wrong terminology to describe it because they do not understand COINTELPRO.

The primary purpose of COINTELPRO operations today is to cause the extremely serious problems of nonconsensual testing to be treated as paranoid delusions because the accompanying COINTELPRO experiences seem unbelievable and because these experiences are misinterpreted by the victims in a delusional way. Both the experiments and the COINTELPRO operations are totally real and both involve very serious violations of the law and the Constitution by federal agencies, but the truth has been made to seem unbelievable so that no one will believe the truth and so that the truth about federal agency crimes will be dismissed as paranoid delusions.

9. The COINTELPRO experiences of nearly all victims of present nonconsensual electronic experimentation are proof that the total program is being carried out by federal agencies.

The COINTELPRO experiences which I have described above and other harassment and crime experiences, which I can describe in more detail later, prove that the COINTELPRO operations of the FBI did not end in 1990 and that they are still continuing today. The COINTELPRO operations that I have described have never been used in this country by any organization other than the FBI. They could only be carried out by a federal agency with the capability of the FBI. That is a 100% certainty.

If we know with 100% certainty that the FBI or another federal agency is supplementing non-consensual electronic experimentation with COINTELPRO operations, then there is no need to prove independently with 100% certainty that the electronic experiments are being performed by a government agency. The fact that the FBI is supporting the experiments in the way that I have described means that a government agency is responsible for the performance of the experiments and for covering up the truth about the experiments regardless of who is actually carrying out the experiments.

10. The massive available evidence of highly advanced electronic technology experiments, causing extreme pain and suffering to hundreds of involuntary subjects, necessitate a report to President Obama concluding that present Federal Regulations and international standards do not adequately guard the health and well-being of participants in scientific studies supported by the Federal Government and that a thorough, independent investigation of this evidence is mandatory to determine which federal agencies are presently engaged in nonconsensual experimentation on US citizens so that the torture of this involuntary experimentation can be brought to an end.

It is impossible for the Commission to conclude that there is adequate protection for involuntary participants when DHHS and the FBI both refuse to investigate allegations of non consensual testing and when the FBI is reported by an attorney and by many other victims to be participating in the nonconsensual experiments by engaging in COINTELPRO operations to discredit the victims.

I am submitting herewith testimony of the experiences of 14 other victims of nonconsensual advanced electronic experimentation. Many other victims of these nonconsensual experiments will be submitting their testimony in separate statements and at the forthcoming meeting of the Commission in New York.

Their experiences involve many different forms of advanced electronic experiments. I know from my communications with these victims that nearly all of them have COINTELPRO experiences in addition to the electronic experimentation. Most of them will not discuss the COINTELPRO experiences because they do not recognize the relevance of this information in establishing government responsibility for the total program. Some of them misperceive the COINTELPRO experiences as harassment by local gangs, but all their experiences are similar to what I have described and explained here. I am giving the only possible correct interpretation of the common experiences of all present victims of nonconsensual experimentation and COINTELPRO operations.

The conclusion that must be drawn in the report by the Commission to President Obama is that present Federal Regulations and international standards do not adequately guard the health and well-being of participants in scientific studies supported by the Federal Government.

11. Since the FBI and DHHS have both refused to meet their responsibility to investigate reports of violations of Federal Regulations and of the Geneva Convention and since the FBI has disqualified itself as an objective investigator of its own misconduct relating to these experiments, it is imperative for the Commission to recommend to the President the appointment of an Independent Prosecutor to determine specific responsibility within federal agencies for carrying out illegal experiments on hundreds of involuntary subjects.

The third reason for discussing COINTELPRO evidence is that it demonstrates the FBI must not be assigned the responsibility of investigating the issue of adequate protection against nonconsensual experimentation when the FBI has previously refused to meet its responsibility to investigate this issue and when it has engaged in COINTELPRO operations that have added to the torture now being endured by victims of nonconsensual experimentation. It is essential to have an independent investigation of the FBI's role in covering up non-consensual experimentation by COINTELPRO operations.

The only possible way to obtain an independent investigation of FBI responsibility in the major government wrongdoing that I have described to you is by the appointment of an Independent Prosecutor. This appointment is normally made by congress or by the Attorney-General. Since this report is being made to the President, the normal course of action would be to ask the Attorney-General to make the appointment, but since the Special Prosecutor will need to investigate the Bureau within the Justice Department, it would be more appropriate for the President to select the Independent Prosecutor and recommend his choice to the Attorney-General.

CONCLUSION

I realize that I am attempting to convey to the Commission a government horror story that may seem beyond belief since it has been buried beneath layers of government secrecy and known only to several hundred victims who have been suffering the horrors of a covert government war being waged against them for years.

The history of COINTELPRO crime and harassment is now a faded memory for nearly everyone but the victims of the continuing reality for which they have had no possible legal or practical year. For me the horrors of covert COINTELPRO torment have extended over 57 years.

No one else has lived through this much secret government torture. No one else has the knowledge and the experience that I have with this subject. I stand ready, willing, and able to answer any and all questions that any member of the Commission or the Staff may wish to ask. I can provide documentation to support anything that I have said. If anyone has doubt about the truth of what I say, please give me the chance to prove the truth to you

I am speaking on behalf of several hundred victims of modem government torture who have had nowhere to tum to find a remedy as the torture has continued year after year with no hope of an end in sight. Now at last, we do have hope. We do have a Commission looking at an issue that no one else has been willing to investigate. You are our last chance. If you do not give us a solution, we have nowhere else to turn. There is no other possible solution that we have not tried.

The Bioethics Commission is our last hope. That places a very great responsibility upon each of you to investigate what we tell you fully and thoroughly and to ask questions about any question or issue that may cause you to have doubt or disbelief. I assure you that I can answer any question you ask and that I can document and prove anything that needs to be proved to your full satisfaction. Please don't make assumptions against us without giving me a chance to prove the truth to you.

You now have hundreds of lives in your hands. Please save those lives. Please make those lives worth living again.

Sincerely yours,

Robert S. JD

(exhibits attached)

Bob S. submitted this statement:

I am a retired attomey who has long been an involuntary subject of federal agency experiments using Directed Energy Weapons. I filed a complaint with the Office of Human Research Protection (OHRP) about four years ago.

The answer by this office was that it could not investigate my complaint unless I identified the specific government experiment that I was complaining about. I explained that I had no way to identify the experiment since I had not been asked to volunteer to participate in it. OHRP replied that it could do nothing to help me without identification of the experiment.

OHRP has been denying to me and to all other victims of non-consensual experiments the protection that is supposed to be available under Federal Regulations. More recently the excuse given by OHRP has been reworded as follows in a letter to another victim of non-consensual experimentation:

"OHRP evaluates all substantive allegations of noncompliance involving research projects or institutions over which it has jurisdiction. OHRP has determined that it does not have jurisdiction over the matters referenced in your letter. Therefore, OHRP will not be able to pursue this matter on your behalf."

The intemal policies of DHHS require OHRP to investigate complaints about

experiments being performed by DHH5. If a complaint is about experiments being performed by a different agency, the policy of OHRP is to refer the complaint to the head of the Department that is engaged in the experiments.

What remedy is available to the hundreds of victims who are being used without their consent as subjects of unidentified experiments involving directed energy weapons or implants? These experiments are very likely being performed by the CIA or by DOD , but involuntary participants in the experiments are never told who is experimenting on them. So they have no possible remedy from DHH5 or elsewhere.

OHRP is telling all these hundreds of people that OHRP does not have jurisdiction. No other government office will accept jurisdiction to investigate. 50 the victims of these experiments are being tortured year after year by painful and permanently harmful government experiments with no end in sight and no legal remedies available to them.

This govemment torture of citizens will continue indefinitely unless the Commission meets its responsibility to report to the President that these people are suffering terrible harm as non-consensual subjects of govemment experiments who are desperately in need of a means for ending this govemment torture.

But the members of the Bioethics Commission are ignoring all the pain and permanent harm that is being inflicted on innocent citizens by government agencies. Instead of meeting their responsibility to bring an end to this government torture, Commission members are stating in their public discussion that something like the Guatemala experiments cannot happen again because of the present requirement in Federal Regulations to obtain advance, informed consent. This conclusion is directly contradicted by an enormous amount of evidence that has been submitted to the Commission.

How effective would laws against robbery be if we did not have police who take responsibility for enforcing these laws? That's how effective Federal Regulations are in prohibiting experiments without advance, informed consent when there is no one in DHHS or elsewhere who will enforce the regulations.

Every person who was permitted to make public comments at the March and at May meetings of the Commission reported personal knowledge and experience with years of harmful govemment experiments being performed without obtaining advance, informed consent. I am familiar with a great deal of written evidence submitted to the Commission by myself and by others to document massive federal agency experiments being performed on involuntary subjects. Oblivious to all this reported reality, the Commission is stating publicly that the risk of such things happening has been eliminated by the present requirement of Federal Regulations to obtain advance, informed consent.

The Bioethics Commission is covering up the truth that is being reported to it by citizens in overwhelming oral and written submissions.

My letter of May 2,2011 to the Commission is at www.CointelproToday.org.

Bob S

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