My Opt-Out Form Sent to the Department of Health and Human Services and to the late Senator Lautenberg's office, former Congressman Holt, and to Senator Menedez

Introduction:

In the Bioethics Commission's report released on December 15, 2011, the Bioethics Commission suggested that to keep track of the more than 55,000 research projects using human subjects, the Federal government should create a central online portal and database where basic information about the projects are archived and made easily accessible and further concluded that it "**cannot say that all federally funded research provides optimal protections against avoidable harms and unethical treatment**". The Bioethics Commission also said although human subjects in US government-funded research are generally protected by existing rules and regulations, their safety and well-being could be enhanced with stronger measures, including increased public transparency and a system of compensating subjects who sustain research-related injuries.

Human subject research should adhere to the ethical principles and guidelines for the protection of human research participants summarized in the uniform set of regulations, called the Federal Policy for the Protection of Human Subjects, 45 CFR 46, Subpart A, formally known as the "Common Rule." The 45 CFR 46 regulations are based in large part on the Belmont Report and were written to offer basic protections to human subjects involved in both biomedical and behavioral research. Today, 45 CFR 46, Subjects A and E: Registration of Institutional Review Boards (added 1/15/2009) is shared by 17 Departments and Agencies, representing most, but not all, of the Federal Departments and Agencies sponsoring human subjects research. Many of them have not adopted Subpart B: Additional Protections for Pregnant Women, Human Fetuses & Neonates Involved in Research, Subpart C: Additional Protections Pertaining to Biomedical & Behavior Research Involving Prisoners as Subjects, or Subject D: Additional Protections for Children Involved as Subjects in Research. For the past 20 years, 45 CFR 46, have been considered merely "guidelines" and is not a lawfully, promulgated regulation.

Before a research project involving human subjects is initiated, it must be reviewed and approved by an Institutional Review Board (IRB). The IRB has a central role in ensuring that all human subject research is planned and conducted in an ethical manner, and in compliance with federal, state and local regulations. The major responsibilities of the IRB are to assess the risks and benefits of proposed research and to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Research is defined by the Common Rule regulations as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." ***Medical experiment*** is defined by California Law, Health & Safety Code Section 24171 as "the severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice of research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.

Human Subject is defined by the Common Rule regulations as "a living individual about whom an investigator (whether professional or student) conducting research obtains either a) data through intervention or interaction with the individual or b) identifiable private information." ***Human subject*** is defined by FDA regulations as "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. Subject [also] means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control."

Failure of OHRP to Investigate Allegations

In the March 14, 2006 letter to the then HHS Secretary Michael Leavitt from Senator Charles Grassley states, "I am personally troubled that, for all intents and purposes, the FDA allowed a clinical trial to proceed, which makes the inhabitants of 32 communities in 18 states, and anyone living or traveling near these communities, potential "guinea pigs" without their consent and, absent consent, without full awareness of the risks and benefits of the blood substitute… My requests to the FDA did not seem unreasonable to me, especially given the serious nature of the ethical and safety issues included with the PolyHeme Study." According to the Alliance for Human Research Protection (AHRP), OHRP does not appear to have the authority to put on hold a commercially sponsored unethical human experiment that is under FDA jurisdiction. If OHRP has such authority and failed to exercise it, then the public should know that there are, in effect, no protections preventing unethical experiments to be conducted at the nation's hospitals. **The public must be protected by an authorized agency not under the influence of biotech-pharmaceutical companies.**

On behalf of the Secretary, HHS, the Office on Human Research Protections (OHRP) approves the terms of these written institutional assurances, which constitute binding commitments. In essence, OHRP holds accountable and depends on institutional officials, committees, researchers, and other agents of the institution to comply with the institution's assurance and the regulations. In carrying out its oversight responsibility, OHRP's Division of Compliance Oversight monitors compliance through not-for-cause compliance oversight surveillance activities and for-cause compliance oversight evaluations of allegations or indications of noncompliance with the regulations. **OHRP has the authority under Title IV of the Public Health Service Act (42 USC 281 et seq.) to investigate complaints about human subject protections in HHS-conducted or -funded research, as well as any other research covered by the institution's Assurance of Compliance.** OHRP also promotes compliance through its Division of Policy and Assurances, which provides policy and guidance documents pertaining to the regulatory requirements in 45 CFR 46. If HHS receives an allegation or indication of noncompliance related to human subject research that is conducted or supported solely by a Common Rule department/agency other than HHS, HHS will refer the matter to that department/agency for review and action as appropriate" as stated at http://www.hhs.gov/ohrp/humansubjects/commonrule/.

On April 26, 2011, I met with Kristina C. Borror Ph.D., Division of Compliance Oversight Director to file a formal complaint and to find out which Federal agency was responsible for conducting non-consensual human experimentation on me and others. I was told by Ms. Borror that there was nothing that her office could do for me and that I should contact each agency and file a FOIA request with each one." I knew there were a lot of research projects using human subjects and it would be like looking for a needle in a haystack. It would be very difficult, if not impossible to find, since there are more than 55,000 projects that involve human subjects. Since January 15, 2009, all IRBs must use the Internet-based registration maintained by HHS as stated in 45 CFR 46.501. Is the answer right on HHS's website since all IRBs have to register with HHS?

Non-Consensual Human Subjects Testimonies & Request for a Moratorium

Congress and HHS are sponsoring projects involving human subjects, without 45 CFR 46 being an enforceable lawfully, promulgated regulation, informed consent being on the books or a ratified Human Subjects Research Protection Law. As a result, "the absence of Federal jurisdiction over much privately funded research means that the **U.S. government cannot know how many Americans currently are subjects in experiments, cannot influence how they have been recruited, cannot ensure that research subjects know and understand the risks they are undertaking, and cannot ascertain whether they have been harmed**." Many non-consensual human subjects testified at the Bioethics Commission's Meeting 4 Session 10 (March 1, 2011) and Meeting 5 Session 6 (May 18, 2011): Public Comments. There were others who submitted their written testimonies. The archived transcripts and videos are available at bioethics.gov/cms/meeting-four and bioethics.gov/cms/meeting-five. Several months later, the Office of Human Research Protections (OHRP)

requested public comments pertaining to the update of 45 CFR 46 and has received 600+ pages of testimonies from human subjects and over 1100 responses, which did not include the public comments from the Bioethics Commission.

A moratorium is being requested so that the "Federal Government can get it right". This is a massive undertaken, which should require the support of HHS and Congress to ensure that any new regulations will benefit and protect the rights, safety, and welfare of future human subjects. We are requesting Congress to conduct investigative hearings about illegal "COINTELPRO" activities, ratify laws to protect the rights & welfare of the human subjects so that informed consent is finally on the books and oversee the activities pertaining to the revision of 45 CFR 46 by HHS so that it will become a lawfully, promulgated regulation. Will the revised 45 CFR 46 address the issues of ACHRE, NBAC, Executive Orders/Memos by former President Clinton, results of the EPA lawsuit, and former Senator John Glenn? How will 45 CFR 46 interact with FDA regulations (21 CFR 50, 56), HIPAA Privacy Rule (45 CFR 164), Public Health Service Act (42 USC 281) & other Federal & State regulations that impact the conduct of human subjects research? The Common Rule offers more exceptions than FDA regulations do. Should that be true? More importantly, will 45 CFR 46 become a strict, ethical, and enforceable, lawfully promulgated Federal regulation, which researchers will be held accountable for their actions so that unethical, human subject research/experiments will be eliminated in the future?

Request to "Opt-Out" or Discontinue Participation as a "Non-consensual" Human Subject

I, **Letitia Peters**have been ***randomly selected*** to be a participant or human subject in a research/experiment without my voluntary, informed consent, either orally or written and without my knowledge. In this research/ experiment, I am/have been exposed to electronic/electromagnetic radiation technology (including gamma rays, microwave, & infrared) and weapons (chemical, biological, direct energy, & radiological). In addition, my body has been infiltrated with many "unidentified metal devices". I meet the requirement of a "human subject" in a "research/experiment" as defined above. I **already had** a compromised immune system because of my exposure to toxic molds/mycotoxins while working in the Washington, DC Federal buildings. I was far from being that "healthy person with no major health ailments", but I was working towards it everyday so that I would have a better quality of life and become a productive U.S. citizen in the workplace and community once again. **I am on disability retirement & I would have never consented to be a "volunteer" in any human subject research with all of my confirmed diagnoses; especially one which uses gamma rays, microwave, infrared and weapons (biological, chemical, directed energy & radiological). I believe that my selection was not equitable in my case as defined in 45 CFR 46.113. I have endured unnecessary & unimaginable pain and suffering that presents a danger to my well-being by continuing in this human research. I am in a life-threatening situation everyday that I continue to be in this human subject research. Furthermore, this violates my religious principles and beliefs. I want out now! In addition, the National Commission for the Protection of Human Subjects believed that those who are already burdened (e.g., by disabilities or institutionalization) should not be asked to accept the burdens of research unless other appropriate subjects cannot be found (i.e., if the research concerns their particular disability or circumstance).**

This human subject research/experiment involves noncompliance with 45 CFR 46. This part of the "Common Rule" is intended to allow IRBs to waive informed consent in its entirety or any of the required elements of informed consent In order for this human subject/experiment to waive informed consent it had to meet the 4 criteria in 45 CFR 46.116 (d). An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that: (1) **The research involves no more than minimal risk to the subjects**; (2) **The waiver or alteration will not adversely affect the rights and welfare of the subjects**; (3) **The research could not practicably be carried out without the waiver or alteration;**

and (4) **Whenever appropriate, the subjects will be provided with additional pertinent information after participation.**

Risk is defined in The IRB Guidebook as the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." **Minimal risk** is defined in the Common Rule as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

The **daily** exposures of electronic/electromagnetic radiation technology (including gamma rays, microwave, & infrared) and weapons (chemical, biological, direct energy, & radiological) presents a danger to my overall well-being and has violated my rights and welfare as a human subject. The human research practices, which I am experiencing, should be reclassified as "cruel and unusual punishment" or "crimes against humanity", which goes way beyond the physical or psychological harm that is "normally" encountered in our daily lives or in the routine medical, dental, or psychological examination. I am experiencing intentional infliction of severe physical pain or suffering, which violates my rights and falls under the purview of 18 USC § 2340 Torture. I am in pain everyday, but the degree of the pain varies from day to day and from hour to hour; from minor discomfort pain to excruciating, agonizing pain, where I am in tears and crying out for Jesus Christ to deliver me. It has been very unbearable. There have been times that I could not even get out of bed to bathe or even cook for myself because of the extreme fatigue and the severity of the pain in my body. I am in excruciating pain for hours and days while suffering in silence because I did not want my parents to worry and also they do not believe that we are in a human subject research. My feet would become so swollen due to edema that I could barely walk. Each step that I would take the shooting pain would resonate throughout my legs. My legs looked like they were going to "pop". I would have to elevate them and stay completely off my feet for a day or several days before they would return to normal & there was no pain. My stomach, fingers, eyelids, face & head also swells. I would experience constant throbbing of pain for hours. I went "temporary blind" after being intentionally dosed with chemical: pesticides/insecticides and the emergency medical care failed to treat me. I could hear my rapid heart rate when I am in the bed or resting; sometimes I would have heart palpitations. One incident I developed "red fine bumps" in my head and a couple of days later, my hair fell out in "clumps" as I was combing it. The National Academy of Sciences states this only occurs with radiation exposures at 200 rems or higher. My vision has become blurry after these exposures. My body is under tremendous stress, undue distress and inflicted pain, which affects my performance to try to run my own business and to live a normal life. My body has been infiltrated with "unidentifiable metal devices", which is being picked up by a simple carpenter's tool: a stud sensor/finder. I could see two in my neck, because that particular area of my neck pulsates, when my heart rate increases and another one came out of place in my wrist, which I saw through my skin. I developed very painful red, blisters/mouth sores overnight, while I am sleeping. According to the Mayo Clinic's website in order for the blisters/mouth sores to develop, radiation was aimed at my head or neck. I have a very dry, metallic taste in my mouth. My eyes are very dry. I also woke up to an excruciating pounding, headache, which has been with me all day. My body is "aching" all over, as well as, my parents' bodies. All of our diseases have been exacerbated; my father has developed cancer, which could have been a contributing factor from the environment and I recently spent the night in the hospital with my mother due to her chest pains and very high blood pressure, which never occurred before. Even people who visit us are being exposed, including children.

Personal privacy is important to ethical research as stated in 45 CFR 46.111. My confidentiality and privacy rights have been violated. 45 CFR 46.116 (f) clearly states, "nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law." The "researchers" have interfered with the physicians to provide me with the "appropriate" emergency care. The physicians released private health information, did not

adequately addressed my complaints, failed to ensure patient care was provided in a safe and effective manner, did not provide appropriate medical screening exams for me, and failed to treat a sick and injured patient before releasing me, which violates the Emergency Medical Treatment and Active Labor Act (EMTALA). Now there is a significant high health risk of me developing a radiation-related disease that could have been greatly minimized through early detection and appropriate medical treatment. The "researchers" have used disinformation to cause humiliation, social stigmatization, and discrimination. Invasion of privacy concerns access to a person's body and the "researchers" has access to my body 24/7 and there are countless of men, women and children, also called "informants" or "perps" who have access to my body 24/7 without my informed consent or knowledge.

Human Subject Research Violates the Rights & Welfare of Vulnerable Population: Children

Children have been included in this human subject research, without receiving the parental/guardian permission consent documentation as defined in 45 CFR 46.408 and these children/minors are not wards of the state or any other agency, institution, or entity as defined in 45 CFR 46.409. No adequate provisions were made for soliciting the assent of children and the no permission was granted from their parents or guardians, as set forth in 45 CFR 46.408 as stated in 45 CFR 46.407 (iii). These children/minor are involve in research, which involves greater than minimal risk as defined in 45 CFR 46.404 and does not present the prospect of direct benefit to them at defined in 45 CFR 46.406. Some of these children are not economically or educationally disadvantaged, but they have been placed in because of their race. This research is not being conducted in accordance with sound ethical principles as stated in 45 CFR 46.607 (ii).

Both the **National Commission for the Protection of Human Subjects and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research** recommended that such waivers be granted only if subjects will not be denied benefits or services to which they are otherwise legally entitled. The waiver of informed consent has diminished the protection of my rights and welfare as a non-consensual human subject. I have received no respect as a non-consensual human subject. There is a non-verbal element that "whatever happens to the human subject is of no personal concern to the researcher. They can do whatever they want to the human subject and there is nothing that the human subject can do about because no one will help the human subject."

The waiver of informed consent has caused adverse consequences for my welfare and for my general well-being, as well as, my loved ones. In addition, our rights, safety, dignity, welfare, and privacy as non-consensual human subjects have been violated and do not comply with 45 CFR 46. This human subject research/experiment is incompliance with the policy, 45 CFR 46 therefore, as stated in 45 CFR 46.123, it should be terminated. If I continue in this "loosely controlled" research/experiment, it will likely result in irreversible permanent injury, radiation-induced diseases or even pre-mature death for myself (this request also includes my family members who were systematically included in this because of me), because the **"researchers" are operating above the law and below the accepted standard of scientific, ethical, and humane research.** ***I am requesting to "opt-out" or discontinue my participation immediately out of this non-consensual human subject research/experiment without prejudice.*** The "Common Rule", 45 CFR 46.116 (a) (8) states, "and **the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.**" I <u>am not</u> waiving any legal claims, rights or remedies because of my participation as a non-consensual human subject. The legal rights as a human subject may not be waived and the human subject may not be asked to release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

In the National Institutes of Health, Office for Protection from Research Risks (OPRR) 1993 Institutional Review Board Guidebook in the withdrawal from participation section, it states, "attention should be paid to subjects' rights when they decide to withdraw from participation in the study. The federal regulations clearly

require that subjects be free to withdraw from participation without penalty or loss of benefits to which they are otherwise entitled [Federal Policy §116(a) (8)]."

For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are availability of medical treatment and compensation in the case of research-related injury, including who will pay for the treatment and the availability of other financial compensation as stated in 45 CFR 46.116(a)(6). In July 2005 the National Academy of Sciences came to the conclusion that the preponderance of scientific evidence shows that even very low doses of radiation pose a risk of cancer or other health problem and there is no threshold below, which exposure can be viewed as harmless. According to data from Hiroshima and Nagasaki, show that **symptoms may persist for up to 10 years and may also have an increased long-term risk for leukemia and lymphoma.** The effects of radiation on the human body can be found at www.atomicarchive.com/Effects/radeffects.shtml. Will the human subjects be compensated due to research-related injury?

I, Letitia Peters certify that my decision to "opt-out" or discontinue participation in this human experiment is without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on my decision. I am requesting to "opt-out" or discontinue my participation because of my rights as a human subject as stated in 45 CFR 46 116 (a) (8). This request includes all of my immediate family members (my elderly parents, my sister's family and my brother's family) who were thrust in this unethical, human subject research/experiment without their consent or without their knowledge.