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The Presidential Commission for the Study of Bioethical Issues
1425 New York Ave. NW Ste C-100
Washington, DC 20005

Via Email to: info@bioethics.gov

Public Comment in Response to: Federal Register 76:41 (March 2, 2011) pp. 11482-11483

Citizens for Responsible Care & Research, Inc. (CIRCARE) welcomes this opportunity to provide public comment in response to the request issued by the Presidential Commission for the Study of Bioethical Issues. CIRCARE is a 501(c) 3 nonprofit organization dedicated to effective protection of human subjects in research. CIRCARE officers and board members serve without compensation and CIRCARE does not accept funding from drug or device manufacturers. Additional information about CIRARE is available on our web site. (1)

Our comments are organized in two part. In the first part we offer suggestions for the Commission to consider; in the second we briefly describe examples of troubling contemporary research, similar in several aspects to the 1946 Guatemala study. The purpose of the latter is to identify areas in which our current system has yet to live up to the ideals and principles upon which it is based.

Part 1: Suggestions To Consider

As suggested in the Federal Register notice, in order assist the Commission in developing a thorough understanding of the adequacy of current U.S. and international standards for protecting the health and well-being of human subjects in scientific studies supported by the federal government, we refer the Commission to the public comment of CIRCARE vice president Gerald Schatz, J.D., in which he describes international law, requirements of which the bioethics community is apparently oblivious. For your convenience we reproduce the relevant portion of his comment:

> "There is the International Covenant on Civil and Political Rights the United States ratified in 1992 and it makes informed consent an absolute requirement, no exceptions, not even in emergencies, subject to those normal legal fictions of consenting for the incapacitated patient to medical care and so forth.
>
> Additionally, the Geneva Conventions and Additional Protocols to the Geneva Conventions make research very, very difficult or prohibited altogether for those individuals who are caught up in the war and armed conflicts." (2)

Over the past several years the International Compilation of Human Subjects Protections posted on the OHRP website has been significantly strengthened by additions of the International Covenant on Civil and Political Rights, the Geneva Conventions and Additional Protocols to the Geneva Conventions. (3) A persistent problem, however, has been a lack of OHRP guidance on the significance and applicability of this law. An additional difficulty seems to be that no only is there failure to acknowledge this law and its applicability inside and outside the U.S., it is almost surely the case that neither OHRP nor FDA are adequately resourced to implementation of this law. Consequently we urge the Commission to recommend information about this law be distributed to appropriate U.S. agencies, research partner governments, research institutions, commercial research sponsors, and appropriate NGOs. Links to the Michigan State University faculty response as drafted by Gerald Schatz to the 2005 OHRP request for comment on equivalent protections as described above, two legal articles, and electronic versions of the law in question are provided in the references at the end of this document. (3)

Likewise, to assist the Commission in determining the extent to which current U.S. standards provide adequate protections to research subjects in domestic and international research sponsored by the federal government, we urge the Commission to examine implementation. Does the current implementation of U.S. regulations effectively protect the rights and welfare of research subjects? There are several issues that impede implementation of regulations for the protection of research subjects promulgated by the U.S. Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP). Chief among these issues are the *post hoc* nature of the system and, unsurprisingly, inadequate annual appropriations.

CIRCARE holds FDA and OHRP in high regard and commends staff for their accomplishments. Practically speaking, our *post hoc* system means that failures of protections occasion the bulk of regulatory oversight of institutions or individuals. The opening paragraph of a typical FDA warning letter refers to an inspection conducted many months earlier and addresses objectionable conduct in one or more clinical investigations which ended years previously. (4) The definition of the verb “to protect” is “to cover or shield from exposure, injury, damage, or destruction; (to) defend.” (5) We challenge the Commission to consider if is it reasonable to believe *post hoc* action provides meaningful protection of human subjects in research.

A typical FDA warning letter offers two challenging paradoxes the Commission should to consider. Prior to 2007 boiler-plate language informed warning letter recipients that FDA inspections are conducted under a program, one aspect of which is to ensure the integrity of data submitted in drug or medical device marketing applications, the other aspect of which is to ensure that human subjects are protected from undue hazard or risk in clinical investigations. More recently this language has been revised to state that inspections are conducted pursuant to FDA’s Bioresearch Monitoring Program to evaluate the conduct, i.e. data integrity, and to ensure that the rights, safety, and welfare of human subjects *have been* protected. (*op sit*, p.1) The past tense of the copulative verb “have been” illustrates the paradox of a *post hoc* system in which the regulator proposes to protect the welfare of human subjects by inspection and enforcement after the fact. The

other, second aspect of subject safety is just that: secondary to data integrity. In FDA warning letters, OHRP determination letters, and elsewhere objectionable conduct related to protection of research subjects is generally subsumed under the heading of failure to protect the rights and welfare of research subjects. Parties involved in research protections frequently use the term "rights and welfare of research subjects" yet FDA and OHRP regulations do not create rights for individuals, rather the regulations provide remedies for the regulator to halt non-compliance. The Commission may wish to consider what rights, if any, research subjects have, or what rights they should have in the context of implementation of current U.S. regulations.

To be sure, the issue of appropriations is as important as the nature of our research protections system. More than a decade ago it was estimated that roughly 25 million Americans were enrolled annually in research funded by the National Institutes of Health, with slightly more than half of that number enrolled in biomedical research. (6) Since the time of that estimate biomedical research has boomed. Whether we believe commercially sponsored research increases this estimated figure by 5% or 100%, there is little doubt many millions of human subjects are enrolled in biomedical research every year. More than 10,000 institutions currently have Federal Wide Assurances on file with OHRP. (7) In stark contrast, the 2011 requested budget allocation for OHRP is slightly more than 7 million dollars and the current OHRP staff roster lists 29 employees, of which 3 individuals comprise the Division of Compliance Oversight. (8) A recent report published by the National Council of University Research Administrators (NCURA) identified a precipitous decline in OHRP determination letters, leading some to question the agency commitment to oversight of subjects' safety in federally funded research. (9) According to the report OHRP posted 16 determination letters in 2010, the lowest number since the agency was reorganized 11 years ago, and approximately half the number of determination letters published in each of the preceding five years. Although OHRP stated neither increasing compliance nor annual appropriation accounted for the decline, we note that at a hearing on IRB oversight held by the Committee on Energy and Commerce, Subcommittee on Oversight and Investigation in March 2009, OHRP director Menikoff testified that the agency, in the course of evaluating assurances, does not currently consider the adequacy of the proposed IRB in light of the anticipated scope of the institution's research, as set forth in the Common Rule at 45 CFR 46.101(d). (10) Part of the cause of the two foregoing items is likely explained by the extraordinary mismatch between the presently slim resources of OHRP and the 10,000-odd institutions it regulates. We refer the Commission to the 2009 GAO report that prompted the hearing at which OHRP director Menikoff testified. (11) The report of the so-called "Coast IRB Sting" conducted by the GAO is by turns hilarious and terrifying and raises serious questions about the adequacy of our current system of human research protections. At present we have the curious situation wherein the OHRP Federalwide Assurance database carries this disclaimer:

> "Please note: the fact that the Office for Human Research Protections (OHRP) has approved an institution's assurance does not mean that OHRP has determined that the institution is complying with the requirements of the Department of Health and Human Services (HHS) Protection of Human Subjects regulations, 45 CFR part 46. It means that an institution has submitted all of the documentation OHRP

requires to constitute a commitment by the institution to comply with the requirements of 45 CFR part 46 when its employees or agents engage in non-exempt human subjects research conducted or supported by HHS or other research covered by the assurance. The Federalwide Assurance is the only type of assurance accepted and approved by OHRP." (12)

Returning to the NCURA report, OHRP suggested one reason for the decline in determination letters is the declining number of institutions over which the agency has jurisdiction. Although this may be the case, and we do not doubt the statement, we know for certain that the number of institutions electing to extend the Common Rule at 45 CFR 46 to cover all research conducted at their institution regardless of funding source has declined significantly since 2002 – in other words the amount of research over which OHRP has jurisdiction has declined. In a recent article OHRP personnel reported that based on an informal review of a sample of institutions, 74% of domestic institutions "check the box" by electing to apply either subpart A or subparts A, B, C, and D of the Common Rule at 45 CFR 46 to all research regardless of source of funding. Previously more than 90% of institutions checked the box. (7) What reason can institutions offer for declining to check the box save the self-serving desire to evade potential, and public, OHRP enforcement activity? Is it unreasonable to believe that checking the box is an equitable condition in return for receiving coveted federal research funding?

Like OHRP, FDA too is outmatched in terms of appropriations versus its mission. As a result of its legislative authority to regulate interstate commerce of drugs and medical devices, *inter alia*, the great majority of FDA inspections are of phase 3 trials of drug and medical devices, data from which are submitted in marketing applications. A 2008 report by the U.S. Department of Health and Human Services Office of Inspector General noted that FDA inspected a mere 1% of clinical trials testing drugs under Investigational New Drug applications. (13)

To be sure, we are aware that FDA and OHRP engage in educational activities designed to support oversight and compliance efforts yet in the final analysis such efforts entrust the protection of research subjects to the goodwill and unique and largely unknown capabilities of tens of thousands of entities, including sponsors, institutions, IRBs, and clinical investigators.

Part 2: Troubling Contemporary Trials

The following two studies share disturbing elements with the 1946 Guatemala study. In 2004 researchers from the Touch Research Institute at the University of Miami School of Medicine published initial data from a clinical trial testing massage to treat children with HIV/AIDS residing in the Dominican Republic. (14) The trial is conspicuous because no antiretroviral drugs were provided to subjects with HIV/AIDS. The research was supported by NIH/NCCAM grant 1R21AT01160 and NIH/FIC grant D43TW00017. According to the 2004 article the trial was reviewed and approved by the University of Miami School of Medicine IRB as well as by a local IRB in the Dominican Republic. It is difficult to understand how the IRBs made requisite findings for approval

at 45 CFR 46.111 Risks to subjects were surely not minimized to the extent possible in as much as lifesaving drug treatment for HIV/AIDS was not provided to these children. We wonder if the researchers would propose to conduct this same trial in Miami. One suspects the choice of the Dominican Republic reflects the unacceptability of declining to provide drug treatment to children with HIV/AIDS inside the U.S. Not withstanding the investigators apparent excuse that antiretroviral drugs were "not available" in the Dominican Republic, the Common Rule attaches to NIH funding and applies no matter where research is conducted. To be sure it does not appear that the protocol was based upon sound science. In the first place, the hypothesis that massage, or therapeutic touch if you please, could ameliorate HIV/AIDS lacks biological plausibility. In the second place, investigators erroneously claimed massage improved immune function, as purportedly demonstrated by pre- and post-intervention CD4 T Cell counts. By convention, however, an increase in CD4 T Cells is defined as a predetermined increase in two or more serial counts above baseline. This definition is designed in consideration of the fact that CD4 T Cell levels are subject to natural fluctuation. In relying on only two CD4 T Cell counts to measure efficacy, the investigators demonstrated that CD4 T Cell counts fluctuate, a fact already known and so not sufficient to justify exposing subjects to risk in research. As for finding and documenting the required elements in subpart D of the Common Rule at 45 CFR 46, it's anyone's guess how the IRBs managed this.

Between 1993 and 1997 Dr. Henry Heimlich and the Heimlich Institute promoted and funded one or more clinical trials in which Chinese men and women with HIV/AIDS were deliberately infected with *Plasmodium vivax* malaria, so called malariotherapy – fever therapy – to test the hypothesis that deliberate infection with malaria followed by a several week delay in antimalarial drug treatment would beneficially effect the immune system so as to produce significant improvement in CD4 T Cell counts and stabilize or decrease HIV viral loads. (15) The exact particulars of why this research was conducted in China may never be known but we can safely conclude relevant factors included tenacious outspoken opposition of this research by the U.S. Centers for Disease Control, widespread professional condemnation, and concerted action by concerned members of the public, and especially that of California physician Dr. Paul Bronston. In 1993 Dr. Bronston solicited written expert reviews of Dr. Heimlich's malariotherapy for HIV/AIDS protocol which was under consideration at the time by the Search Alliance in Los Angeles, California. Dr. Bronston was able to prevent the trial from being conducted in the U.S. and when Dr. Heimlich subsequently tried to conduct the trial in Mexico, Dr. Bronston in cooperation with Mexican health authorities forestalled the move south. Malariotherapy for HIV/AIDS in China was apparently approved by an egregiously non-compliant entity called the Great Lakes College of Clinical Medicine IRB (GLCCM IRB). According to its website circa 1999 the purpose of the GLCCM IRB was to provide protection for organization members against medical board actions by offering the specie of *bona fide* IRB-approved research for a fee. Following an FDA warning letter suspending the IRB's authority to review and approve FDA regulated products and termination of half a dozen trials the GLCCM IRB disbanded in 2001. The Materials and Methods section of the 1999 publication of data on 8 subjects indicates 5 subjects were infected with HIV as a result of IV drug use. Since IV drug use or addiction is subject to criminal penalties in China, we speculate but cannot prove these 5 subjects may have

been prisoners infected with HIV. Obviously this raises concerns about coercion and voluntary consent.

Although it's hard to believe, NIH funds were used to support this research in China. UCLA researcher Dr. John Fahey approached Dr. Heimlich and his Chinese collaborator Dr. X. P. Chen and offered his assistance, apparently in part for access to data or biological samples. Links to documents obtained under the Freedom of Information Act related to UCLA's investigation of this matter with summary prefaces and news reports are provided in the references. The tale has yet to end unfortunately. In 2004 news stories revealed that Dr. Heimlich was involved in more research testing malariotherapy for HIV/AIDS. In this second round, rather than using *Plasmodium vivax* malaria, subjects with HIV/AIDS in Ethiopia infected with the potentially lethal *Falciparum* malaria were left untreated for an unspecified number of weeks to provide the desired effect. As recently as 2008 Dr. Heimlich claimed this research was enrolling subjects and biological samples were being regularly shipped to the U.S. and Germany for testing. In 2004 The Heimlich Institute hired Victoria Wells Wulsin, M.D. to write a report that included a literature review of malariotherapy and a business plan for additional research. Dr. Wulsin released her report, to which she added an explanatory "Executive Summary," in the fall of 2006 following media inquiries during her campaign for congress. The report included data from an uncontrolled trial of malariotherapy in subjects with HIV/AIDS conducted in East Africa by an unnamed American sponsor. Demographic information provided in Wells Wulsin's report indicate 7 of 8 subjects were/are females between the ages of 18 and 35, suggesting the possibility the trial recruited, or more properly preyed upon, sex workers.

The appalling non-compliance, ethical breaches, and unsound science makes for difficult summarization. For this reason in the references we provide links to collections of information about these trials. We have identified what's available where in the hope the Commission will browse selectively or strategically as they are individually inclined.

We will gladly answer questions and supply additional documentation.

Yours Sincerely,

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NB: Copyright publications will be available on the CIRCARE website for 30 days as a courtesy to the Commission.

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