THE REBECCA PROJECT FOR HUMAN RIGHTS
UNITED AFRICANS FOR WOMEN & CHILDREN RIGHTS
NATIONAL COUNCIL OF NEGRO WOMEN

POLICY BRIEF

NON-CONSENSUAL RESEARCH IN AFRICA
THE OUTSOURCING OF TUSKEGEE

A Ugandan medical officer carries out an HIV vaccine clinical trial on an [infant] baby[1] not infected with HIV/AIDS. INSET: Dr. Pontiano Kaleebu the Director at the Medical Research Council/Uganda Virus Research Institute, a board member of the newly formed Africa AIDS Vaccine Program hosted by Uganda and one of the first doctors to conduct AIDS trials in Africa.[2] Sources claim that consent was received from infants' parents for this trial.[3] U.S. and African human rights advocates are investigating why impoverished mothers in Africa and South Asia would allow their healthy babies to participate in foreign supported clinical trials to find cures for diseases when that phenomenon is virtually absent in the United States and Europe. These healthy babies are being exposed to drugs that could have lethal side effects.

[1] According the U.S. National Institute of Allergy and Infectious Diseases (NIAID) at the National Institute of Health (NIH), however, they are not currently supporting any unethical HIV/AIDS vaccine trials using infants as human subjects.
[2] U.S. National Institute of Allergy and Infectious Diseases (AI-35173 and AI-36219) and Fogarty International Center (TW-00011) provided funding for first AIDS trial in Uganda, Aventis Pasteur provided the vaccine.
[3] Lirri, E. (2011)

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SUMMARY

United States biomedical researchers and pharmaceutical companies are conducting and paying African doctors to conduct unethical and illegal testing of human subjects. Non-consensual research on human subjects is an atrocity that occurred in Tuskegee, Alabama, and in Guatemala for over forty years. Once outlawed in the U.S., medical researchers began experimenting on thousands of human research subjects without their consent in Cameroon, Ghana, Namibia, Nigeria, Uganda, South Africa, Zimbabwe and other African countries.

Believing they were receiving routine medical care, some African women and children were used to test medication for HIV, malaria, and meningitis, often resulting in infection, and/or even death. These unethical research practices coupled with the failure to get signed informed consent violate multiple U.S. and international laws.

The Rebecca Project recommends holding congressional hearings, convening a "*Global Leadership Ethical Research Forum*" through the *Council on Foundations* for government and private funders, Food and Drug Administration (FDA) reform, and further collaboration with advocates and law enforcement to help protect victims and whistleblowers by ending these Crimes Against Humanity.

LEGAL DEFINITION OF CRIMES AGAINST HUMANITY

"Crimes Against Humanity" are defined in international law as **murder, extermination, enslavement, deportation, and other inhumane acts** committed against any civilian population as part of a widespread or systematic practice. Crimes Against Humanity cannot be isolated events. The doctrine of the guiding law for the Nuremberg Trials (1945-1946), Article 6 (Paragraph 6) of the *London Charter of the International Military Tribunal*, was drafted after World War II to include not only traditional war crimes and crimes against peace, but also Crimes Against Humanity.[4]

UNDERSTANDING CRIMES AGAINST HUMANITY

We often hear officials from the United Nations, the U.S. government, and other world leaders speak about Crimes Against Humanity. But what really constitutes Crimes Against Humanity? Are they a special category of crimes for only a select group of dictators that leaders of international organizations often chastise at press conferences? The answer must be no. A real-world definition of Crimes Against Humanity could be stated as offensive, cruel acts that are so horrendous, dehumanizing, and/or degrading that they shock the sensibilities of all reasonable men and women and cause harm or death to hundreds of human beings, depriving them of life, liberty, and the pursuit of happiness.

These crimes against humanity are particularly odious offenses in that they constitute a serious attack on human dignity or grave humiliation or a degradation of one or more human beings. They are not isolated

[4] Charter of the International Military Tribunal art. 6, Aug. 8, 1945, 59 Stat. 1544, 82 U.N.T.S. 279.

or sporadic events, but are part either of a government policy (although the perpetrators need not identify themselves with this policy) or of a wide practice of atrocities tolerated or condoned by a government or a de facto authority.[5] Therefore, the African Slave Trade, the widespread systematic kidnapping and trafficking of thousands of girls and women into sex/labor slavery, the use of Jews as human subjects for research and experimentation by German Nazi doctors during World War II, and the Tuskegee Experiment all constitute examples of Crimes Against Humanity. The Tuskegee Experiment consisted of illegal medical research conducted between 1932 and 1972 in Tuskegee, Alabama, by the U.S. Public Health Service to study the progression of untreated syphilis in **600 impoverished, African-American men** without informed consent. Some of the men were intentionally infected with the disease and all of them were denied the cure. No medical researchers were ever held accountable for the Tuskegee Experiment.

Between 1946 and 1948, U.S. researchers infected another marginalized population of **1,500 human subjects in Guatemala** with syphilis without their informed consent. Researcher, Dr. John Cutler, participated in both the Tuskegee and Guatemala experiments, and was known for his ardent support of population control. Recognizing the egregiousness of these experiments that were made public by Susan Reverby (professor of women's studies at Wellesley College), **President Obama with the Secretary of State Hillary Clinton apologized on behalf of the United States in October 2010** and families of victims in Guatemala are now seeking a compensation settlement from the United States government. According to Associated Press reporter Mike Stobbe, President Obama took an additional step by requesting that the Presidential Commission for the Study of Bioethical Issues seek a new evaluation of international medical studies.[6] To further illustrate the tangled web between the U.S. medical research establishment and unethical international research, Stobbe explains that, "**The President also asked the Institute of Medicine (IOM) to further probe the Guatemala study, but the IOM relinquished the assignment in November 2010, after reporting its own conflict of interest:** In the 1940s, five members of one of **the IOM's sister organizations played prominent roles in federal syphilis research and had links to the Guatemala study.**"[7]

Research misconduct became a congressional issue in the United States in 1981 when former Congressman, Albert Gore, Jr. (D-TN), then chairman of the U.S. House of Representatives, House Science and Technology Committee of the Investigations and Oversight Subcommittee, held the first hearing on the emerging problem.[8,9] The hearing was prompted by the public disclosure of research misconduct cases at four major research centers in 1980. Some twelve cases of research misconduct were disclosed in this country between 1974-1981. Congressional attention to research misconduct was maintained throughout the 1980s by additional allegations of research misconduct and reports that the National Institutes of Health (NIH), universities, and other research institutions were inadequately responding to these allegations. Congress passed the Health Research Extension Act of 1985,[10] after which the Office of Research Integrity (ORI) was formed in 1992.[11] The Office of Research Integrity (ORI) oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services.

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[5] Rome Statute of the International Criminal Court, art. cited, July 17, 1998, 2187 U.N.T.S. 90.
[6] Presidential Commission for the Study of Bioethical Issues (2011)
[7] Stobbe, M. (2011)
[8] *Fraud in Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight of the H. Comm. on Science and Technology*, 97th Cong., 1st Sess. (1981).
[9] *Human Total Body Irradiation (TBI) Program at Oak Ridge: Hearing Before the Subcomm. on Investigations and Oversight of the H. Comm. on Science and Technology*, 97th Cong., 1st Sess. (1981) [hereinafter *Gore Hearing*].
[10] Health Research Extension Act of 1985, PL 99–158, 99 Stat. 820 (codified as amended at 42 U.S.C. §201 (1985)).
[11] 42 CFR Part 50, Subpart A

HOW RESEARCH CRIMES AFFECT HEALTH AND HUMAN RIGHTS IN AFRICA

Unethical drug trials have occurred in many African countries. Human subjects are typically impoverished, undereducated, and lack full understanding of their rights as participants in medical research. **Physicians systematically mislead African human subjects** into believing they are accessing routine medical services. However, these patients are never informed of their actual participation in research and/or are not provided with detailed informed consent forms (ICFs). U.S. researchers working under the veil of African government approval inform ailing and impoverished African human subjects that African government health services or Ministries of Health are providing free treatment for health ailments and/or family planning. U.S. biomedical researchers seek funding to conduct and publish the results of experiments in health and medical journals. It is essential that the U.S. government take immediate action to protect these vulnerable populations in Africa from further abuse by American researchers, drug companies, and African health officials who routinely endorse these illegal and intrusive biomedical practices.

African doctors and researchers are generally paid as much as ten times more by foreign researchers and institutions in comparison to their local incomes. Moreover, African government health officials "look the other way" when foreign researchers carry out unethical research because African towns and villages receive much needed financial and medical resources when foreign research teams employ locals, rent homes, and purchase goods and services. In addition, African doctors and health officials receive the opportunity to publish with preeminent U.S. doctors, through which they gain fellowships to advance their careers in the United States. These doctors, after studying abroad, return to their home countries with new contacts and demands from foreign researchers and continue supporting the same corrupt international research cartel. It is an insidious catch-22 from which African doctors understandably feel powerless to extricate themselves. Therefore, these doctors defend their unethical conduct to keep their financing and reputations intact.[12]

EXAMPLES OF BIOMEDICAL RESEARCH AND CLINICAL FRAUD AND ABUSE IN AFRICA

CAMEROON:

From 2004 to 2005, Gilead Sciences Inc., the Centers for Disease Control, and the Bill & Melinda Gates Foundation sponsored HIV research using the anti-viral drug Tenofovir (Viread), a Gilead drug. Family Health International (FHI), the NIH contractor,[13] conducted the research in Cameroon and Nigeria. According to a report by SOMO, an independent research watchdog group, in Cameroon, the 400 human subjects participating in the trial of the antiretroviral drug, Tenofovir, were inadequately informed about the risks of the study. Researchers allegedly infected five women with HIV while conducting the study. Further, researchers provided details about the experiment in English though many of the human subjects spoke only French and were illiterate. Researchers administered no antiretroviral drugs (ARVs) to the patients who were infected during the trial.[14] In Nigeria, researchers aborted this clinical trial to avoid the scandal.[15] At the time, researchers were planning to conduct the same trials in Botswana, Ghana and Malawi.

[12] Interviews in 2010 with former public health officials and research associates who worked with Dr. James Phillips--Columbia University & Population Council.
[13] Originally responsible for monitoring the Nevirapine trials in Uganda, as well (see below)
[14] SOMO (2008)
[15] IRIN (2011)

All fair-minded people can understand and accept that there is a reasonable expectation that human subjects could be infected during research. In each of these cases, however, there is no evidence that researchers and drug companies provided detailed, signed ICFs to the Africans who were abused as human subjects. Therefore, U.S. researchers and drug companies cannot be indemnified.

GHANA:

In Navrongo, Ghana, human-subject research experiments have been designed and conducted by Dr. James Phillips who, like Tuskegee's Dr. Cutler, is devoted to population control. Dr. James Phillips is also a preeminent professor at Columbia University's Mailman School of Public Health and serves as a Population Council consultant.[16] Other Population Council researchers were also associated with the Navrongo research experiment, which received its funding mainly from the Population Council, United States Agency for International Development (USAID), and the Rockefeller Foundation.[17]

In the Navrongo Experiment (1999 to 2006), researchers allegedly **injected thousands of impoverished and illiterate Ghanaian women** with a Pfizer contraceptive, Depo Provera, and administered other unidentified oral contraceptives during human research experiments to reduce population and modify healthcare. Dr. James Phillips and other researchers associated with the Population Council did not provide the vulnerable human subjects with Informed Consent Forms or full disclosure of adverse events. Similar to Pfizer's researchers in Nigeria who had support from the Nigeria Health Service and the Tuskegee Experiment researchers who had approval from the U.S. Health Service, Dr. James Phillips and his team of researchers designed and conducted the experiment with the approval of the Ghana Health Service to "provide routine healthcare" and "modify healthcare deliveries" for the benefit of the poor vulnerable populations.[18] In fact, Dr. Phillips and his Ghana Health Service team of doctors were conducting population experiments on impoverished and undereducated women without their consent[19,20]. To his credit, Dr. Phillips helped fund the growth of the Navrongo Health Research Center (NHRC) with funding from the Gates Foundation, Rockefeller Foundation, USAID and several others. Unfortunately, further scrutiny exposes the same unethical practices in the NHRC as found in Tuskegee and Guatemala. Although Dr. Phillips was not involved in the first NHRC "Vitamin A Supplementation" clinical trial on children in 1988 that was performed without valid informed consent forms, the NHRC performed virtually all human-subject research, including Dr. Phillips' Navrongo Experiment, without valid, signed Informed Consent Forms. The assigned principle investigator in the Navrongo Experiment was Dr. Fred Newton Binka, the current Dean of the School of Public Health at the University of Ghana.

When women and children in the United States go to a clinic for family planning or medical treatment, it is unethical for doctors to access and publish medical records through research institutions, prominent universities, and public health journals.[21] Doctors are required to obtain informed consent to legally publish research. Unlike the United States and Europe, most African countries lack an Office of Research Integrity[22] and ethical research Institutional Review Boards (IRBs). Unfortunately, even when

[16] Phillips, J.F. (2011)
[17] Bulletin of the World Health Organization (2006)
[18] Population Council (2011)
[19] Population Council, http://www.popcouncil.org/ "Navrongo Experiment" Adongo, Philip B.; Binka, Fred N.; Phillips, James.
[20] Phillips, Bawah, Binka (December 2006). Accelerating reproductive and child health programme impact with community based services: the Navrongo Experiment Ghana. Bulletin of the World Health Organization, 84 (12).
[21] Office of Research, University of California Irvine (2008)
[22] http://ori.hhs.gov/

legitimate IRBs exist, they often lack independence and are controlled by corrupt government officials and foreign researchers, which is the predicament in Ghana and other African countries.

NIGERIA:

In Nigeria in 1996, Pfizer physicians and researchers injected children with an antibiotic called Trovan during a meningitis outbreak without providing families with ICFs that fully disclosed the side effects and purpose of the experiment. Eleven children died, others suffered permanent brain damage and paralysis. No one knows accurately how many children participated in the trails, because there are no Informed Consent Forms—estimates range from 100 to 200. During the Pfizer clinical trials, Dr. Waterspiel, a Pfizer infectious disease specialist assigned to test the effectiveness of Trovan on meningitis, repeatedly told Pfizer management that the company was violating international law, federal regulations, and medical ethics standards. He refused to go to Nigeria to help with the Trovan drug trial and was subsequently dismissed by Pfizer.[23] Another former Pfizer employee who shed light on fraudulent practices is Dr. Peter Rost, a former Pfizer Vice President and most well-known for testifying in the United States Congress against the business methods of the pharmaceutical industry. He is also an author of the insider books, *The Whistleblower: Confessions of a Healthcare Hitman* and *Killer Drug*. He testified before the U.S. Senate, as well as many state congresses and conducted numerous press conferences with U.S. Senators, Members of U.S. Congress, and State Governors.

This pattern of retribution against ethical doctors and public health researchers who adhere to good clinical practices (GCP) is a recurring trend in US research. Moreover, in a modus operandi using African governments as a veil of approval to proceed with unethical conduct (see Navrongo Experiment, Nevirapine Experiments, and other clinical trials in Africa), Pfizer's US research team recruited and assigned the title of Principle Investigator to an African, Dr. Abdulhamid Isa Dutse, the Chief medical director in Aminu Kano Teaching Hospital, Kano, Nigeria. Other doctors involved in the Trovan trials include: Dr. Scott Hopkins, MD, chief medical officer in Rib-X Pharmaceuticals and researcher for Trovan Clinical Trials in 1996; Dr. Debra Williams researcher for Trovan Clinical Trials in 1996; and Dr. Mike Dunne, Chief Medical Officer at Durata Therapeutics and researcher for Trovan Clinical Trials in 1996.[24]

Pfizer **physicians conducted clinical trials of Trovan on children infected with bacterial meningitis** by selecting sick children from the many children who were awaiting treatment, dividing the children into two groups. Researchers treated one group with Trovan and purposefully treated the other group with a low-dose of ceftriaxone, a successful FDA-approved meningitis drug. The experiment was an attempt to demonstrate the efficacy of Trovan. Pfizer has not produced any evidence that they had informed consent from the children's parents, acknowledging that the proposed treatment was experimental, that the families could refuse or withdraw participation, that serious risks were involved, and that other organizations at the same site were offering more conventional and successful meningitis treatment for free. Many individuals do not want to believe that U.S. doctors would behave in such a callous manner. If those allegations made by Nigerian families and plaintiffs' attorneys are true, then Pfizer's doctors clearly demonstrated bad faith and unethical conduct because they **knowingly withheld vital information that could have saved lives** during the epidemic in Nigeria.[25] In July 2009, a U.S. Court of Appeals ruling against Pfizer found that the prohibition of non-consensual medical experimentation on humans is binding under customary international law, thereby allowing Nigerians

[23] *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009)
[24] *Id.*
[25] SOMO (2008)

the right to seek relief for damages against Pfizer in U.S. courts.[26] Pfizer is now settling out of court claims with Nigerian families and the government, costing the pharmaceutical company millions of dollars.[27]

SOUTH AFRICA & NAMIBIA:

South African and Namibian mothers infected with HIV and/or AIDS are routinely sterilized without their informed consent.[28] Many countries that perform these procedures have been awarded grants or incentives from USAID and other aid agencies.[29] This issue of forced sterilization became such a serious problem that, in 1999, Representatives Todd Tiahrt (R-KN), Christopher Smith (R-NJ), and Tom Coburn (R-OK) offered the Tiahrt amendment,[30] prohibiting U.S. funds from being used for "coercive family planning" abroad. These illegal biomedical practices occur while patients believe they are receiving standard health care.[31] Some mothers do not realize they have been sterilized after giving birth until several years later when they fail to conceive.[32] In each of these cases, women are coerced into sterilization. Consent is obtained through intimidation, pressure, or cash payments.

Too frequently it is the case that sterilized women cannot read, write, or speak English. In the United States, before medical sterilization procedures are performed on non-English speaking women, interpreters must be provided. Additionally, impoverished and undereducated mothers do not understand the contents of the documents they do sign, and health personnel fail to explain the process fully and accurately.

Moreover, the process of sterilizing HIV+ or AIDS-infected mothers in 2011 is draconian and outdated because Mother-to-Child Transmission is preventable. In the United States, Mother-to-Child Transmission rates are less than 1% when clinical interventions are used. Without any clinical interventions, approximately three out of every 10 HIV+ pregnant women transmit HIV to their babies.[33]

While African health officials and U.S. organizations may have good intentions, their conduct is often coercive, misleading, and unethical. Antiretroviral drugs and mandatory anti-sterilization trainings would serve as a good first step toward righting the many wrongs of the decades during which U.S and European multinational drug companies and doctors have used African people as human research subjects.

UGANDA:

In Uganda (1997-2003), pharmaceutical company Boehringer Ingelheim (BI) and the U.S. NIH sponsored the research of Nevirapine/Viramune for use in Preventing Mother–to-Child Transmission (PMTCT) of HIV. The human subjects involved in the trial were allegedly not allowed to return home until the experiment was completed. Researchers failed to get patients' informed consent about changes in the experiment and administered wrong doses. There were serious problems in record keeping, as well as delays and underreporting of fatal and life threatening problems. **Fourteen deaths were not reported**, and researchers only acknowledged that side effects were not disclosed and "procedures for divulging serious adverse events were not followed. BI, the company that markets the drug and audited

[26] *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009).
[27] McNeil Jr. (2011)
[28] http://www.stoptortureinhealthcare.org/ Open Society Foundation report funded by George Soros.
[29] Edwards, C. (2000)
[30] Tiahrt Amendment for Voluntary Family Planning, H.Amdt.904, (*amending* Foreign Operations, Export Financing and Related Programs Appropriations Act, 1999, H.R. 4569), 105th Cong. (1999).
[31] http://safaids.net/content/us-project-planning-sterilise-hiv-women-south-africa
[32] IRIN (2011)
[33] Connor, E.M., Sperling, R.S., & Gelber, R. (1994).

the trials, asked the U.S. NIH to destroy an early copy of the research report in case the study would be audited by the U.S. Food and Drug Administration (FDA)."[34] In 2002, Nevirapine was deemed unsafe for the U.S. market.[35,36]

According to Michael Stobbe of the Associated Press, U.S.-funded doctors failed to give the AIDS drug Azidothymidine (AZT) to all of the HIV-infected pregnant women in another study in Uganda even though it would have protected their newborns. As was the case with the Tuskegee Experiment, the Ugandan women believed they were receiving routine healthcare for HIV and did not know they were r**eceiving placebos as part of a non-consensual research experiment**.[37] It is important to note that Ugandan Dr. Pontiano Kaleebu (picture on our cover page) and his colleagues were recruited as investigators by U.S. researchers for the first AIDS trial in Uganda (1997). Now Dr. Kaleebu is performing AIDS trials on healthy babies in Uganda sponsored by foreign funders. In the United States there are no AIDS trials by the National Institutes of Health or Johns Hopkins University using healthy babies as human subjects.

ZIMBABWE:

In Zimbabwe and Uganda and Côte d'Ivoire (2003 to 2009), U.S. researchers, sponsored by the Rockefeller Foundation, UK Medical Research Council (MRC), Gilead, GlaxoSmithKline, and Boehringer-Ingelheim, conducted antiretroviral research using Lamivudine/Zidovudine and Tenofovir in a six-year clinical trial called Development of Anti-Retroviral Therapy (DART), which used an estimated **3,000 human subjects**.[38] The Development of Anti-Retroviral Therapy in Africa (DART) trial was a randomized trial to compare standard continuous therapy (CT) with structured treatment interruption (STI) of 12 weeks on and 12 weeks off anti-retroviral therapy (ART).[39]

> The trial had recruited 3,300 volunteers at the Joint Clinical Research Centre (Kampala, Uganda), the MRC/UVRI Uganda Research Unit on AIDS (Entebbe), and the University of Zimbabwe College of Health Sciences (Harare). On 14 March 2006, it was decided that all patients in the STI arm of the trial would be switched to continuous therapy as interim data demonstrated they had a greater rate of clinical HIV-related disease. Critics say they had sounded alarms the year before already because of the relatively high number of fatalities in the STI arm in Uganda, but investigators replied their concerns were unfounded. Attempts to put patients whose situation deteriorated during treatment interruption back on Anti- Retroviral Therapy failed and some of the patients died during the interruption period. There have also been complaints about enrolment of patients desperate to get free treatment, insufficient arrangements for post-trial treatment access, the use of a drug regimen that is not readily available to the general population, and omission of important risks in the consent forms. Some violated norms in the DART trial include: The population in which the research was carried out might not benefit from the results of the study, as Tenofovir is not readily available in Uganda and Zimbabwe; "Voluntary informed consent" was obtained for each patient, but this may have been compromised by patients being desperate to get access to free treatment, and risks may not have been sufficiently explained; Post-trial access arrangements were unclear and apparently not described in the trial protocol. This would also effectively inhibit patients to leave the trial.[40]

[34] SOMO, p.6 (2008)
[35] SOMO (2008)
[36] Farber, C. (2006)
[37] Stobbe, M. (2011)
[38] DART (2010)
[39] SOMO, Excerpted from page 4 and 5(2008)
[40] *Id*

CASE STUDY UGANDA: ENDEMIC INTERNATIONAL RESEARCH MISCONDUCT

(Excerpted from Harper's Magazine, Celia Farber, *AIDS and the Corruption of Medical Science*, March 2006)
Read Celia Farber's full article at: http://www.harpers.org/archive/2006/03/0080961

The story of Nevirapine demonstrates the fraudulent conduct of some international researchers and serious flaws in the institutional review on the use of human subjects. It begins in 1996, when the German pharmaceutical company, Boehringer Ingelheim (BI), applied for authorization of the drug in Canada. BI had been developing Nevirapine since the early 1990s. Nevirapine was found to be highly toxic and Canada rejected the drug twice, once in 1996 and again in 1998. Meanwhile, Nevirapine was being used for a clinical trial at the University of Tennessee Medical Group that was sponsored by the Division of AIDS (DAIDS)—the chief branch of HIV/AIDS research within the National Institutes of Health.

During this same period, Johns Hopkins AIDS researcher Dr. Brooks Jackson had secured significant funding from the NIH and BI to carry out a large trial for Nevirapine in Uganda [and, therefore, ignored warnings]. The HIV/AIDS research branch of the NIH, DAIDS, carried out the Uganda trials called HIVNET 012, which consisted of testing the toxicity of Nevirapine in pregnant women. ***Please note that pregnant women and children are in a special vulnerable class of human subjects under U.S. law (see Belmont Report on page 10).*** Dr. Jackson is now Director of Pathology at the Bloomberg School of Public Health at Johns Hopkins, and Director of Johns Hopkins Center for Global Health.

In 2001, Boehringer Ingelheim submitted its supplemental licensing request to the FDA. The request was submitted based entirely on the data results of HIVNET, as published in *The Lancet*. The FDA decided to go to Kampala, inspect the site, and review the data itself. Since Boehringer had not originally intended to use this study for licensing purposes, it decided to perform its own inspection before the FDA arrived. Boehringer's team arrived in Kampala and did a sample. **BI's own auditors reported "serious non-compliance with FDA Regulations [were] found"** with regard to reporting serious adverse events (SAEs). Major problems were also reported in the management of the trial drug and in informed-consent procedures.

DAIDS then hired a private contractor, Westat, to go to Uganda and do another pre-inspection. This time the findings were even more alarming. One of the main problems was a **"loss of critical records."** One of two master logs that included follow-up data on adverse events, including deaths, was said to be missing as the result of a flood. The records failed to make clear which mothers had received which drug, when they'd received the drug, or even whether they were still alive at various follow-up points after the study. **Drugs were given to the wrong babies**, documents were altered, and there was infrequent follow up, even though one third of the mothers were marked "abnormal" in their charts at discharge. Further, the records of which mothers had received which drug, when they'd received it, or whether they were still living at various points of follow-up after the study were frighteningly unclear. **Deaths were regularly not reported or were listed as serious adverse events**. In one case, "a still birth was reported as a Grade 3 adverse event for the mother." The audit also discovered that half of the HIV positive babies in the HIVNET trial were simultaneously enrolled in a vitamin A trial, which invalidates any data associated with them.

Dr. Brooks Jackson personally "noted that many thousands of unreported AE's and SAE's occurred" during the trial. However, according to Dr. Brooks Jacksons' colleagues at DAIDS, the problem with HIVNET was that it was **"unfairly assailed by *pedantic saboteurs* who could not grasp the necessary difference between U.S. safety standards and the more lenient standards that a country like Uganda deserved."** The U.S. doctors' perspectives are emblematic of the callous mindset of many American international researchers.[41]

[41] Ugandan Dr. Pontiano Kaleebu (picture on our cover page) and his colleagues were recruited as investigators by U.S. researchers for the first AIDS trial in Uganda (1997). Now Dr. Kaleebu is performing AIDS trials on healthy babies in Uganda sponsored by foreign funders. In the United States there are no AIDS trials by the National Institutes of Health or Johns Hopkins University using healthy babies as human subjects.

U.S. AND INTERNATIONAL LAWS VIOLATED BY RESEARCHERS IN AFRICA

In each of these cases, U.S. researchers and drug companies violated the laws and protocols of the Declaration at Helsinki (1964), and the **Belmont Report—U.S. National Research Act- PL 93-348 (Codified in 1974 after the Tuskegee Experiment)**. The Declaration at Helsinki strengthens the foundation of the Nuremberg Code (1947) by requiring researchers to obtain certifiable consent from the research subject involved in the research.[42] The emphasis on informed consent is clearly stated in international documents, including the International Human Protection provision contained in the Nuremberg Code, Article 7 of the convention on Human Rights (ICCPR), Guidelines by the Council for International Organizations of Medical Services and the United Nations World Health Organization.[43]

The 1974 National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission wrote ethical principles for the protection of human subjects that are referred to as the "**Belmont Report**." All U.S. doctors and researchers are governed by the three fundamental doctrines of the Belmont Report: **Respect for Persons, Beneficence, and Justice**.

1. **Respect for Persons Doctrine**
   Respect for Persons incorporates two ethical concepts: 1) individuals should be treated as autonomous (i.e., independent in mind or judgment) agents, and 2) individuals with diminished autonomy (i.e., vulnerable subject populations) must be protected. Vulnerable populations are groups that cannot fully appreciate or participate freely in the informed consent process. Such groups include children, prisoners, pregnant women, some mentally incapacitated individuals, and individuals with dementia or other cognitive disorders. Additionally, anyone who is decisionally-impaired or a subordinate individual (e.g., students and employees) is considered vulnerable when approached for study recruitment.

   Respect for Persons is applied first in the recruitment and the informed consent process. **Obtaining informed consent is not just a signature on a form**; it must involve a process of information exchange that includes a question and answer session and the subject's affirmative agreement to participate. It is the investigator's responsibility to judge the subject's comprehension of the consent information including the understanding that participation is voluntary and that the subject has the right to withdraw at any time during the study. If the investigator doubts the subject's consent comprehension, he/she should not enroll the subject in the study.

2. **Beneficence Doctrine**
   Research studies must be designed with beneficence: the risks of research must be justified by the potential benefits and the risks must be minimized to the extent possible to achieve the desired research benefit. The IRB performs a risk assessment by weighing the probability and magnitude of possible harms (risks) and the anticipated benefits.

[42] National Institutes of Health. (2004). World Medical Association Declaration of Helsinki; Ethical Principles for Medical Research Involving Human Subjects. *Office of Human Subjects Research.* Retrieved from: http://ohsr.od.nih.gov/guidelines/ helsinki.html
[43] National Institutes of Health. (1949). Directives for Human Experimentation: Nuremburg Code. *Office of Human Subjects Research*. Retrieved from: http://ohsr.od.nih.gov/guidelines/nuremberg.html

3. **Justice Doctrine**
   Justice means that the risks and potential benefits of research are shared equally among those who may benefit. Justice requires equitable subject recruitment and selection on two levels: the social and the individual. Research must include diverse populations and groups so that they may also benefit from the findings of research. Justice requires fairness in the exclusion and inclusion criteria of a research study. Those who are likely to benefit from research participation must not be systematically excluded. Additionally, vulnerable subject populations must not be targeted (included) for convenience. [44,45]

WHY INFORMED CONSENT FORMS ARE IMPORTANT

Informed Consent Forms (ICFs) are the foundational requirements of IRB protocols in ethical human subject research.[46] ICFs attest to the efficacy and verifiability of research data by:

1. Validating the legal number of human subjects observed in all health research;

2. Verifying that human subjects have been reasonably informed of research objectives and procedures;

3. Detailing drugs and doses to be administered and/or medical devices to be tested;

4. Detailing probable and foreseeable side effects;

5. Detailing procedures for reporting adverse events (AEs) and serious adverse events (SAEs), specifically deaths; and

6. Explicitly stating the right for all human subjects to withdraw at any time from the experiment for any reason without penalty or reimbursement of payments (if human subjects receive payment).

[44] Department of Health, Education, and Welfare. (1979). The Belmont Report: Ethical Principles and Guidelines for the protection of human subjects of research. *The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.* Retrieved from: http://ohsr.od.nih.gov/guidelines/belmont.html
[45] Office of Research, University of California Irvine (2008)
[46] Office for Human Research Protections (1993)

LAUNDERING FRAUDULENT AFRICAN RESEARCH IN THE UNITED STATES

By failing to obtain informed consent, provable by Informed Consent Forms, U.S. researchers in Africa are knowingly and deliberately designing and executing research schemes to **circumvent the verifiability of research results.** As was the case in the Navrongo Experiment in Ghana and the Trovan Experiment in Nigeria, researchers manipulate data to obtain the desired results. This category of patent research fraud is widespread in Africa. Unfortunately, fraudulent international research conducted in Africa is then laundered in America and Europe by a simple rubber-stamp process called "Peer Review." Richard Horton, Editor-in-Chief of the medical journal, *The Lancet*, told the House of Commons Science and Technology Committee in the United Kingdom: "editors have had to face an upsurge in the discovery of episodes of research misconduct (fabrication, falsification, and plagiarism)."[47] Additionally, BBC reporter, David Boettcher, explains, "peer-reviewed has become a byword for 'scientifically sound and approved,' but complaints have arisen in recent years that the process can sometimes work to suppress radical new ideas, and can fail to catch fraudulent research."[48]

Preeminent researchers and public health institutions conduct peer reviews. Although the public and many academics believe that these panels are teams of experts with allegiance only to research quality, these "peers" are too often involved in similar illegal research schemes or overlook unethical conduct because of the coerced possibility of professional alienation. To paraphrase a medical researcher from Johns Hopkins, whose name has been withheld (2010), a researcher cannot expose fraud and expect to have a stellar career or continue working, because these powerful doctors have high-level contacts with funders and government officials in the United States and Africa— they will ruin you. Funders genuinely want to find health solutions for people. They approach universities and preeminent researchers in order to achieve outcomes. This results-oriented approach motivates program officers to implicitly condone unethical conduct to achieve their goals. This is the case with Drs. John Cutler of the U.S. Public Health Service (Tuskegee Experiment, 1932- 1972) and James Phillips of Columbia University and Population Council (Navrongo Experiment, 1999- 2006).

Conflict of Interest (COI) arising from peer reviews and dealings with powerful research funders are similar to the powerful bank credit rating agencies' scam. In that scam, Moody's and Standard & Poor's endorsed insolvent banking instruments with favorable ratings because the rating agencies derived their funds from the same banks they reviewed and rated. Their scam contributed to a worldwide banking collapse. Similarly, the research fraud in Africa is a colossal scam by brilliant preeminent doctors who endorse unethical research designs for additional funding and academic rewards, thereby contributing to a human and economic toll that costs U.S. taxpayers and private foundations billions of dollars in misallocated funding to Africa and FDA drugs approved by unethically exploiting and harming Africans.

Every so often, however, groups fight back vehemently, as was the case in Nigeria. Unfortunately, a majority of other African countries do not have Nigeria's resources or innate fortitude to fight U.S. multinational drug corporations and regimes of knowledge that contribute to the "scientific-medical complex."[49] Therefore, the vicious cycle of African research fraud continues unabated.[50]

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[47] House of Commons Science and Technology Committee (2011), Section 6, Publication ethics and research integrity, Paragraph 245, "Frequency of Misconduct"

[48] Boettcher (2011)

[49] Farber, C. (2006)

[50] All certified demands and requests from Rebecca Project to Dr. Phillips, Columbia University's General Counsel, Dean of the Mailman School and Population Council, to prove ethical results of experiments in Africa have been unanswered. (July 2010). They have no valid ICFs to present in a United States court of law to prevail in a libel lawsuit against human rights advocates.

CASE OF DR. JONATHAN FISHBEIN: Unethical Reviews and Coercive Alienation by Peers

(Excerpted from Harper's Magazine, Celia Farber, *AIDS and the Corruption of Medical Science*, March 2006)

The story of Dr. Jonathan Fishbein demonstrates how ethical doctors that support good clinical practice (GCP) are systematically alienated from their professional communities and finally terminated or pressured to give up their jobs. Dr. Jonathan Fishbein was hired as the director of the Office for Policy in Clinical Research Operations at the Division of AIDS (DAIDS), the HIV/AIDS research branch of the NIH, in 2003. Fishbein wrote an email to his boss, DAIDS director Ed Tramont, alerting him that "there was a fulminant liver failure resulting in death" in a DAIDS trial and that it looked like "Nevirapine was the likely culprit." He said that the FDA was being informed. Dr. Tramont emailed him back, "Ouch. Not much we can do about dumb docs!" This email exchange came to light in December 2004, when AP reporter John Solomon broke the story that Fishbein was seeking whistle-blower protection, in part because he had refused to sign off on the reprimand of an NIH officer who had sent the FDA a safety report concerning the DAIDS trial that launched the worldwide use of Nevirapine for pregnant women. The study was called HIVNET 012, and it began in Uganda in 1997.

While Dr. Fishbein was overseeing the study, a troubling finding was brought to his attention regarding the HIVNET 012 trial in Uganda. An NIH medical officer noticed a pattern of elevated liver counts among some of the babies in the trial and drafted a safety report that was given to Mary Anne Luzar, a DAIDS regulatory affairs branch chief. When Luzar sent the report to the FDA, the HIVNET researchers were furious. Tramont went as far as ordering a new version to be drafted, retracting the previous one that had been submitted to the FDA. Dr. Fishbein refused to reprimand Luzar for sending a safety report concerning the DAIDS trial that launched worldwide use of Nevirapine for pregnant women.

Dr. Fishbein's refusal to participate in a cover-up of the adverse effects of Nevirapine on pregnant women and other unethical practices in the DAIDS trial led to Dr. Tramont's malicious personal and professional campaign against him. Fishbein spent months trying to get a fair hearing, petitioning everyone from the director of the NIH, to the Secretary of Health. Nobody addressed him in the hallways, in the elevators, in the commissary. "There was an active campaign to humiliate me," he says.

Fishbein persisted, meeting with congressional staff, and finally attracted enough attention on Capitol Hill to force the NIH to agree to a study by the National Academy's Institute of Medicine (IOM) [the same IOM involved in the illegal Guatemala Experiment 1946-1948]. The terms of that review were biased from the outset. The panel ignored Fishbein's evidence that DAIDS had covered up the study's failures and relied on testimony from the HIVNET investigators and NIH officials. What is more, **six of the nine members on the panel were NIH grant recipients, with yearly grants ranging from $120,000 to almost $2 million.** Not surprisingly, it found that HIVNET's conclusions were valid.

As Celia Farber pointedly articulates, Fishbein's story "lays bare the political machinery of American science, and reveals its reflexive hostility to ideas that challenge the dominant paradigm…Today's scientists are almost wholly dependent upon the goodwill of government researchers and powerful peer-review boards, who control a financial network binding together the National Institutes of Health, academia, and the biotech and pharmaceutical industries [demonstrating conduct indicative of cartels]. Many scientists live in fear of losing their funding." As one former drug developer, Dr. David Rasnick, put it, "The scientific-medical complex is a $2 trillion industry. You can buy a tremendous amount of consensus for that kind of money."

For more information regarding human-subject IRB research protocol, please go to this University of California-Irvine's tutorial at: http://apps.research.uci.edu/tutorial/ 1) click on: I want to take the tutorial as a visitor; 2) click on: Human Research Tutorial

Read Celia Farber's full article at: http://www.harpers.org/archive/2006/03/0080961

VICIOUS CYCLE OF AFRICAN RESEARCH FRAUD

LACK OF LAW ENFORCEMENT BY U.S. DEPARTMENT OF JUSTICE

We can all understand why the public might find it difficult to accept that established blue-chip American corporations such as Pfizer and preeminent American institutions such as Columbia University, Johns Hopkins University, or the Population Council would be involved in unethical research that violates and harms children and women in Africa. However, the American public needs to recognize that, for the past seventy years, researchers have been able to systematically violate impoverished and vulnerable individuals here in America with impunity because there is a general lack of enforcement by the U.S. Department of Justice. For example, in the 1980s and 1990s, during the same period that Dr. James Phillips and several other American doctors were conducting unethical research on Africans in Cameroon, Ghana, Nigeria, Uganda, and other countries, **Columbia University researchers in the United States were conducting unethical AIDS research experiments using over 650 African-American, Biracial and/or Hispanic foster children as human subjects** in New York and Illinois. [51] In a letter dated May 23 2005, the Office for Human and Research Protections (OHRP) at the Department of Health and Human Services (HHS) cited Columbia Presbyterian for violating U.S. research law in approximately four AIDS studies involving vulnerable minority foster children. Columbia University's violations, which should have been further investigated by the Department of Justice (DOJ), include: 1) Failing to obtain sufficient information regarding the selection of wards of the state and foster children as research subjects. 2) Failing to obtain sufficient information regarding the

[51] Solomon, J. (2005)

process for obtaining permission of parents or guardians for wards of the state or foster children [lack of valid ICFs]. 3) Failing to have enough information to ensure the selection of patients for the studies was equitable. In its determination letter to the doctors at Columbia University, OHRP noted: "When some or all of the subjects (e.g., children) are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the HHS regulations [Belmont Report—U.S. Federal Law- PL 93-348] to protect the rights and welfare of these [human] subjects."[52] Those doctors along with a litany of doctors have not been prosecuted in a court of law in the United States by the DOJ in the face of mounting evidence. This said, the public raised enough concern regarding protection of foster children in their enrollment in clinical drug trials that a House Subcommittee Hearing was held on May 18, 2005.[53,54] Civil judgments for monetary compensation are not satisfactory because these research violations by unethical doctors are crimes against the United States and they cause death or permanent harm to human beings.

When U.S. or foreign bankers attempt to circumvent US Federal Laws, they are investigated, charged with a crime, and prosecuted in a court of law if US funds are involved. For example, Credit Suisse Bankers: Markus Walder, Susanne Ruegg, Andreas Bach, and Joseff Dorig were charged by the DOJ in 2011 with conspiring to defraud the US. Their scheme called "illegal cross-border banking" was designed to help US funded customers circumvent US law by opening and maintaining accounts in other foreign banks. Similarly, when US doctors from the NIH, Columbia University, Pfizer and John Hopkins circumvent US laws by conspiring to conduct "illegal cross-border research-experiments" with research design schemes that utilize U.S. 501(c)3 tax-free funding from private foundations or U.S. government institutions (NIH), they have to be investigated, charged and prosecuted in a court of law for fraud and/or manslaughter if human-subjects have died without valid informed consent. There have been no major investigations or prosecutions by Attorney General Holder even after an Appeals Court ruling against Pfizer (see page 6), and there have been no prosecutions by the Department of Justice even though there is mounting evidence that human subjects targeted for illegal research in the US or Africa are generally impoverished Africans, African-Americans, and Hispanics. Similar to Guatemala, President Obama should mandate that Attorney General Holder and congress and/or related agencies interrogate how federal law has been systematically evaded and broken by specific American doctors without any major prosecutions for the past seventy years. Yet the DOJ continues to prosecute bankers and politicians for lesser crimes that do not involve imminent harm or death to human subjects. If the U.S. expect bankers and politicians to conduct themselves ethically and obey federal laws, then the same or a higher ethical standard should apply to medical researchers who have the ability and proximity to cause imminent harm to human beings. Their crimes of illegal experimentation can be quantified beyond the scope of Tuskegee and Guatemala. Therefore, a warning from the HHS in these cases is tantamount to the SEC giving a warning letter to Bernard Madoff and Raj Rajaratnam for their financial crimes. The DOJ should execute equal justice under US law.

REQUEST FOR PUBLIC HEARINGS

U.S. doctors and pharmaceutical companies routinely use and exploit impoverished African women and families, as human research subjects for experimentation and other intrusive medical procedures without

[52] Letter of Noncompliance from Karena Cooper, JD, MSW, Compliance Oversight Coordinator, Office of Human Research Protections, to Dr. Harvey R. Colten, Vice President and Senior Associate Dean for the Faculties of Health Sciences and Medicine, Columbia University Medical Center, and Dr. Laura L. Forese, Vice President and Chief Medical Officer, New York Presbyterian Hospital (May 23, 2005) (on file with author), *available at* http://www.hhs.gov/ohrp/compliance/letters/2005.html

[53] *Protections for Foster Children Enrolled in Clinical Trials: Hearing Before the Subcomm. On Human Resources of the H. Comm. On Ways and Means*, 109th Cong. 2 (2005).

[54] Health and Human Services. HHS Survey of States on the Participation of Foster Children in Clinical Drug Trials. *Committee on Ways and Means.* Retrieved from: waysandmeans.house.gov/media/pdf/welfare/062405hhssurvey.pdf

their informed consent. The Rebecca Project for Human Rights, United Africans for Women & Children Rights, National Council of Negro Women and a coalition of civil and human rights advocates request Congressional Hearings to **investigate and remedy regulatory and policy failures** leading to continued and expanded, non-consensual research. We also seek to **end the forced sterilization of African women**. This request for public hearings comes at a critical time when illegal human subject research on vulnerable populations in Africa, especially women and children, is a significant problem.

U.S. American drug companies and U.S. international researchers have silently and effectively outsourced the Tuskegee Experiment to Africa. *Nigeria v. Pfizer* directly confronted the issue.[55] In a July 2009 ruling, a U.S. Court of Appeals found that the prohibition of non-consensual medical experimentation on humans is binding under customary international law, thereby allowing Nigerians the right to seek relief for damages against Pfizer in U.S. courts.[56] In June 2010, the U.S. Supreme Court rejected Pfizer's appeal after the U.S. Acting Solicitor General, Neal Katyal, submitted his brief urging the court to deny Pfizer's petition.[57] Nigeria filed criminal charges against Pfizer's researchers, but charges were later dropped and the case is being settled out of court. Abuses like the ones that occurred in Nigeria are prevalent in Africa and other developing countries. Unfortunately, the media and press rarely expose these Crimes Against Humanity to the American public, and U.S. researchers go unpunished, leaving impoverished and injured African populations without remedy.

IMMEDIATE GOALS AND POLICY RECOMMENDATIONS

1. Bring this issue to the attention of Congress for hearings where victims of nonconsensual human-subject research, researchers from academic institutions, drug companies, and funders will testify to bring this issue to the public's attention.

2. Ask Congress to compel Health Ministers and Health Directors from Africa who receive funding from the U.S. government and USAID to testify and attest that policies are in place to protect whistleblowers. African Health Ministers and Directors must also recognize and codify all customary International Research Laws and Principles of the Nuremberg Code, Belmont Report, and Declaration at Helsinki.

3. Work with Congress to develop or amend current legislation to direct the Food and Drug Administration (FDA) to tie approval of drugs tested in Africa to a monitoring scheme to ensure that U.S. drug companies and researchers adhere to internationally recognized ethical research principles and laws in Africa (*Nigeria vs. Pfizer*). Furthermore, all African research published in U.S. Public Health or Medical Journals and funded by tax-exempt U.S. foundations and research institutions must be tied to an ethical monitoring scheme. These monitoring schemes will be similar to the "Kimberly Process" for diamonds (PL 108–19). If millions of diamonds sold in the United States are screened and certified for ethical distribution in the U.S. from non-conflict regions in Africa, then the U.S. can demand a similar screening process for scores of research projects to enforce ethical conduct by U.S. researchers. This would ensure that marginalized Africans are protected from harm and exploitation.

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[55] Nigeria Lawsuit against Pfizer: Appeals Court ruling / Supreme Court document at: http://www.scotuswiki.com/index.php?title=Pfizer,_Inc._v._Abdullahi

[56] *Id.* 562 F.3d at 186-87.

[57] Nigeria Lawsuit against Pfizer: Appeals Court ruling / Supreme Court document at: http://www.scotuswiki.com/index.php?title=Pfizer,_Inc._v._Abdullahi

4. Propose targeted and specific travel sanctions on African doctors, researchers, and government health officials who design research projects to circumvent ethical research laws, and/or facilitate the unethical research conduct and practices of U.S. researchers by providing access to vulnerable populations of women and children in African research locations.

    - Authorize the U.S. Department of State or the U.S. Office of Research Integrity (ORI) to publish a list of implicated African doctors and health officials who are to be deemed *persona non grata* and banned from the United States. Public interest groups will cooperate by submitting names of verified research offenders to the State Department and/or ORI. The banned researchers must be allowed a reasonable period of two years to appeal the travel ban. The travel ban will be lifted after the doctors or health officials provide specific evidence indicating that this health community is not implicated in research misconduct or that they are in compliance with international research laws and principles. For example, providing detailed ICFs with verifiable signatures of human subjects will prove compliance; and where human subjects are illiterate, witnessed video recordings of full detailed informed consent agreements shall be considered reasonable and acceptable.

        - The "Travel Ban" will be a powerful deterrent, because access to the United States is a vital source of funding, personal income, and professional prestige for African doctors. They will not risk their careers if they can no longer profit from supporting unethical research practices.

    - Incorporate sanctions as an effective tool for enforcement (borrowing from a similar scheme used during the Apartheid regime in South Africa). U.S. government officials, U.S foundations, medical researchers, and private citizens will be banned from funding, supporting, and conducting medical experiments with African doctors and African government health officials that appear on the sanctioned list.

5. Identify government officials and researchers who conduct systematic illegal human-subject research experiments without ICFs, resulting in the harming of hundreds of vulnerable women, children, and families. These government officials and medical researchers shall be investigated, indicted, and prosecuted in a United Nations Special International Court for Crimes Against Humanity for violating international research laws and humane principles. This should have been the case in the *Nigeria Pfizer-Trovan Experiment, Ghana Navrongo Experiment*, and several other egregious cases where children and women have died or deaths are unknown because Serious Adverse Events (SAEs) cannot be accurately tracked without completed Informed Consent Forms.

6. Support public health advocates and whistleblowers in their efforts to codify internationally accepted ethical research laws and expose illegal research activity.

7. Work with international and local law enforcement to provide evidence and witnesses of illegal research to lead to successful prosecutions of researchers.

8. Convene a "*Global Leadership Ethical Research Forum*" to create a coalition with advocates, concerned foundations, and public health institutions to monitor grantees and employees conducting research in Africa. Funders will sign a non-binding *Ethical Research Funding Pledge*

to proactively monitor, end funding to unethical doctors and develop open lines of direct communication with advocates for information about unethical research.

9. Continue to create new health workshops to educate and inform vulnerable populations in Africa about rights regarding biomedical research and monitor researchers to encourage legal and ethical professional conduct.

CONCLUSION

Currently in the United States, there are two separate and unequal standards of ethical and professional conduct: one, for American doctors conducting research on Americans in the United States and the other, for American doctors conducting research experiments on Africans in Africa and other developing nations. This is illegal under both United States federal law and is also a Crime Against Humanity under the Nuremburg Code's international human subject experiment doctrine. We call on all fair-minded legislators and law enforcement officers to help put an end to these inhumane biomedical research crimes. It is important to note that we do not hold any government or private funders of research in Africa responsible for unethical conduct. However, we hold U.S. researchers and doctors versed in research policy liable because they are directly involved in the design and implementation of research on the ground in Africa. The only acceptable documents that researchers can provide to prove that they followed legal research IRB protocols are evidence of signed Informed Consent Forms (or witnessed video recordings of full informed consent agreements) that detail the experiments goals, drugs, doses, monitoring, adverse risks, serious adverse event procedures, and right to withdraw, as required by United States and International Law.

Under U.S. Federal Law (PL 93-348), the *Justice Doctrine* requires that research risks and potential benefits of drugs like penicillin, Nevirapine, azidothymidine (AZT) and various contraceptives have to be shared equally among those who may benefit, and requires equitable human-subject recruitment and selection. The *Respect of Persons Doctrine* under PL 93-348 incorporates two ethical concepts: 1) individuals should be treated as autonomous (i.e., independent in mind or judgment) agents, therefore government officials cannot consent for individual citizens, and 2) vulnerable individuals and those with diminished autonomy (for example: children, employees, mentally incapacitated individuals, prisoners, pregnant women, students) must be protected as a vulnerable class during recruitment. Regrettably, almost all human-subject research conducted in Africa is conducted in the same dehumanizing manner as Tuskegee and Guatemala were conducted in the 1940s. The valid right of ethical informed consent is still a *privilege* reserved primarily for Americans and Europeans, not Africans. Nevertheless, at this moment in time, with the credence of political, legal, social, academic and scientific advancements in America, it is our moral obligation and our legal duty to retire these crimes that have contributed to this painful and wretched part of our history.

The new African revolutionary movements for human rights and democracy in Algeria, Egypt, Ivory Coast, Libya, Tunisia and Uganda, do not simply seek to swap corrupt Heads of State. The revolutions are changing corrupt institutions and support systems because only legitimate, ethical institutions can permanently transform African societies and establish ethical governance. To achieve that goal, African nations, international law enforcement, the U.S. Executive Branch (specifically NIH, DOJ), congress, and private foundations can no longer support unethical conduct by their officials, agents, and staff as a means to an end. The women, children and families in Africa are endowed with inalienable universal rights. Therefore, all conscientious human beings should take offense to the indefensible and egregious criminal conduct of American researchers and drug companies that act contrary to humanity and basic human rights principles.

THE REBECCA PROJECT FOR HUMAN RIGHTS

The Rebecca Project for Human rights (RPHR) is a legal and policy advocacy organization in the United States and Africa. In the past two years some of our donors include: Abell Foundation, Blavatnik Provident Foundation, Carnegie Corporation, Dept. of Health, Dept. of Justice, Derald H Runttenberg Foundation & Perri Peltz, Diller-Von Furstenberg Foundation, Dozoretz Family Foundation, Ford Foundation, General Services Foundation, Goldman Sachs, Hewlett-Packard, Harold & Kayrita Anderson Family Foundation, JP Morgan, Law Students for Reproductive Justice, Liliane Willens Gift Fund, Moriah Fund, MS. Foundation for Women, Novo Foundation, Noyes Foundation, Robert Wood Johnson Foundation, Tides Foundation, Talia Milgrom-Elcott, and others. The Rebecca Project for Human Rights offers a gendered leadership approach that departs from prevailing cultural concepts to embrace the essential belief that global leadership is about courageously taking a firm stand for humanity, having a vision for a more just and equitable society for women and girls, and strategically advocating for concrete outcomes. In that process, we educate and train women and girls to seek leadership, accept agency and to empower themselves as deliberate conscious agents and advocates of social and political change.

Founded in 2003 by Malika Saada Saar and Imani Walker, the Rebecca Project for Human Rights has successfully accomplished over 90 percent of its advocacy goals. Our achievements include training and building a national network of marginalized women and girl advocates; starting the same network of woman and girl advocates in Africa; advocating to substantially increase funding for comprehensive drug treatment for mothers; advocating to expand long-term comprehensive treatment as an alternative to incarceration for non-violent female prisoners; advocating for juvenile justice programs and reforms; advocating to end shackling of pregnant mothers during childbirth in federal prisons; working successfully to end shackling in other states; presenting our 20,000 by 2012 Anti Child Sex Trafficking Project at the Clinton Global Initiative; advocating to shut down the Craigslist Adult Site to help end the domestic trafficking of under-age girls in the United States; and now advocating to end non-consensual research on women and children in Africa by U.S. researchers and academic institutions that receive tax-free funding from the public foundations and U.S. government.

The examples of fraud presented in this brief document are only a handful of cases. To date, the only foundation that has shown any genuine concern has been the Gates Foundation. After we contacted foundations during our preliminary investigations last year, their General Counsel, Ms. Connie Collingsworth, called the Rebecca Project and asked how they could help. The foundation then followed up again through their deputy counsel. Instead of only educating policymakers and the public, our advocacy strategy on this issue involves setting up meetings with the executive committees and boards of foundations to educate them on the important issue of illegal research in Africa. The Rebecca Project and human rights advocates are ensuring that, in this age of rapid information, it will be very difficult to suppress the unethical and inhumane conduct that occurs in every corner of the world. At our planned advocacy meetings with foundation board members and policymakers, we will provide extensive evidence of research fraud that is institutional, systemic and vast, far beyond the scope of Tuskegee and Guatemala. We deliberately excluded specific countries in Africa because the perceptions of illegal experimentation by unethical foreign researchers are causing entry problems for reputable vaccine programs, such as those managed by John Snow, Inc. Some areas in Nigeria reject important vaccines outright.

Funders, such as the Rockefeller Foundation, that the public sincerely believes "*promote the well-being of humanity"* by supporting researchers and institutions conducting research in Africa, should not summarily dismiss claims of research fraud and harm to impoverished women and children in Africa made by legitimate human rights advocates, ethical doctors and credible reporters. A simple phone call to research grantees requesting documentation of informed consent forms and research data would verify this global fraud and start a process of healing through proactive policy change at foundations. That is the least we expect from institutions and individuals who are leading proponents of virtuous global social change, ethical conduct, and more equitable societies.

Our question is, if funders in the United States are not willing to acknowledge or investigate evidence presented by their own legitimate U.S. advocates, doctors and reporters; then how can an illiterate African mother, barely earning less than two dollars a day, find her voice of courage to question powerful researchers coercing her with political pressure and financial incentives to inject her healthy newborn baby to test for the efficacy of a potentially lethal HIV drug? Where will she find the strength to refuse to sign a document she does not understand if she believes it is the only way she can obtain free routine medical care for herself and her baby? As an American family of advocates, reporters, doctors and funders, we all have to live up to the sacred creed to protect the most vulnerable human beings in our global society. Otherwise, there is no point to our advocacy efforts and mission statements that proclaim our care for humanity and pursuit of justice. We respectfully call on funders to uphold the tenets of their mission statements by imposing a moratorium on all research in Africa involving human subjects to halt these crimes against the humanity of African women and children and to begin a comprehensive review and reform of programs.

UNITED AFRICANS FOR WOMEN AND CHILDREN RIGHTS

www.africanwomenrights.org

United Africans for Women and Children Rights (UAWCR) is a non-governmental organization dedicated to safeguarding the rights of vulnerable women and children, which is significant in attaining a peaceful and healthy community, and is crucial for building democratic institutions and economic development. UAWCR promotes democratic non-violent principles, gender equity, and child protection in Africa through education and grass roots advocacy. The agency advocates to governments and the United Nations for legislation and policies that support effective development and work to end violence against women and girls.

Grace Akallo is the founder and Executive Director of UAWCR. At age 15, she was abducted by the one of the most brutal rebel militia groups in Uganda, the Lord's Resistance Army (LRA), and was forced into becoming a child soldier. After seven anguished months of being held in captivity as a child soldier with the LRA, Ms. Akallo orchestrated her life or death escape from Sudan where the LRA had camps, bringing with her eight other former child soldiers. She persevered and earned not just a high school degree, but also went on to university and even graduated from Clark University in Massachusetts with a Masters in International Development and Social Change. Ms. Akallo, who spoke about her ordeal on the Oprah Winfrey Show, is the co-author of *Girl Soldier: A Story of Hope for Northern Ugandan Children*, in which she narrates the horrors that she faced while in the rebel's camp.

Founded in 2009, UAWCR advocates for ending the prosecution of child soldiers; ensures prosecution of rebel groups and government forces that subject children to rape/sexual abuse, human trafficking, and kidnapping; advocates for government protection of women and girls' rights in order to improve women's socio-economic and political status; advocates for the participation of women and the incorporation of women's perspectives at all levels of decision making in order to achieve equality, development and peace; advocates for mothers' rights to be able to access basic maternal healthcare without the additional burden of being used unknowingly as human subjects in experiments and other non-consensual medical procedures; advocates for the end of illegal research and clinical trials where women and children are used as human subjects without their signed informed consent; trains women and girls to advocate for themselves; educates both children and the perpetrators of human rights abuse on the importance of respecting human rights, being tolerant and for the need to promote justice; strengthens linkages between sexual and reproductive health, HIV prevention, care and access to treatment at no or at affordable costs; promotes safe motherhood, pre and post natal services; and conducts health education workshops for women in order to create awareness and empower them and their families with information regarding their rights to participate or refuse drugs unless they are provided with and sign an informed consent form.

THE NATIONAL COUNCIL OF NEGRO WOMEN

www.ncnw.org

The National Council of Negro Women's (NCNW) mission is to lead, develop, and advocate for women of African descent as they support their families and communities. NCNW fulfills this purpose through research, advocacy, and national and community-based services and programs on issues of health, education, and economic empowerment in the United States and Africa.

Mary McLeod Bethune (1875-1955), from her vantage point as Advisor of Minority Affairs to President Franklin Delano Roosevelt, said that she could not rest to see the unharnessed womanpower among our women and founded NCNW in 1935. Some of NCNW's national and international programs and objectives include:

- Women & girls leadership and empowerment training in US & Africa.
- The high-profile annual Black Family Reunion Celebration.
- A national obesity abatement initiative.
- A partnership with national women's organizations in Benin to deliver technology, literacy, microcredit and economic empowerment programs.
- Small business incubator program in Senegal.

Dr. Avis A. Jones-DeWeever is the Executive Director of NCNW. Following in the dynamic footsteps of her predecessor, Dorothy Height, Dr. Jones-DeWeever is a thoughtful and inspiring leader widely revered as an expert in the fields of Race, Gender, Politics, and Policy. She has devoted her professional life to examining how policies impact the lives of women and communities of color while also seeking to advance effective programmatic solutions to long-standing societal challenges. Her career spans stints at several highly esteemed organizations including the Joint Center for Political and Economic Studies, the Congressional Black Caucus Foundation, and the Institute for Women's Policy Research. She is also an affiliated scholar at the Institute for Women's Policy Research, where she was formerly the Director of Poverty, Education, and Social Justice Programs.

Dr. Jones-DeWeever is a Magna Cum Laude graduate of Virginia State University and holds a Ph.D. in Government and Politics from the University of Maryland, College Park where she studied under tremendous scholars such as Drs. Linda Williams, Ronald Walters, and Clarence Stone. She is a published author, public speaker, policy analyst, and strategist. Dr. Jones-DeWeever has appeared on multiple television and radio networks including CNN, C-SPAN, ABC, PBS, NPR, Sirius/XM, BBC and American Urban Networks among others. She has also been quoted in numerous major print publications including the Washington Post, New York Times, Los Angeles Times, Washington Times and Essence and Glamour magazines.

Dr. Jones-DeWeever has authored or coauthored numerous publications including *When the Spirit Blooms: Acquiring Higher Education in the Context of Welfare Reform; Saving Ourselves: African American Women and the HIV/AIDS Crisis;* and *The Women of New Orleans and the Golf Coast: Multiple Disadvantages and Key Assets for Recovery.*

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AHRP details research fraud and unethical conduct by Columbia, Harvard, Johns Hopkins and other institutions. They investigated and initially reported the illegal research on foster kids by Columbia U.

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