The City Project

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The Honorable Jerry Menikoff
Director, Office for Human Research Protections,
Office of the Assistant Secretary for Health
United States Department of Health and Human Services
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240 453-6900
200 Independence Avenue SW
Washington, DC 20201

Re: Revise the Common Rule in Light of the US Guatemala STD Experiments
Docket ID number HHS-OPHS-2015-0008

Dear Mr. Menikoff:

Latino Coalition for a Healthy California, Henry Dahl, and The City Project submit these public comments to revise the Common Rule by incorporating lessons learned from the US STD experiments in Guatemala in order to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects.[1] LCHC serves as the leading voice for Latino health in California by initiating and advancing policies to build healthy communities. Henry Dahl is an attorney with experience in international law and human rights.

The City Project represents the Catholic Archdiocese of Guatemala in the petition before the Inter-American Commission on Human Rights against the US and Guatemala for crimes against humanity and human rights violations in the STD experiments. The US and Guatemala infected innocent Guatemalan people with STDs without their knowledge or consent beginning in the 1940s before, during, and after the convictions and executions of German doctors at Nuremberg, and has left them untreated and uncompensated to the present day. The experiments were covered up until Prof. Susan Reverby exposed them while doing research on the Tuskegee syphilis experiments. President Barack Obama apologized to the people of Guatemala in 2011. The government of Guatemala has published three reports documenting that the experiments were crimes against humanity that violated international human rights law and domestic laws, and were motivated by discrimination against vulnerable people in Guatemala. The US published two reports documenting that the experiments were unethical by the standards of the day and by contemporary standards. While the US reports are silent on the legality of the experiments, silence on that point is a tacit admission that the experiments did indeed violate international and domestic laws. Revising the Common Rule is necessary in light of the lessons of the Guatemala STD experiments to ensure nonconsensual human medical experiments never happen again.

[1] The Common Rule, Title 45, Part 46, Subpart A, Code of Federal Regulations, was issued by the US Department of Health and Human Services in 1991. The rule is available at www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

Researchers intentionally infected innocent people with STDs without their knowledge or consent. The STD experiments involved at least 5,128 vulnerable people, including children, orphans, child and adult prostitutes, Guatemalan Indians, leprosy patients, mental patients, prisoners, and soldiers. Health officials intentionally infected at least 1,308 of these people with syphilis, gonorrhea, and chancroid, and conducted serology tests on others. The Archdiocese of Guatemala has filed the petition before the Inter-American Commission on Human Rights. Victims have filed a lawsuit for damages against Johns Hopkins University, the Rockefeller Foundation, Bristol-Myers Squibb Company, and others in the federal district court for the District of Maryland, 1:15 CV 950 MJG. A criminal complaint has been filed in Guatemala against the former president, vice-president, and attorney general of Guatemala.

1. The Common Rule must explicitly recognize that nonconsensual human medical experiments violate domestic and international laws.

The United States Court of Appeals for the Second Circuit held that nonconsensual medical experimentation on human beings violates customary international law and is actionable under the Alien Tort Statute because the prohibition is specific, universal, and obligatory among nations around the world. *See Abdullahi v Pfizer*, 562 F.3d 163 (2009), *cert. denied*, 130 S.Ct. 3541 (2010). The court relied in part on the Nuremberg Code, which was adopted in 1947 upon the conviction by the US of German doctors for nonconsensual medical experiments. The Common Rule must ensure that the legal as well as the ethical and moral underpinnings of the rule are made explicit. The responsibilities of individual investigators must be made clear in the rule.

The three reports by the Guatemalan government cited below agree that the STD experiments violated international human rights and domestic laws. The report by the Guatemalan presidential commission concludes that the STD experiments were crimes against humanity, and that racism and discrimination permeated the experiments. The technical report recognizes at page 96: "Given the applicable laws during that period, all directly responsible committed crimes punishable by law, and its cover up suggests knowledge of criminal responsibility." The archival report concludes at page 165: "It is evident that people responsible for these experiments took advantage of the conditions and vulnerability of these groups to carry out these practices, which were a crime against humanity and a clear violation of the Nuremberg Code."

Ethical prohibitions are inadequate to deter crimes against humanity and human rights violations in medical research. The US presidential report acknowledges that the experiments in Guatemala were "ethically impossible" by the standards of the time and today. Yet Dr. John Cutler led the STD experiments in Guatemala, and was later responsible for the Tuskegee experiments that left African American men untreated for syphilis for decades.[2] Cutler nevertheless died a hero at the

[2] In Tuskegee, researchers left hundreds of African American men who were already infected with syphilis untreated from the 1930s until the media exposed the experiments in 1972, and the victims settled a successful civil rights lawsuit. Fred D. Gray, *The Tuskegee Syphilis Study* (1998).

University of Pittsburgh even after the Tuskegee experiments were exposed.[3] Cutler died without ever disclosing the Guatemala experiments. Sonia Shah has described unethical research in Tuskegee and in developing nations. Prof. Henry Beecher published twenty-two examples of unethical human research.[4]

2. The content of the Common Rule must be strengthened to recognize that voluntary consent of the human subject is absolutely essential.

The voluntary consent of the human subject is absolutely essential under the Nuremberg Code. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This is the formulation of the Nuremberg Code and it should not be watered down.[5] Research that poses greater risk to subjects should receive more oversight and deliberation than less risky research. The Common Rule must reflect these requirements.

As framed by Dr. Marcia Angell, the former editor of the New England Journal of Medicine:

> "[T]he Common Rule itself needs to be revised, because it is almost devoid of ethical content. Instead, it should deal with difficult substantive issues. These include the "therapeutic misconception" (patients' belief . . . that the researchers are there to provide them with individual care); the higher likelihood of harms than benefits because experimental treatments are usually no better, and often worse, than current treatments; the trade-off between individual benefits and benefits to science and society; whether the scientific merit of the research should be given weight (as called for in the Nuremberg Code); and whether to limit the move to conduct clinical trials in developing countries where there is almost certainly less oversight. . . . As it now stands, the term 'informed consent' is virtually meaningless."[6]

All federal agencies funding or conducting human subjects research must adopt human subjects regulations that are consistent with the legal and ethical requirements and underpinnings of the Common Rule.

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[3] Jan Ackerman, *Obituary: John Charles Cutler / Pioneer in preventing sexual diseases*, Post-Gazette, Feb. 12, 2003, available at old.post-gazette.com/obituaries/20030212cutler0212p3.asp.
[4] Sonia Shah, *The Body Hunters: Testing New Drugs on the World's Poorest Patients* (2006); Henry K. Beecher, *Ethics and Clinical Research,* New England Journal of Medicine, Vol. 274, No. 24 (June 16, 1966).
[5] Nuremberg Code, paragraph 1, available at www.hhs.gov/ohrp/archive/nurcode.html#; *"Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10",* Vol. 2, pp. 181-182, U.S. Government Printing Office (1949). *See generally* George J. Annas and Michael A. Grodin, *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* (1992).
[6] Marcia Angell, *Medical Research on Humans: Making It Ethical,* N.Y. Review of Books *(Dec. 3, 2015).*

Recommendations of the US Presidential Commission for the Study of Bioethical Issues, *Moral Science: Protecting Participants in Human Subjects Research* (2011, updated 2012), generally should be implemented. The present comments reflect recommendations 3, 6, 9, 11, and 13.

3. The Common Rule must be revised to address the special problems of human medical research in developing countries.

The present rule says almost nothing about the special problems of human medical research in developing countries. This imbalance arises from economic domination by the US of developing nations, discrimination by US researchers against host subjects based on race, color, national origin, gender, religion, income, and other factors; extreme poverty in many regions; cultural differences between researchers and subjects; and the greater likelihood of corruption involving US researchers and agents in the host nation. "Poor study design, lack of informed consent, improper handling of adverse outcomes, distortion of findings, outright lying and forgery, blackmail: this notorious case [involving the underlying facts in *Abdullahi v Pfizer,* discussed above] illustrates a wide variety of ways that [US] researchers may engage in unethical behavior to pursue profit."[7]

The Guatemalan experiments are instructive. The Guatemalan presidential report concludes that racism and discrimination permeated the experiments. There was discrimination by US officials against Guatemalan people, and within Guatemala by elites against lower-class indigenous and non-indigenous people. Discrimination is an aggravating, unacceptable factor for the experiments. The archival report concludes the experiments took advantage of the conditions and vulnerability of these groups to carry out these practices.

The Common Rule must be revised to create a new category to provide special protections in developing nations, as the present rule provides for pregnant women, children and prisoners. For example:

- Institutional review boards must include subjects from the host nation who have no interest in the research, or other disinterested international monitors with relevant multicultural fluency.
- The Common Rule must provide justifications and operational criteria for legal and ethical site selection, whether international or domestic, taking into consideration whether site selection can respond to the needs of the broader community.
- The consent form, nature of the experiment, risks, and right not to take part must be clear to subjects in light of their own language, dialect, and cultural norms. The consent

[7] Robert Klitzman, *The Ethics Police: The Struggle to Make Human Research Safe* at page 302. *See id.* at 302-20 (2015) (research in the developing world). In *Abdullahi* researchers allegedly experimented without consent on children with a new antibiotic during an epidemic of bacterial meningitis in Nigeria and left the children without administering follow up care, causing the death of 11 children and leaving many others blind, deaf, paralyzed, or brain damaged. *See also* Sonia Shah, *The Body Hunters: Testing New Drugs on the World's Poorest Patients* (2006) (unethical research in developing countries).

process should be videotaped, as a signature or mark on a written form may mean nothing to a person who does not read or write.

- Community engagement and respect for cultural differences are applicable to medical research both domestically and abroad. The Common Rule must provide a standardized framework for community engagement. The guidelines of the Joint United Nations Program on HIV/AIDS and the AVAC Good Participatory Practice Guidelines, for example, provide such a framework.
- Reports on medical experiments in developing nations must be published in the language of the host nation, not only in English, for the people of the host nation to understand the matter. Such reports must consider the perspective of the host nation. For example, the US report *"Ethically Impossible"* has been published in English and Spanish. In contrast, the US has published the recommendations report *Moral Science* only in English and should publish it in Spanish, too. Both US reports ignore the reports by the Guatemalan government.

4. The Common Rule must provide for treatment and compensation for research-related injury.

Because subjects harmed in the course of human research should not individually bear the costs of care required to treat harms resulting directly from that research, the Common Rule must provide for compensation and treatment for research-related injuries like those in Tuskegee, Guatemala, and Nigeria in *Abdullahi v Pfizer*. Surviving family members should also be made whole for harm incurred, whether direct (*e.g.,* disease transmission) or indirect (*e.g.,* emotional distress, loss of a family member at a younger age) in nature.

5. The US should waive sovereign immunity and other procedural obstacles involving federally funded medical experiments abroad.

The federal US District Court for the District of Columbia threw out the lawsuit by Guatemala STD victims against the US on the grounds that the US has not consented to be sued. The court concluded that "the Guatemala Study is a deeply troubling chapter in our Nation's history. Yet . . . this Court is powerless to provide any redress to the plaintiffs." *Gudiel Garcia v. Sebelius*, 867 F.Supp. 2d 125, 144 (D.D.C. 2012), *appeal dismissed*, 2013 U.S. App. LEXIS 13873. US courts and international tribunals should provide relief to the victims to prevent the US from acting with impunity. *See* Michael A. Rodriguez and Robert García, *First, Do No Harm: The US Sexually Transmitted Disease Experiments in Guatemala*, American Journal of Public Health (Dec. 2013, Vol. 103, No. 12, pp. 2122-2126), available at www.cityprojectca.org/blog/archives/30389.

Conclusion

The Common Rule must be revised so that nonconsensual human medical experiments never happen again. The Common Rule must reflect the central lessons of the US Guatemala STD experiments.

Very truly yours,

Robert García
Founding Director and Counsel
The City Project

Resources

The following materials are available on The City Project blog at www.cityprojectca.org/blog/archives/41463:

- The City Project, *Archdiocese of Guatemala Files International Petition against US and Guatemala for Human Rights Violations and Crimes Against Humanity in STD Experiments*.
- The Guatemala Presidential Commission Report, *Consenting to the Damage: Presidential Commission Report for Elucidation of the Experiments Carried Out on Humans in Guatemala* (2011) (The US State Department provided this English translation to The City Project under the Freedom of Information Act).
- Comisión Técnica, Comisión Presidencial para el Esclarecimiento de los Experimentos en Humanos en Guatemala 1946-48, *Experimentos en Seres Humanos: el Caso Guatemala 1946-48* (Abril 2011). The discussion of domestic and international laws in the technical report is available in English too.
- Archivo General de Centro América (AGCA), el Archivo Histórico de la Policía Nacional (AHPN), y la Dirección de los Archivos de la Paz (DAP) de la Secretaría de la Paz, *Investigación archivística sobre experimentos practicados en seres humanos en Guatemala, 1947-1948* (Mayo 2011). The discussion of domestic and international laws in the archival report is available in English too.
- The US Presidential Commission for the Study of Bioethical Issues, *"Ethically Impossible": STD Research in Guatemala from 1946 to 1948* (2011).
- The US Presidential Commission for the Study of Bioethical Issues, *Moral Science: Protecting Participants in Human Subjects Research* (2011, updated 2012).