



The Presidential Commission for the Study of Bioethical Issues

Valerie H. Bonham,
Executive Director

**Secretary's Advisory Committee on Human
Research Protections**

July 19, 2011



Creation of the Commission

“As our nation invests in science and innovation and pursues advances in biomedical research and health care, it’s imperative that we do so in a responsible manner.”

- President Barack Obama

Federal Register
Vol. 74, No. 228
Monday, November 30, 2009

Title 3—
The President

Presidential Documents

Executive Order 13521 of November 24, 2009

Establishing the Presidential Commission for the Study of Bioethical Issues

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Establishment. There is established within the Department of Health and Human Services the Presidential Commission for the Study of Bioethical Issues (Commission).

Sec. 2. Mission.

(a) The Commission shall advise the President on bioethical issues that may emerge as a consequence of advances in biomedicine and related areas of science and technology. The Commission shall pursue its work with the goal of identifying and promoting policies and practices that ensure scientific research, healthcare delivery, and technological innovation are conducted in an ethically responsible manner. To achieve this goal, the Commission shall:

- (i) identify and examine specific bioethical, legal, and social issues related to the potential impacts of advances in biomedical and behavioral research, healthcare delivery, or other areas of science and technology;
- (ii) recommend any legal, regulatory, or policy actions it deems appropriate to address these issues; and
- (iii) critically examine diverse perspectives and explore possibilities for useful international collaboration on these issues.

(b) In support of its mission, the Commission may examine issues linked to specific technologies, including but not limited to the creation of stem cells by novel means; intellectual property issues involving genetic sequencing, biomarkers, and other screening tests used for risk assessment; and the application of neuro- and robotic sciences. It may also examine broader issues not linked to specific technologies, including but not limited to the protection of human research participants; scientific integrity and conflicts of interest in research; and the intersection of science and human rights.

(c) The Commission shall not be responsible for the review and approval of specific projects.

(d) The Commission may accept suggestions of issues for consideration from executive departments and agencies and the public as it deems appropriate in support of its mission.

(e) In establishing priorities for its activities, the Commission shall consider, among other things, the significance of particular issues; the need for legal, regulatory, and policy guidance with respect to such issues; the connection of the issues to the goal of Federal advancement of science and technology; and the availability of other appropriate entities or fora for deliberating on the issues.

(f) The Commission is authorized to conduct original empirical and conceptual research, commission papers and studies, hold hearings, and establish committees and subcommittees, as necessary. The Commission is authorized to develop reports or other materials.

Sec. 3. Membership.

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(a) The Commission shall be an expert panel composed of not more than 13 members appointed by the President, drawn from the fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social sciences, at least one and not more than three of whom may be bioethicists or scientists drawn from the executive branch, as designated by the President.

(b) The President shall designate a Chair and Vice Chair from among the members of the Commission. The Chair shall convene and preside at meetings of the Commission, determine its agenda, and direct its work. The Vice Chair shall perform the duties of the Chair in the absence or disability of the Chair and shall perform such other functions as the Chair may from time to time assign.

(c) Members shall serve for a term of 2 years and shall be eligible for reappointment. Members may continue to serve after the expiration of their terms until the appointment of a successor.

Sec. 4. Administration.

(a) The Department of Health and Human Services shall provide funding and administrative support for the Commission to the extent permitted by law and within existing appropriations.

(b) All executive departments and agencies and all entities within the Executive Office of the President shall provide information and assistance to the Commission as the Chair may request for purposes of carrying out the Commission's functions, to the extent permitted by law.

(c) The Commission shall have a staff headed by an Executive Director, who shall be appointed by the Secretary of Health and Human Services in consultation with the Chair and Vice Chair.

(d) Members of the Commission shall serve without compensation, but shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in Government service (5 U.S.C. 5701–5707), consistent with the availability of funds.

Sec. 5. Termination. The Commission shall terminate 2 years after the date of this order unless extended by the President.

Sec. 6. General Provisions.

(a) This order supersedes Executive Order 13237 of November 28, 2001.

(b) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.), may apply to the Commission, any functions of the President under that Act, except that of reporting to the Congress, shall be performed by the Secretary of Health and Human Services in accordance with the guidelines that have been issued by the Administrator of General Services.

(c) Nothing in this order shall be construed to impair or otherwise affect:
(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(d) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(e) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



The Commission

AMY GUTMANN, PH.D., CHAIR

JAMES W. WAGNER, PH.D., VICE CHAIR

YOLANDA ALI, M.B.A.

JOHN D. ARRAS, PH.D.

NITA A. FARAHANY, J.D., PH.D.

CHRISTINE GRADY, R.N., PH.D.

RAJU S. KUCHERLAPATI, PH.D.

DANIEL P. SULMASY, M.D., PH.D.

VALERIE BONHAM, J.D., EXECUTIVE DIRECTOR



ANITA L. ALLEN, J.D., PH.D.

BARBARA F. ATKINSON, M.D.

ALEXANDER G. GARZA, M.D.

STEPHEN L. HAUSER, M.D.

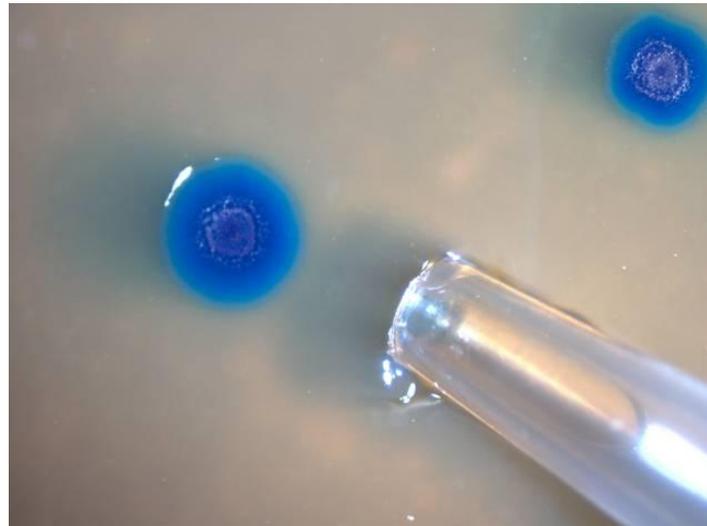
NELSON L. MICHAEL, M.D., PH.D.



Synthetic Biology



“Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome”



Gibson, D.G., et al. (2010). Creation of a bacterial cell controlled by a chemically synthesized genome. *Science* 329(5987):52-56.



Immediate Public Reaction



Synthetic life? Synthetic hysteria more like

Mail Online
Scientist accused of playing God after creating artificial life by making designer microbe from scratch - but could it wipe out humanity?

Was life really created in a test tube? And does it disprove biblical creation?

HOW TO MAKE ARTIFICIAL LIFE

- 1 Entire DNA of Mycoplasma mycoides, a bug that usually infects goats, is decoded.
- 2 Researchers buy fragments of DNA from a mail order catalogue. Each of the four bottles of chemicals contains a section of the code.
- 3 The fragments are put into yeast, which 'stitches' them together naturally.



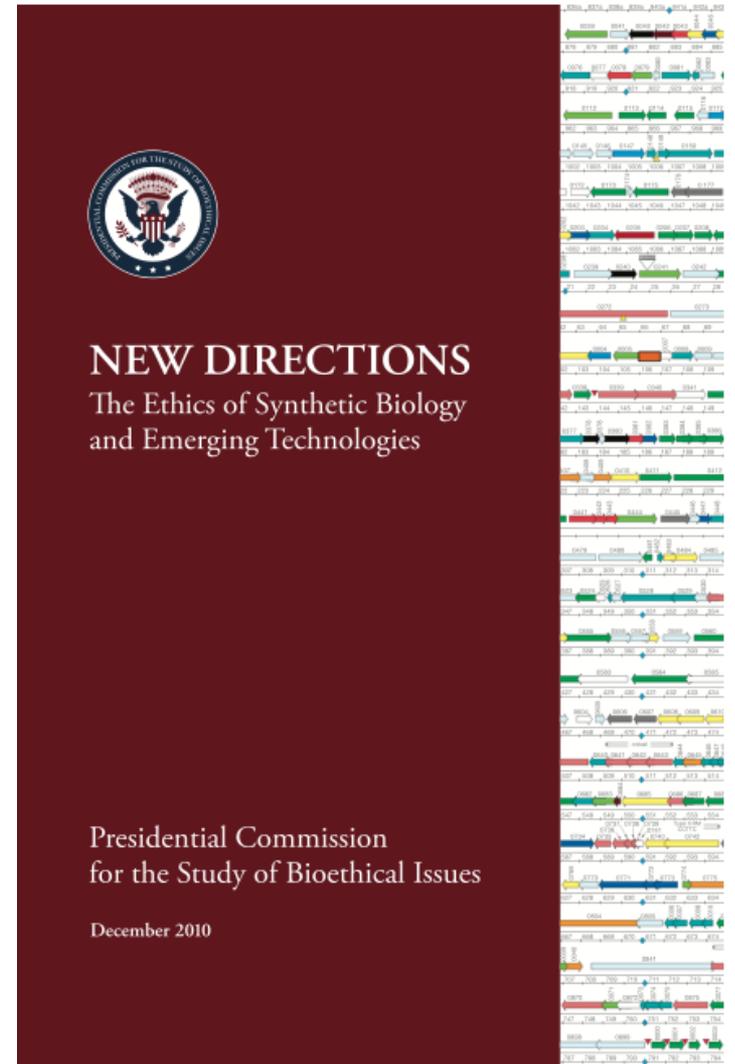
Request from President Obama

May 20, 2010

- Review the developing field of synthetic biology
- Consider the potential medical, environmental, security, and other benefits as well as potential health, security, or other risks
- Identify appropriate ethical boundaries to maximize public benefits and minimize risks



The Commission submitted its first report to President Obama on December 15, 2010





Developed Principles for Assessing *All* Emerging Technologies

- Public Beneficence
- Responsible Stewardship
- Intellectual Freedom and Responsibility
- Democratic Deliberation
- Justice and Fairness



**'Synthetic biology'
holds promise, but
vigilance needed**

The Washington Post

**Presidential commission urges caution on
'synthetic biology'**

Dr. Venter, whose work precipitated the commission's study, also praised the recommendations as "wise, warranted and restrained, which will help to ensure that this young field of research will flourish in a positive manner."

The New York Times



**Bioethics Commission calls for enhanced federal
oversight in new field of synthetic biology**



Human Subjects Protection



SUSAN M. REVERBY

“Normal Exposure” and Inoculation Syphilis: A PHS “Tuskegee” Doctor in Guatemala, 1946–1948

Policy is often made based on historical understandings of particular events, and the story of the “Tuskegee” study has, arguably more than any other medical research experiment, shaped policy surrounding human subjects.¹ The forty-year study of “untreated syphilis in the male Negro” sparked outrage in 1972 after it became widely known, and it inspired the political push for requirements for informed consent, the protection of vulnerable subjects, and oversight by institutional review boards.²

I am grateful to Marianne Kasica at the University of Pittsburgh Archives for her assistance in doing what archivists are supposed to do: make the papers in their archives available to legitimate researchers. Thank you to Zachary Schrag for his editing, encouragement, and questions, as well as those of my colleagues who heard this paper when I first presented it at the annual meeting of the American Association for the History of Medicine in May 2010. I also appreciate the comments of former CDC director Dr. David Sencer, who did not know the details of this study, which did not take place on his watch. Without his concern, connections, and respect for the importance of history, knowledge of this study might never have garnered such an extraordinary response. Dr. John Douglas of the CDC did an amazing report on short notice that confirmed my work and provided the clear statistics on the subjects. I am grateful to the U.S. government officials who saw the wrongs here and stepped forward to acknowledge them. I appreciate all those who took the time to think about this, to communicate their concern publicly and privately, and to be part of the continued struggle for the balance of human rights and medical progress.



Telegraph.co.uk

US apologises for syphilis experiment

The United States apologised on Friday for an experiment conducted in the 1940s in which government medical researchers deliberately infected Guatemalan prison inmates with syphilis.

THE TIMES OF INDIA

US infected mentally ill in Guatemala with syphilis, gonorrhoea

Bangkok Post : Obama apologizes to Guatemala for US sex-disease study

Ghana Business News

How the US infected Guatemala citizens with syphilis other STDs

El Periodico, Guatemala

U.S. Must Come Clean About 'Horrorfying Experiment'

Irish Examiner



Secretary of State Hillary Clinton
US apologises for infecting prisoners with syphilis



THE WHITE HOUSE
WASHINGTON

November 24, 2010

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MEMORANDUM FOR DR. AMY GUTMANN
Chair, Presidential Commission for the Study of
Bioethical Issues

SUBJECT: Review of Human Subjects Protection

Recently, we discovered that the U.S. Public Health Service conducted research on sexually transmitted diseases in Guatemala from 1946 to 1948 involving the intentional infection of vulnerable human populations. The research was clearly unethical. In light of this revelation, I want to be assured that current rules for research participants protect people from harm or unethical treatment, domestically as well as internationally.

I ask you, as the Chair of the Presidential Commission for the Study of Bioethical Issues, to convene a panel to conduct, beginning in January 2011, a thorough review of human subjects protection to determine if Federal regulations and international standards adequately guard the health and well-being of participants in scientific studies supported by the Federal Government. I also request that the Commission oversee a thorough fact-finding investigation into the specifics of the U.S. Public Health Service Sexually Transmitted Diseases Inoculation Study.

In fulfilling this charge, the Commission should seek the insights and perspective of international experts, including from Guatemala; consult with its counterparts in the global community; and convene at least one meeting outside the United States. I expect the Commission to complete its work within 9 months and provide me with a report of its findings and recommendations.

While I believe the research community has made tremendous progress in the area of human subjects protection, what took place in Guatemala is a sobering reminder of past abuses. It is especially important for the Commission to use its vast expertise spanning the fields of science, policy, ethics, and religious values to carry out this mission. We owe it to the people of Guatemala and future generations of volunteers who participate in medical research.

A handwritten signature in black ink, appearing to be "Barack Obama", written in a cursive style.



Human Subjects Protection

- Commission started work in January.
 - Historical Review of US Public Health Service Inoculation Study in Guatemala
 - Review of Contemporary Standards
- First public meeting on Human Subjects Protection on March 1, 2011 (Washington, DC)



International Research Panel

- Members, hailing from around the globe

John Arras (US)

Julius Ecuru (Uganda)

Christine Grady (US)

Dirceu Greco (Brazil)

Amy Gutmann (US)

Unni Karunakara (India)

Nandini Kumar (India)

Sergio Litewka (Argentina)

Luis López (Guatemala)

Adel Mahmoud (Egypt)

Nelson Michael (US)

Peter Piot (Belgium)

Huanming Yang (China)

Boris Yudin (Russia)

- Mission

- The dominant norms, and competing alternatives, driving the ethics of medical research in different global regions outside of the U.S.;
- The conflicts, if any, between U.S. norms and international standards;
- The challenges facing researchers conducting U.S.-funded research in global settings; and
- How best to address any major differences in regional norms for medical research.



Public Input

- RFI

(Federal Register, Request for Public Input /Vol. 76, No. 41 /March 2, 2011)

SUMMARY: The Presidential Commission for the Study of Bioethical Issues is requesting public comment on the Federal and international standards for protecting the health and well-being of participants in scientific studies supported by the Federal Government.

DATES: To assure consideration, comments must be received by May 2,

- The existing standards for protecting human subjects.
- How the current system of global research works in practice.
- The ethical and social justice issues that emerge from the current research system.



Ongoing Activities

Preliminary plans to address:

- *Genes to Genomes: Collecting, Using and Governing Genome Sequence Data*
 - Addressing how the scale of collected and available genetic data raises the bar on data protection, privacy, consent, counseling, etc.
- *Neuroimaging and the Self*
 - Focusing on advances in neuroimaging and the implications for moral philosophy and for moral and legal responsibility



Additional Information

- Future meetings open to the public:
 - August 29-30 in Washington, DC
 - November 16-17 in Boston, MA
- Comments? Address to: info@bioethics.gov
- More Information: www.bioethics.gov



SACHRP Input?