



The Presidential Commission for the Study of Bioethical Issues

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Staff Report on Current Human Subject Studies
Supported by the Federal Government

August 30, 2011



THE WHITE HOUSE
WASHINGTON

November 24, 2010

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", is written over a white background.

“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.”



Challenges to Meeting the Charge

- No systematic data are available across federal agencies and departments about the scientific studies supported by the federal government
 - Types of studies
 - Location of studies
 - Federal investment
- Limited available systematic information about the extent to which regulations and standards guard the health and well-being of participants
- Such data are needed to inform the Commission's deliberations and formulations of sound policy recommendations



Filling the Gaps

- Landscape Project
- Potential Projects



Empirical Advisory Group

- Formulate research questions to guide data analyses in the Commission's Landscape project; and
- Propose and evaluate other empirical projects that may inform the Commission's response to President Obama's charge.



Empirical Advisory Group

- Commission Member Christine Grady, RN, PhD
- Commission Member Daniel Sulmasy, MD, PhD
- Robert Califf, MD
- Ruth Faden, PhD, MPH
- Ken Getz, MBA
- Phillip Lavori, PhD, MA
- Bernard Lo, MD
- Kathleen MacQueen, PhD, MPH



Landscape Project Goals

- To define and understand the landscape of “scientific studies supported by the Federal Government”; and
- To enable and provide needed analyses on the volume, scope, and related trends in Federally supported research.



Agencies

- Agency for International Development
- Central Intelligence Agency
- Consumer Product Safety Commission
- Department of Agriculture
- Department of Commerce
- Department of Defense
- Department of Education
- Department of Energy
- Department of Health and Human Services
- Department of Homeland Security
- Department of Housing and Urban Development
- Department of Justice
- Department of Transportation
- Department of Veterans Affairs
- Environmental Protection Agency
- National Aeronautics and Space Administration
- National Science Foundation
- Social Security Administration



Timeline

March – June:

Agency liaisons requested

Data requests sent to agency liaisons

Data requests clarified with liaisons

Development of tools

July:

Excel and XML tools to delivered to agencies

Upload website launched

August:

FY10 data due

September:

FY06-FY09 data due

November:

Commission meeting



Current Status

- All agencies contacted have responded to the Commission's data request.
 - 17 agencies have provided some or all project-level FY10 data
 - DOD has provided only aggregate FY10 data
- The Empirical Advisory Group provided guidance on analyses to be conducted
- We are close to securing a statistician to analyze these data.



Initial Analyses

- How many scientific studies involving human participants are supported by the federal government? How many are located internationally?
- How many institutions/investigators are provided with direct federal funding for scientific studies involving human participants? How many of those institutions/investigators are located internationally?
- How much funding does the federal government invest in scientific studies involving human participants? How much of this funding is directed internationally? How do both of these vary by agency/department?
- What trends emerge over the last five years?



Possible Next Steps

1. Link the Commission's database to ClinicalTrials.gov
 - a) Learn additional "landscape" data about a subset of federally supported studies (e.g., participant information, type of study)
 - b) Examine whether or not all studies that should be registered in ClinicalTrials.gov, in fact, are.
2. Review abstracts for projects not in ClinicalTrials.gov
 - a) Assess human subjects research not considered to be a clinical trial
3. Natural language analyses
 - a) Identify study types (e.g., disciplinary range, methodology) and populations (e.g., children, pregnant women, prisoners) in the Commission's database.



Other Empirical Projects to Consider

- Web-based survey of investigators
- Systematic assessment of human subjects protections



Web-Based Investigators Survey

- **Perspectives of key stakeholders**
- **Potential domains**
 - Whether community engagement occurred and with whom;
 - Experiences with human subjects protection training and education; and
 - Whether important research projects have been delayed or abandoned because of procedural constraints.



Systematic Review of Human Subjects Protections

- Sample from the Commission's database
- Staged approach
 - Centralized protocol review;
 - Interviews with key stakeholders; and
 - Site visits.
- Might serve as a pilot for a periodic program evaluation of human subjects research protections.