



PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

International Research Panel

Terms of Reference

I. Introduction

In October 2010, the U.S. Government disclosed that the U.S. Public Health Service (USPHS) supported research on sexually transmitted diseases in Guatemala from 1946 to 1948 involving the intentional infection of vulnerable human populations. Concurrently, the U.S. Government announced plans to undertake two tasks: 1) conduct a thorough fact-finding investigation into the case; and 2) seek independent advice on the effectiveness of current U.S. rules and international standards for the protection of human subjects in scientific studies supported by the U.S. Government.

Subsequently, on November 24, 2010, President Obama directed the Presidential Commission for the Study of Bioethical Issues (Commission), beginning in January 2011, to “oversee a thorough fact-finding investigation into the specifics” of the USPHS supported research and to conduct a review of the adequacy of contemporary human subjects protection across the international field of research. President Obama directed the Commission Chair to convene a panel of international experts to consider current U.S. Government regulations and international standards that guard the health and well-being of participants in scientific studies supported by the U.S. Government. The President asked specifically for assurance that “the current rules for research participants protect people from harm or unethical treatment, domestically as well as internationally.”

In order to carry out this charge, the International Research Panel (Panel, or IRP) is hereby established in accordance with E.O. 13521 and 41 C.F.R. 102-3.35 as a subcommittee of the Commission to review and advise the Commission on the matters described above.

II. Purpose

The Panel will undertake a consultation process to examine the following issues:

- a. The dominant norms, and competing alternatives, driving the ethics of medical research in different global regions outside of the United States;
- b. The conflicts, if any, between U.S. norms and international standards;
- c. The challenges facing researchers conducting U.S.-funded research in global settings; and
- d. Possible strategies to address differences in regional norms for medical research.

III. Composition

- a. Qualifications
 - i. Members will be selected from the United States and the international bioethics and medical/science communities.
 - ii. A majority of members will come from outside the United States.
- b. Responsibilities
 - i. Members are expected to contribute their unique knowledge and experience in the conduct of global research, the ethical and social justice issues that exist in the current global research system, and the challenges faced by international researchers collaborating on U.S. funded research.
 - ii. Panel member contributions are based on their own experience and expertise; members are not acting as formal representatives of their countries' positions.

IV. Operations

- a. Proceedings
 - i. Decision-making shall be based on consultation and consensus.
 - ii. A final Summary of the Proceedings will be developed based on the Panel consultations.
 - iii. Meetings will be conducted in English.

b. Number of Consultations

- i. The Panel will convene for 3 in-person meetings. At least one of the meetings will take place outside the United States.
- ii. Panel Members are expected to attend at least 2 of 3 meetings.

c. Public Information

- i. A Summary of the Proceedings will be distributed publicly.

V. Term

The Consultation is expected to conclude within four months of the Panel's first meeting, however, it is understood that the Panel may meet thereafter, as needed, to complete its work before the Commission reports to President Obama.