

CODE 709096
HUMAN SUBJECT EXPERIMENTATION
AUDIT GUIDELINES

OSD1.950315.008

Objectives: Identify the magnitude, possible impact, and government actions to address problems resulting from experiments sponsored or conducted by federal agencies for national security purposes in which humans were deliberately exposed to hazardous or potentially hazardous chemical, biological, and/or nuclear material. Specifically, summarize available information on (1) the experiments and the approximate number of human subjects involved, (2) the potential effects of these experiments on human subjects, (3) the government's efforts to notify the participants and provide medical care and/or compensation, and (4) current laws, policies and procedures to ensure that the government obtains informed consent from participants in experiments.

Potential Agencies to Contact:

Department of Defense

OSD: Assistant to the Secretary of Defense (Atomic Energy)
Army
Navy/Marine Corps
Air Force
Defense Nuclear Agency
National Security Agency
Defense Intelligence Agency

Other Government Agencies

Veterans Administration
Central Intelligence Agency
Department of Energy
NASA
Presidential Advisory Committee on Human Radioactive Experiments

Audit Steps: Contact appropriate officials in the above listed agencies, use prior GAO reports and other existing studies and documents to meet the following objectives:

OBJECTIVE (1) Identify program, experiments, and number of participants.

Purpose: To meet this objective we will gather information to support a testimony section in which we discuss, in general terms, the scope of tests that have been conducted by the federal government for national security purposes. It is not designed to develop an all-inclusive list, but to give the Committee as much information as possible within the time available concerning the extent and nature of experiments conducted. It will define "experiment", identify some of the more egregious examples, and summarize agencies' efforts to identify experiments and participants.

Specific audit steps are:

- a. Determine how each agency defines human use experiments.
- b. Determine what experiments were conducted by each agency. Describe the purpose, experimental agent(s) used, the number of subjects, and the dates of the experiments.
- c. Determine efforts taken or being taken by each agency to identify the experiments and the participants.
 - (1) prior efforts
 - (2) ongoing efforts
 - (3) resources dedicated to these efforts
 - (4) search methodology (e.g. archival research, outreach programs to identify participants, etc.)
- d. Identify the difficulties agencies are encountering in identifying experiments and participants.

OBJECTIVE (2) Potential Effects of Experiments on Subjects

Purpose: To meet this objective we will gather information to develop a testimony section that summarizes federal agencies' efforts to identify the effects of their experiments on human

subjects. Prior work in this area has shown that agencies are generally ignorant of any potential long-term effects related to the agents or contaminants used in their experiments. This, in turn, leads to problems when participants allege their current medical problems are the result of experiments conducted many years ago. Where these questions exist, it appears agencies have an obligation to determine whether, in fact, people have suffered negative health effects. These audit steps are meant to determine the extent of those efforts.

From the list identified in step 1b above, determine:

- a. What were the risks of the experiments to the human subjects identified at the time of the experiments?
- b. What studies have been done or are currently underway to identify the possible long term health effects of the experimental agents (including radioactive material) used in the experiments?

OBJECTIVE (3) Government's Efforts to Notify Participants, and Provide Medical Care and/or Compensation

Purpose: To meet this objective we will gather information to support a testimony section that summarizes federal agencies' efforts to locate and provide assistance to experiment subjects. From prior work in this area, we know that agencies do not always have comprehensive lists of experiment participants. This causes problems when experiment participants are required to prove participation in the experiments in order to receive medical care and/or compensation.

From the list identified in step 1b above, determine:

- a. What efforts have the agencies taken to locate both civilian and military subjects of the experiments?

- b. What criteria must the subjects meet in order to receive compensation and/or medical care?
- c. What is the level of compensation that human subjects have received?
- d. What barriers do the agencies perceive participants face in getting compensation?
- e. Identify private bills introduced by Congressional Representatives to obtain compensation for constituents (may be obtained from legislative searches rather than agencies).
- f. Identify agency points of contact that interested parties can contact to obtain information about their participation in human subject experiments.

(4) Current Laws, Policies, etc. to Ensure Informed Consent of Human Test Subjects

Purpose: This audit step will develop a testimony section that briefly summarizes the history of informed consent requirements, and current requirements designed to ensure that current human subjects are informed of the risks of their participation in an experiment.

- a. Summarize current Code of Federal Regulations requirements, laws, etc.
- b. Identify milestones in the legislative history of informed consent (Nurenborg Guidelines, 1975 Law, etc.).