Inspection of Human Subject Research in Intelligence and Intelligence- Related Projects

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memorandum

DATE: January 16, 1996

REPLY TO
ATTN OF: IG-1

SUBJECT: INFORMATION: Report on "Inspection of Human Subject Research in Intelligence and Intelligence-Related Projects"

TO: The Secretary

BACKGROUND:

Executive Order 12333, "United States Intelligence Activities," 1) designates the Department's intelligence element as a member of the Intelligence Community, and 2) states that no agency within the Intelligence Community shall sponsor, contract for or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services. The Federal policy for the Protection of Human Subjects, which was based on Department of Health and Human Services regulations, was promulgated in Title 10 Code of Federal Regulations Part 745 by the Department of Energy. The purpose of this inspection was to review the internal control procedures used by the Office of Nonproliferation and National Security to manage selected intelligence and intelligence-related projects that involve human subject research.

DISCUSSION:

We did not find evidence to lead us to believe that Departmental officials and contractors knowingly violated Federal regulations and Departmental directives regarding the conduct of projects involving human subject research. We did find, however, that selected officials and contractors did not comply with such directives because they did not recognize that they were conducting human subject research, as defined by 10 CFR 745, or were unfamiliar with Departmental procedures developed to conduct human subject research.

For example, we found that officials at the Idaho Operations Office and the Idaho National Engineering Laboratory did not recognize that three intelligence-related Work for Others projects that they had accepted and were conducting involved human subject research. As a result, the Office of Health and Environmental Research issued Idaho a stop work order on the three projects until the conduct of the projects came into compliance with provisions of 10 CFR 745. We also found that the Sandia National Laboratories obtained approval of six

projects involving human subject research but initiated such research in two of these projects prior to obtaining required human subject approvals. As a result, Sandia expended Federal funds without satisfying requirements of 10 CFR 745 and did not act in accordance with the Department's Intelligence Procedures.

We also found that the Office of Nonproliferation and National Security did not fully implement the procedures they had developed to identify human subject research projects. As a result, selected project records did not identify all departmental-funded projects and intelligence and intelligence-related Work for Others projects that involved human subject research. In addition, the Office of Energy Intelligence approved three intelligence-related Work for Others projects involving human subject research that were not conducted in accordance with the Department's Intelligence Procedures.

We found that the Office of Energy Intelligence had not ensured that Management and Operating contractors, who were not members of a Departmental Field Intelligence Element but were engaged in intelligence-related Work for Others projects, had received training to familiarize them with Executive Order 12333, "United States Intelligence Activities," and the Department's Intelligence Procedures, as required.

In commenting on our report, management concurred with all recommendations and have completed or identified corrective actions.

John C. Layton
Inspector General

cc: Deputy Secretary
Under Secretary
Director, Office of Energy Research
Director, Office of Nonproliferation and National Security
Manager, Albuquerque Operations Office
Manager, Idaho Operations Office

U.S. DEPARTMENT OF ENERGY
OFFICE OF INSPECTOR GENERAL

REPORT ON THE
INSPECTION OF HUMAN SUBJECT RESEARCH IN
INTELLIGENCE AND INTELLIGENCE-RELATED PROJECTS

Report No. DOE/IG-0383
Date Issued: January 16, 1996

Office of Inspections
Washington, D.C. 20585

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js MASTER

OFFICE OF THE ATTORNEY GENERAL

**REPORT ON THE
INSPECTION OF HUMAN SUBJECT RESEARCH IN
INTELLIGENCE AND INTELLIGENCE-RELATED PROJECTS**

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I. INTRODUCTION AND PURPOSE:

Executive Order (EO) 12863, "President's Foreign Intelligence Advisory Board," dated September 13, 1993, requires Inspectors General of the Intelligence Community to submit reports to the Intelligence Oversight Board, on at least a quarterly basis, on intelligence activities which they have reason to believe may have been unlawful or contrary to Executive order or Presidential directive. Within the Department of Energy (DOE) Office of Inspector General, responsibility for oversight of the Department's intelligence activities, pursuant to EO 12863, has been assigned to the Deputy Inspector General for Inspections.

To carry out this responsibility, the Office of Inspections performs reviews to determine whether intelligence activities within DOE are conducted in accordance with selected intelligence-related laws, Executive orders, and DOE orders, guidelines, and implementing instructions. Accordingly, the purpose of this inspection was to review the internal control process used by the Office of Nonproliferation and National Security to manage selected intelligence and intelligence-related projects that involve human subject research. Our primary objectives were to:

- o Identify the intelligence and intelligence-related projects managed by the Office of Nonproliferation and National Security, which involved human subject research;
- o Evaluate the internal control procedures used by the Office of Nonproliferation and National Security for accepting and managing intelligence-related Work for Others projects that involve human subject research; and
- o Evaluate implementation of policies and procedures at selected field locations regarding intelligence-related Work for Others projects that involve human subject research.

II. SCOPE AND METHODOLOGY

In conducting this inspection, we interviewed officials and reviewed selected records at DOE Headquarters and at field locations. At DOE Headquarters, we interviewed officials in the Office of Nonproliferation and National Security and in the Office of Health and Environmental Research. We reviewed project records on 428 intelligence and intelligence-related Work for Others projects that were reviewed, accepted, and coordinated by the Office of Energy Intelligence, which was previously designated as the Office of Intelligence. This total included project records on 218 active projects and 210 inactive/closed projects, as of

June 30, 1994. We also reviewed automated and manual Human Subject Research Records maintained by the Office of Health and Environmental Research. These records summarize all research projects involving human subjects currently funded by DOE or performed at DOE facilities with support from others, as reported to DOE by DOE grantees and contractors.

At field locations, we interviewed officials and reviewed selected records at the Idaho Operations Office, the Albuquerque Operations Office, the Kirtland and Los Alamos Area Offices, the Idaho National Engineering Laboratory, the Los Alamos National Laboratory, and the Sandia National Laboratories. In addition, we interviewed an official at the Special Technologies Laboratory. Our inspection was conducted from May 1994 to June 1995.

This inspection was conducted in accordance with the Quality Standards for Inspections issued by the President's Council on Integrity and Efficiency.

III. SUMMARY RESULTS OF INSPECTION

We found that officials at the Idaho Operations Office and the Idaho National Engineering Laboratory did not recognize that three intelligence-related Work for Others (WFO) projects involved human subject research, as defined by Title 10 Code of Federal Regulations Part 745, Protection of Human Subjects (10 CFR 745).

As a result, by accepting the three projects and conducting two of them, the Idaho Operations Office and the Idaho National Engineering Laboratory (INEL) did not comply with Federal regulations and DOE directives, as follows: (1) INEL did not provide written assurance to DOE that the laboratory would comply with 10 CFR 745; (2) an Institutional Review Board did not review and approve the projects; (3) the Office of Health and Environmental Research did not review and approve the projects; (4) informed consent was not obtained from the subjects involved in the projects; (5) Federal funds were expended on the projects without satisfying 10 CFR 745 requirements; (6) INEL did not provide the Idaho Operations Office required information regarding human subject research; (7) the process used by the Idaho Operations Office to review and approve WFO projects did not identify human subject research; and (8) INEL did not act in accordance with the "Department of Energy Procedures for Intelligence Activities" (DOE Intelligence Procedures) in their conduct of the projects.

As a result of our review, the Program Manager, Human Research Subject Activities, Office of Health and Environmental Research,

issued the Idaho Operations Office a stop work order on the three projects until the conduct of the projects came into compliance with provisions of 10 CFR 745. Within approximately three months, the Idaho Operations Office had taken corrective actions and had received approval from the Office of Health and Environmental Research to conduct the human subject research.

We found that the Sandia National Laboratories (SNL) had obtained approval of six projects involving human subject research that had been identified and processed using SNL-developed procedures. We also found, however, that SNL had initiated human subject research in two of these projects prior to obtaining required human subject approvals. As a result, SNL expended Federal funds without satisfying requirements of 10 CFR 745 and did not act in accordance with the DOE Intelligence Procedures.

We found that the Office of Nonproliferation and National Security (NN) did not fully implement the procedures they had developed to identify human subject research projects. As a result, selected project records did not identify all NN-funded projects and intelligence and intelligence-related WFO projects that involved human subject research. Additionally, the Office of Intelligence approved three intelligence-related WFO projects involving human subject research that were not conducted in accordance with the DOE Intelligence Procedures.

We found that the Director, Office of Energy Intelligence, had not ensured that DOE Management and Operating contractors, who were not members of a DOE Field Intelligence Element but were engaged in intelligence-related WFO projects, had received required training to familiarize them with Executive Order 12333, "United States Intelligence Activities," dated December 4, 1981, and the DOE Intelligence Procedures. As a result, the Director, Office of Energy Intelligence, issued a memorandum to the Directors of each Field Intelligence Element which stated they were responsible for ensuring that all employees involved in intelligence-related activities received appropriate training on EO 12333 and the DOE Intelligence Procedures.

IV. BACKGROUND

The Federal policy for the Protection of Human Subjects was set forth in 56 Federal Register 28002, "Federal Policy for the Protection of Human Subjects; Notices and Rules," dated June 18, 1991, and was promulgated in Title 10 Code of Federal Regulations Part 745, Protection of Human Subjects, effective August 19, 1991, by DOE. This policy was based on regulations issued by the

Department of Health and Human Services for the protection of human research subjects.

Applicability of 10 CFR 745

10 CFR 745 "applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research." "Human Subject" is defined in 10 CFR 745 as:

"a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* (italics added) includes communication or interpersonal contact between investigator and subject. 'Private information' includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

"Research" is defined in 10 CFR 745 as:

"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."

DOE Order 1300.3 Implements Policy in 10 CFR 745

Based on a draft of 10 CFR 745, DOE issued DOE Order 1300.3, "Policy on the Protection of Human Subjects," dated August 23, 1990, to establish responsibilities for implementing policy set forth in 10 CFR 745. The order states that the Director of Energy

Research is responsible for implementation of 10 CFR 745 in DOE. In the Office of Energy Research, the Program Manager, Human Research Subject Activities, Office of Health and Environmental Research, provides the principal human research subject expertise and "is the final authority" in this area.

Executive Order 12333 Governs Conduct of Intelligence Activities

Executive Order 12333, "United States Intelligence Activities," (1) governs conduct of intelligence activities by all agencies within the U.S. Intelligence Community, (2) designates the intelligence element of DOE as a member of the Intelligence Community, and (3) authorizes agencies within the Intelligence Community to provide in part the following assistance to law enforcement authorities:

- "Provide specialized equipment [and] technical knowledge . . . for use by any department or agency"
- "Render any other assistance and cooperation to law enforcement authorities not precluded by applicable law."

EO 12333 additionally states that, "No agency within the Intelligence Community shall sponsor, contract for or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services. The subject's informed consent shall be documented as required by those guidelines."

DOE Intelligence Procedures Adopted Pursuant to EO 12333

EO 12333 authorizes Intelligence Community agencies to collect, retain or disseminate information concerning U.S. persons only in accordance with procedures established by the agency head and approved by the Attorney General. On October 7, 1992, the former Attorney General approved the "Department of Energy Procedures for Intelligence Activities," which were adopted pursuant to EO 12333. Supplements 1 and 2 to the DOE Intelligence Procedures were issued on April 18, 1994, and July 27, 1994, respectively.

The DOE Intelligence Procedures apply to DOE Intelligence Components, which are defined in the Procedures. These Components include eight DOE Field Intelligence Elements as designated by the former Director of the Office of Intelligence. Two of the Field Intelligence Elements are the Defense Programs Technology, Idaho National Engineering Laboratory, and the Systems Research Center, Sandia National Laboratories.

The DOE Intelligence Procedures also apply to all DOE Management and Operating contractors, their subcontractors and employees engaged in intelligence-related Work for Others. Such work includes in part: (1) work for which the cognizant technical DOE Headquarters official is the Director of Intelligence, and (2) the Special Technologies Program that assists, processes, and coordinates all requests from other Federal agencies seeking DOE technical assistance in support of intelligence, counterintelligence, counterterrorism, counternarcotics, and related activities.

Supplement 2 to the DOE Intelligence Procedures states that the DOE Senior Intelligence Officer has the delegated EO 12333 responsibility to oversee and coordinate the intelligence and intelligence-related WFO program within DOE and its contractors, including requests from other intelligence and law enforcement agencies for technical, analytical or research assistance. According to its approved charter, the Special Technologies Program is responsible for such coordination with law enforcement agencies.

According to the "Restrictions" paragraph in the DOE Intelligence Procedures, Executive Order 12333, "United States Intelligence Activities," "prohibits or restricts DOE intelligence components and elements from engaging in . . . research on human beings except with the subject's informed consent and in accordance with Executive Order 12333."

V. RESULTS OF INSPECTION

A. Human Subject Research Projects Not Recognized at the Idaho National Engineering Laboratory

We found that officials at the Idaho Operations Office and the Idaho National Engineering Laboratory did not recognize that three intelligence-related Work for Others projects involved human subject research, as defined by 10 CFR 745. As a result, by accepting the three projects and conducting two of them, the Idaho Operations Office and the Idaho National Engineering Laboratory did not comply with Federal regulations and DOE directives, as follows: (1) INEL did not provide written assurance to DOE that the laboratory would comply with 10 CFR 745; (2) an Institutional Review Board did not review and approve the projects; (3) the Office of Health and Environmental Research did not review and approve the projects; (4) informed consent was not obtained from the subjects involved in the projects; (5) Federal funds were expended on the projects without satisfying 10 CFR 745 requirements; (6) INEL did not provide the Idaho Operations Office

required information regarding human subject research; (7) the process used by the Idaho Operations Office to review and approve WFO projects did not identify human subject research; and (8) INEL did not act in accordance with the DOE Intelligence Procedures in their conduct of the projects. As a result of our review, the Program Manager, Human Research Subject Activities, Office of Health and Environmental Research, issued the Idaho Operations Office a stop work order on the three projects until the conduct of the projects came into compliance with provisions of 10 CFR 745. Within approximately three months, the Idaho Operations Office had taken corrective actions and had received approval from the Office of Health and Environmental Research to conduct the human subject research.

DOE Order 1300.3, "Policy on the Protection of Human Subjects," states that it is the policy of DOE that no research activity involving human subjects shall be initiated until "requirements of this Order and 10 CFR 745 have been met"

Human Subject Research Projects Identified During Our Review

During our review of active intelligence and intelligence-related WFO project records in the Office of Energy Intelligence, we noted three projects sponsored by the National Institute of Justice (NIJ), U.S. Department of Justice (DOJ), that were not identified in the records as being human subject research projects. The three projects were the: (1) "Airbag Restraint System for Patrol Vehicles" (Airbag Restraint System), DOJ 007; (2) "Retractable Spiked Barrier Strip" (Barrier Strip), DOJ 006; and (3) "Fleeing Vehicle Tagging System" (Tagging System), DOJ 008. According to the WFO project records, the Idaho Operations Office accepted the three projects from NIJ in December 1993 for work at INEL. Title 10 Code of Federal Regulations Part 745, Protection of Human Subjects, which became effective on August 19, 1991, was therefore in effect at the time the three NIJ projects were accepted.

In our opinion, the Statements of Work for the three NIJ projects indicated that research on human subjects, as defined by the term "intervention" in 10 CFR 745, would possibly be conducted. The Statement of Work for the Airbag Restraint System project stated that a project objective was to "design and fabricate an airbag device" that, when inflated, could "restrain . . . but not pose a threat of suffocation" to an individual. The Statements of Work for the Barrier Strip and the Tagging System projects stated that the projects built upon a "study currently being done by INEL . . . to determine what mechanical systems or human factors if disrupted could cause a vehicle to be stopped safely by a pursuing police vehicle" (emphasis added) A discussion of the three projects is at Appendix A.

The Human Subject Research Records maintained by the Office of Health and Environmental Research did not contain documentation on the three NIJ projects. The projects, therefore, apparently had not been reported to DOE as being human subject research projects.

We confirmed that the three NIJ projects involved human subject research. The INEL Program Manager for the projects told us that (1) humans had been involved in the conduct of the Airbag Restraint System and Barrier Strip projects, and (2) had been planned for, but not yet been involved, in the conduct of the Tagging System project. The INEL Project Manager/Principal Investigator for the Airbag Restraint System and Barrier Strip projects described how humans had been involved in the conduct of the two projects. We discussed the involvement and planned involvement of humans in the three projects with the Program Manager, Human Research Subject Activities, Office of Health and Environmental Research. We also showed her a video tape regarding how humans were involved in the conduct of the Airbag Restraint System and the Barrier Strip projects. In a followup letter to us she stated, "I would like to confirm that the [three] INEL projects which you identified as utilizing human volunteers, do in fact meet the definition of human subject research as provided in 10 CFR Part 745." She further stated, "It must also be acknowledged that many projects such as these require judgement on whether they fit the definitions Because these projects involve some risk to the volunteer, I am persuaded that the definition must be extended to cover these, despite a less than perfect match with the definition."

Comments from DOE Management

In commenting on a draft of this report, the Director, Health Effects and Life Sciences Division, Office of Health and Environmental Research, stated that "Your office did indeed identify a violation . . . of 10 CFR 745 Protection of Human Subjects." He further stated that "there will always be projects that do not fit neatly into either occupational safety or human research subject categories and must be evaluated on a case by case basis. In the three INEL projects the distinction was not clear. The added individual risk for the involved laboratory personnel created a situation that moved these projects into the human subject protection category."

In commenting on a draft of this report, the then Acting Director, Office of Nonproliferation and National Security, stated, "we believe that the guideline definition of Human Subjects elicits 'gray area' interpretation allowing honest misunderstandings or process errors to occur."

In commenting on a draft of this report, the Chief Financial Officer, Idaho Operations Office, stated that, "The examples and discussion of research activities involving human subject testing in the General Rule all focus on medical research, food testing, surveys, educational testing, and psychological testing. There . . . is [no] reference to the kind of testing that was done at the INEL. The General Rule does not address application of the rule to the testing of devices and machines [Nevertheless,] ID agrees with the DOE Human Subjects Program Manager . . . that when in doubt, consider the project to be a human subject research project."

Following is a discussion of each of the eight items listed on page six, which resulted from the Idaho Operations Office and INEL not recognizing that the three NIJ projects involved human subject research, as defined by 10 CFR 745.

Written Assurance Not Provided to DOE by INEL

The Idaho National Engineering Laboratory conducted two intelligence-related Work for Others projects involving human subject research without providing written assurance to the Secretary of Energy that the laboratory would comply with Title 10 Code of Federal Regulations Part 745.

10 CFR 745 states, "Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy." 10 CFR 745 also states that, "Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section"

DOE Order 1300.3 defines "Assurance" as the "written documentation, satisfactory to the Secretary of Energy [or designee], required from the prospective performing institution that assures institutional compliance with and implementation of DOE regulations for the protection of human research subjects."

DOE officials told us that INEL had not provided DOE written assurance that the laboratory would comply with 10 CFR 745 requirements. The Program Manager, Human Research Subject Activities, Office of Health and Environmental Research (ER-70), who has the responsibility established by DOE Order 1300.3 to approve all human subject assurances, said that INEL had not provided DOE the required assurance. The Assistant Manager, Office of Laboratory Development (Chief Scientist), Idaho

Operations Office, confirmed that INEL had not provided DOE the required assurance.

Projects Not Reviewed by an Institutional Review Board

The Idaho National Engineering Laboratory conducted two intelligence-related Work for Others projects involving human subject research that had not been reviewed and approved by an Institutional Review Board.

According to 10 CFR 745, "Departments and agencies will conduct or support research covered by this policy only if the institution has . . . certified to the department or agency head that the research has been reviewed and approved by an [Institutional Review Board] provided for in the assurance"

DOE Order 1300.3 defines the following:

- Institutional Review Board (IRB) as a "board or committee charged with responsibility for review of research activities involving human subjects conducted at, or sponsored by, the institution and approved by the Department of Health and Human Services" or DOE.
- IRB Approval as the "determination of the IRB that the research has been reviewed and may be conducted at an institution or facility within the constraints set forth by the IRB and by other institutional and Federal requirements."

An Institutional Review Board did not review and approve the Airbag Restraint System and the Barrier Strip projects. As stated previously, we found that INEL had not provided DOE a written assurance, which would have provided for an Institutional Review Board at INEL. In this regard, the Program Manager, Human Research Subject Activities, told us that INEL had not established an Institutional Review Board. She also said that she did not believe that any Institutional Review Board had reviewed and approved the two projects. The Chief Scientist, Idaho Operations Office, confirmed that INEL had not established an Institutional Review Board and that the two projects had not been reviewed and approved by an Institutional Review Board.

Projects Not Reviewed and Approved by ER-70

The Idaho National Engineering Laboratory conducted two intelligence-related Work for Others projects involving human subject research that had not been reviewed and approved by the Associate Director for Health and Environmental Research.

10 CFR 745 states that the department head will evaluate all applications and proposals involving human subjects submitted to the department "through such officers and employees of the department . . . as the department . . . head determines to be appropriate." Additionally, 10 CFR 745 states that on "the basis of this evaluation, the department . . . head may approve or disapprove the application or proposal"

DOE Order 1300.3 assigns the above responsibilities to the following DOE officials:

- the Associate Director for Health and Environmental Research (ER-70), "Reviews all research with human subjects for compliance with DOE regulations and Orders and applicable Federal regulations . . . approves, rejects, or requests additional information on proposed work"
- the Heads of Field Organizations, "request determination of [the] compliance by ER-70" for all Work for Others at DOE-owned or -leased facilities.

The Associate Director for Health and Environmental Research did not review or approve the Airbag Restraint System and the Barrier Strip projects. The Program Manager, Human Research Subject Activities, who reviews and approves human subject research projects for the Associate Director, told us that she had not reviewed or approved the two projects. The Chief Scientist, Idaho Operations Office, confirmed that the two projects had not been submitted to the Associate Director for review and approval.

Informed Consent Not Obtained from Human Subjects

The Idaho National Engineering Laboratory conducted two intelligence-related Work for Others projects involving human subject research without obtaining the informed consent of the subjects.

10 CFR 745 states that:

- "Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject"

- "[I]nformed consent shall be documented by the use of a written consent form approved by the [Institutional Review Board] and signed by the subject"

10 CFR 745 also lists the basic elements of informed consent that must be provided to each human subject.

DOE Order 1300.3 defines "Informed Consent" as the "legally effective consent by the human research subject . . . to participate in research covered under this policy . . . [which] is obtained after providing to the subject the basic elements of informed consent as set forth in 10 CFR Part 745. Informed consent documents shall include disclosure of all potential risks and related consequences or adverse effects, as well as any benefits that may occur as a result of such participation."

INEL did not obtain informed consent from the human subjects involved in the Airbag Restraint System and Barrier Strip projects. The Project Manager/Principal Investigator said that because an Institutional Review Board had not approved the two projects, she did not have a Board-approved written consent form to document the subjects' informed consent. She also said that she had not obtained any form of written consent from the human subjects involved in the two projects. She told us, however, that she had briefed them regarding the conduct of the projects and had obtained their verbal approval to involve them in the projects.

Federal Funds Expended without Satisfying 10 CFR 745

The Idaho National Engineering Laboratory expended Federal funds on two intelligence-related Work for Others projects that involved human subject research without satisfying requirements of Title 10 Code of Federal Regulations Part 745.

10 CFR 745 states, "Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied."

Project records indicated that Federal funds were expended on the Airbag Restraint System and the Barrier Strip projects. According to information in the Office of Energy Intelligence WFO project records, DOE initially obligated \$250,000 to INEL to conduct the two projects and later obligated \$30,000 for modifications. INEL Work Package Documentation for the two projects contained estimated monthly costs, expenditures for specific project activities, and carry over funds into the next fiscal year.

As stated previously, INEL did not satisfy the following requirements of 10 CFR 745 in conducting the Airbag Restraint

System and Barrier Strip projects: (1) provide written assurance to DOE; (2) obtain review and approval by an Institutional Review Board and the Associate Director for Health and Environmental Research; and (3) obtain informed consent of the human subjects.

Required Human Subject Research Information Not Provided

The Idaho National Engineering Laboratory planned to conduct three intelligence-related Work for Others projects without providing DOE required information regarding human subject research because INEL did not recognize that the projects involved such research.

DOE Order 4300.2B, "Non-Department of Energy Funded Work (Work for Others)," with Change 3, dated January 7, 1993, which was in effect at the beginning of this review, requires that DOE contractors who would perform WFO projects must provide to DOE, as applicable, information regarding involvement of human research subjects and an explanation of how the proposed work meets the criteria in paragraph 8a of the order. Paragraph 8a requires responsible contracting officers to certify in writing that WFO projects are consistent with established standards for humane treatment of human subjects involved in research.

The Idaho Operations Office "Work for Other Guidelines" informs INEL personnel who are involved in WFO projects of the procedures that must be followed to assure compliance with existing laws and regulations, including DOE Order 4300.2B. The procedures provide a decision process by which WFO projects are accepted or rejected by the Idaho Operations Office. This decision process includes preparation of a decision package by the contractor in accordance with checklists contained in Appendices E & F of the "Guidelines." The checklist at Appendix E, "Work for Others Check Sheet," states: "Does work require use of human/animal subjects? If yes, DOE-HQ's approval is required." The checklist at Appendix F, "M&O Determination & Certification," states: "Is work consistent with established standards for humane treatment of human or animal subjects involved in research or other activities of the government? If human/animal subjects are involved, DOE-HQ approval is required."

Projects Not Recognized as Human Subject Research by INEL

The consolidated checklists prepared by INEL for the three NIJ projects in accordance with Appendices E & F of the "Work for Other Guidelines" did not state that the projects involved human subject research. The question in Appendix E, "Does work require use of human/animal subjects," was answered, "No." The question in Appendix F, "Is work consistent with established standards for

humane treatment of human or animal subjects involved in research or other activities of the government," was answered, "Yes."

The Program Manager and the Project Manager/Principal Investigator for the three NIJ projects told us that they had thought their projects involved human safety issues, but they had not recognized that they were conducting human subject research. Both project officials said that they thought research on human subjects involved activities such as radiation testing or "sticking needles" in a human. They said that they had therefore not provided the required information regarding human subject research in the decision package to the Idaho Operations Office.

Comments from DOE Management

In commenting on a draft of this report, the Chief Financial Officer, Idaho Operations Office, stated that, "It should be noted that even though ID did not characterize the projects as 'human subject research,' cognitive decisions were made and prudent actions taken . . . all appropriate OSHA requirements were adhered to. The Safety Manager was completely aware of all safety issues"

ID WFO Process Did Not Identify Human Subject Research

The process used by the Idaho Operations Office (ID) to review and approve Work for Others projects did not identify human subject research in three intelligence-related WFO projects because ID officials did not recognize that the projects involved such research.

DOE Order Requirements and Responsibilities

DOE Order 1300.3 states that Heads of Field Organizations have the responsibility to, "Review all proposals and applications to identify research involving human subjects."

DOE Order 4300.2B, with Change 3, requires Heads of Field Elements to review and approve all requests for Work for Others at the facility and include the written determinations required by paragraph eight of the order. Paragraph 8a requires responsible contracting officers to certify in writing that WFO projects are consistent with established standards for humane treatment of human subjects involved in research.

According to the Idaho Operations Office "Work for Other Guidelines," an ID WFO Review Committee meets to determine acceptance or rejection of WFO projects based on criteria set forth in DOE Order 4300.2B and on one criterion established by ID.

The 11 "offices/functions" represented in the WFO Review Committee did not list "Human Subject Research," although "Health and Safety" was listed. If the WFO Review Committee Chairman and the contracting officer decide to accept a project, the "Guidelines" state that a "Determination and Certification" form is prepared and signed by the Contracting Officer. The Contracting Officer's signature indicates that all acceptance criteria for the project have been met.

Projects Not Recognized as Human Subject Research by ID Officials

The "Determination and Certification" form prepared for the three NIJ projects did not state that the projects involved human subject research. The form stated, however, that: (1) the projects were "consistent with established standards for human[e] treatment of human . . . subjects involved in research or other activities" of the Government; (2) the "Request for approval of human subjects [and] DOE/HQ approval" was marked as "not applicable"; (3) the Idaho Operations Office WFO Projects Manager had concluded that "appropriate determinations [were] made as required by DOE Order 4300.2B, paragraph 8.a., and [he recommended] certification of determinations and DOE acceptance"; and (4) the Contracting Officer had certified "that the work to be performed complies with DOE policy as stated in DOE Order 4300.2B . . . Paragraph 8.a."

Officials in the Idaho Operations Office who were responsible for oversight of the three NIJ projects provided us three reasons why they had not recognized that the projects involved human subject research. First, an official in the Office of Intelligence and National Security, said that he relied upon the contractor performing a WFO project at INEL to provide project information regarding the involvement of human research subjects, as required by DOE Order 4300.2B. He told us that INEL project officials, therefore, should have informed him that the three NIJ projects involved human subject research. Second, the officials said that the "prevailing culture" at Idaho Operations Office and at INEL was that human subject research involved the use of radiation. Third, the Human Subjects Point-of-Contact for the Idaho Operations Office at the time of our review said that he was not part of the WFO Review Committee process for reviewing all WFO projects submitted to the Operations Office. He also said, however, that he probably would not have recognized that the three NIJ projects involved human subject research if he had been part of the WFO Review Committee process.

INEL Did Not Act in Accordance with Intelligence Procedures

The Idaho National Engineering Laboratory did not act in accordance with the "Department of Energy Procedures for Intelligence Activities" because the laboratory did not satisfy requirements of Title 10 Code of Federal Regulations Part 745 in conducting two intelligence-related human subject research projects. As stated previously, INEL did not satisfy the following requirements of 10 CFR 745 in conducting the Airbag Restraint System and Barrier Strip projects: (1) provide written assurance to DOE; (2) obtain review and approval by an Institutional Review Board and the Associate Director for Health and Environmental Research; and (3) obtain informed consent of the human subjects.

According to the "Restrictions" paragraph in the DOE Intelligence Procedures, Executive Order 12333, "United States Intelligence Activities," "prohibits or restricts DOE intelligence components and elements from engaging in . . . research on human beings except with the subject's informed consent and in accordance with Executive Order 12333." As stated previously, the DOE Intelligence Procedures were adopted pursuant to EO 12333. In this regard, EO 12333 states that, "No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services. The subject's informed consent shall be documented as required by those guidelines." The Federal policy for the Protection of Human Subjects was based on regulations, i.e., "guidelines," issued by the Department of Health and Human Services for the protection of human research subjects and was promulgated by DOE in 10 CFR 745.

Although INEL officials conducting the Airbag Restraint System and the Barrier Strip projects were not members of the INEL Field Intelligence Element, the DOE Intelligence Procedures were applicable to the conduct of the projects. The DOE Intelligence Procedures apply "to all DOE Management [and] Operating (M&O) contractors, their subcontractors and employees engaged in intelligence-related [Work for Others]." In this regard, the two projects were conducted for the NIJ by employees of the INEL M&O contractor. In addition, two officials and one representative from the Office of Energy Intelligence confirmed that the projects were intelligence-related because they were work (1) for which the Director of Intelligence was the cognizant technical DOE Headquarters official at the time the projects were accepted by DOE, and (2) from a law enforcement agency requesting DOE's technical assistance through the Special Technologies Program.

Stop Work Order Regarding the NIJ Projects Issued

Based on the results of our review at INEL, the Program Manager, Human Research Subject Activities, Office of Health and Environmental Research, issued the Idaho Operations Office a stop work order on November 23, 1994, for the three NIJ projects until the conduct of the projects came into compliance with provisions of 10 CFR 745. According to 10 CFR 745, the "department . . . head may require that department . . . support for any project be terminated or suspended . . . when the department . . . head finds an institution has materially failed to comply with the terms of this policy." DOE Order 1300.3 states that the Office of Health and Environmental Research has the responsibility to investigate "allegations of noncompliance with 10 CFR 745 and this Order, and [recommend] to the . . . Head of [a] Field Organization appropriate action required."

The Chief Scientist, Idaho Operations Office, provided us a copy of his letter dated November 23, 1994, which directed the M&O contractor at INEL to "immediately stop work on any portion of the [three projects] which may involve human subjects in the testing or demonstration of the technologies or products . . . involved." In addition, he told us that he had agreed with the Program Manager, Human Research Subject Activities, that the three NIJ projects involved human subject research.

Conclusions

We found that officials at the Idaho Operations Office and the Idaho National Engineering Laboratory did not comply with Federal regulations and DOE directives because the officials did not recognize that three intelligence-related WFO projects that they had approved and conducted involved human subject research. The Program Manager and the Project Manager/Principal Investigator for the projects said that they thought research on human subjects involved activities such as radiation testing or "sticking needles" in a human subject. Officials in the Idaho Operations Office told us that the "prevailing culture" at the Operations Office and at INEL was that human subject research involved the use of radiation. As a result of our review at INEL, the Program Manager, Human Research Subject Activities, Office of Health and Environmental Research, issued the Idaho Operations Office a stop work order on the three projects until the conduct of the projects came into compliance with provisions of 10 CFR 745.

Recommendations

We recommend that the Manager, Idaho Operations Office:

1. Ensure that the Idaho National Engineering Laboratory provides a written assurance to the Department that INEL will comply with requirements of Title 10 Code of Federal Regulations Part 745, Protection of Human Subjects.
2. Ensure that the Idaho National Engineering Laboratory establishes an Institutional Review Board that satisfies the requirement of Title 10 Code of Federal Regulations Part 745, Protection of Human Subjects.
3. Ensure that requirements of Title 10 Code of Federal Regulations Part 745, Protection of Human Subjects and DOE Order 1300.3, "Policy on the Protection of Human Subjects," dated August 23, 1990, are satisfied before conducting human subject research in the following projects: (1) "Airbag Restraint System for Patrol Vehicles," DOJ 007; (2) "Retractable Spiked Barrier Strip," DOJ 006; and (3) "Fleeing Vehicle Tagging System," DOJ 008.
4. Establish procedures to ensure that the Idaho National Engineering Laboratory recognizes and conducts projects that involve human subject research in accordance with Title 10 Code of Federal Regulations Part 745, Protection of Human Subjects and DOE Order 1300.3, "Policy on the Protection of Human Subjects," dated August 23, 1990.
5. Educate applicable employees of the Idaho Operations Office and the Idaho National Engineering Laboratory in recognizing projects that involve human subject research.

We recommend that the Associate Director for Health and Environmental Research:

6. Provide assistance, as needed, to the Manager, Idaho Operations Office, in establishing a human subject research program that satisfies the requirements of Title 10 Code of Federal Regulations Part 745, Protection of Human Subjects and DOE Order 1300.3, "Policy on the Protection of Human Subjects," dated August 23, 1990.

In commenting on a draft of this report, the Chief Financial Officer, Idaho Operations Office, concurred with recommendations one through five. Regarding the first recommendation, he stated that a written assurance was provided to DOE Headquarters with

documentation requesting review and approval of three Institutional Review Board packages, which were subsequently approved on March 6, 1995. Regarding the second recommendation, he stated that an "ad hoc" INEL Institutional Review Board was established on January 12, 1995. Regarding the third recommendation, the Chief Financial Officer stated that the requirements of 10 CFR 745 and DOE Order 1300.3 were satisfied for the Airbag Restraint System and the Barrier Strip projects, that the projects were approved by DOE Headquarters, and that work involving human subjects had resumed. He added that the Tagging System project was funded as a paper study and "is not subject to any review for human subject testing until the project is funded and the scope of the human subject testing is defined." Regarding the fourth recommendation, he stated that the INEL Institutional Review Board charter was adopted in June 1995, with the Board to meet on an "as needed basis" and at least annually. In our opinion, this statement appears to address the second recommendation. Regarding the fifth recommendation, the Chief Financial Officer stated that applicable training was completed by August 4, 1995. He said that DOE Headquarters developed and provided copies of a brochure to assist applicable ID and INEL personnel to include all "cognizant DOE-ID Program Managers . . . [and] . . . contractor Principal Investigators . . . in recognizing human subject research."

In commenting on a draft of this report, the Director, Health Effects and Life Sciences Division, Office of Health and Environmental Research, concurred with these recommendations and stated that "almost all have been implemented." Regarding recommendations one through three, he stated that actions addressing the recommendations had been implemented. Regarding the fourth recommendation, the Director stated that actions addressing the recommendation had been implemented, but "ongoing education [was] required." Regarding the fifth recommendation, he stated that education in recognizing human subject research was "[o]ngoing at all DOE sites." Regarding the sixth recommendation, the Director stated that assistance had been provided, but "ongoing surveillance/education is required."

B. Human Subject Research Processing Deficiencies at the Sandia National Laboratories

We found that the Sandia National Laboratories had obtained approval of six projects involving human subject research that had been identified and processed using SNL-developed procedures. We also found, however, that SNL had initiated human subject research in two of these projects prior to obtaining required human subject approvals. As a result, SNL expended Federal funds without

satisfying requirements of Title 10 Code of Federal Regulations Part 745, Protection of Human Subjects, and did not act in accordance with the "Department of Energy Procedures for Intelligence Activities."

10 CFR 745 states that:

- "no human subjects may be involved in any project supported by [contracts] until the project has been reviewed and approved by the [Institutional Review Board] as provided in this policy, and certification submitted, by the institution," to the department; and
- the department head will evaluate all applications and proposals involving human subjects submitted to the department through such officers and employees as the department head determines to be appropriate; on the basis of this evaluation, the department head may approve or disapprove the application or proposal.

Approved SNL Projects Listed in Human Subject Research Records

The Human Subject Research Records maintained by the Office of Health and Environmental Research listed six approved human subject research projects at SNL that we believed fell within this review's objectives. The six projects had been (1) identified and processed using SNL-developed procedures and (2) subsequently reviewed and approved by the Sandia Human Studies Board (the SNL Institutional Review Board) and the Associate Director for Health and Environmental Research. We later determined that five of the projects were intelligence-related Work for Others projects, and thus, fell within the objectives of this review. We also determined, however, that the Office of Safeguards and Security, Office of Nonproliferation and National Security, had funded one of the six projects. Although this project was not an intelligence-related WFO project, we decided to review it because Office of Nonproliferation and National Security officials funded and managed the project.

Human Subject Research Initiated Prior to Obtaining Approvals

Based on discussions with the projects' Principal Investigators and a review of project and Human Studies Board records, we found that SNL investigators initiated human subject research in two of the six projects prior to obtaining required approvals. The projects were the (1) "Intelligent Facial Recognition Systems" (Facial Recognition), funded by the Office of Safeguards and Security, and (2) "Smart Gun Technology Project," (Smart Gun), an

intelligence-related WFO project funded by the National Institute of Justice (NIJ), the Department of Justice.

As stated previously, DOE Order 1300.3, "Policy on the Protection of Human Subjects," assigns the following responsibilities:

- Associate Director for Health and Environmental Research (ER-70) reviews all research with human subjects for compliance with DOE regulations and Orders and applicable Federal regulations; approves or rejects proposed work.
- Heads of Field Organizations request determination of compliance by ER-70 for WFO projects and for DOE-funded work originating in the field office.

DOE Order 1300.3 states that no research activity involving human subjects shall be initiated until the requirements of this Order and 10 CFR 745 have been met.

Regarding the Facial Recognition (SNL 9303) and the Smart Gun (SNL 9410) projects, the following chart shows the dates (1) human subject research was initiated and (2) approvals were obtained from the SNL Human Studies Board (IRB) and from the Associate Director for Health and Environmental Research (ER-70).

SNL Project #	Date Human Subject Research Initiated	IRB Approval Date	ER-70 Approval Date
SNL 9303	12/21/92	3/8/93	3/24/93
SNL 9410	7/6/94	7/6/94	8/2/94

The chart shows that SNL initiated human subject research in (1) the Facial Recognition project prior to obtaining approvals from an Institutional Review Board and the Associate Director for Health and Environmental Research; and (2) the Smart Gun project prior to obtaining approval from the Associate Director for Health and Environmental Research.

The Principal Investigators for the two projects discussed with us their reasons for initiating the human subject research prior to obtaining the required approvals. The Principal Investigator for the Facial Recognition project told us that she took video pictures of human volunteers on two days before colleagues informed her that the project possibly had to be reviewed by the SNL Human Studies Board. This activity was the human subject research subsequently approved by the SNL Human Studies Board. She said that she had been aware of human subject research requirements at SNL but had not believed that her project involved

such research. She also said that she did not take any additional pictures until the Human Studies Board and the Associate Director for Health and Environmental Research approved the project.

The Principal Investigator for the Smart Gun project said that he was aware from (1) a monthly bulletin published by the SNL Human Studies Board Administrator regarding information on human subject research and (2) discussions with a colleague conducting another NIJ project which involved human subject research, that the project had to be reviewed by the Human Studies Board. He also said that he thought he could administer a survey, which was the human subject research approved by the Human Studies Board, as soon as the Board approved the project. We noted, however, that the SNL publication, "Information for Principal Investigators," states that a Principal Investigator has the responsibility to show that "approval of the [DOE] Office of Health and Environmental Research (ER-70)" had been received prior to involving any human subject in a research project.

Federal Funds Expended without Satisfying 10 CFR 745

By initiating human subject research in the two projects, and thereby expending Federal funds, prior to obtaining required approvals, SNL also did not satisfy the following requirement in 10 CFR 745: "Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied." The Project Manager for Physical Security Systems, Office of Safeguards and Security, said that DOE had expended \$250,000 on the Facial Recognition project. This sum included funds expended on the project task that involved taking the video pictures. According to WFO project records in the Office of Energy Intelligence, the Department of Justice obligated \$620,000 to SNL to conduct the Smart Gun project. The Interagency Agreement between NIJ and the Albuquerque Operations Office showed an estimated cost of \$45,000 for the project task entitled "Definition of Requirements," which included the survey administered by the project's Principal Investigator.

SNL Did Not Act In Accordance With the DOE Intelligence Procedures

SNL did not act in accordance with the DOE Intelligence Procedures because the laboratory did not satisfy requirements of 10 CFR 745 by initiating human subject research in the Smart Gun project prior to obtaining required approvals. According to the "Restrictions" paragraph in the DOE Intelligence Procedures, Executive Order 12333, "United States Intelligence Activities," prohibits or restricts DOE intelligence components and elements from engaging in human subject research except in accordance with

EO 12333. As stated previously, the DOE Intelligence Procedures were adopted pursuant to EO 12333. In this regard, EO 12333 states that "No agency within the Intelligence Community shall sponsor, contract for or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services." The Federal Policy for the Protection of Human Subjects was based on regulations, i.e., "guidelines," issued by the Department of Health and Human Services and was promulgated by DOE in 10 CFR 745.

Although SNL officials conducting the Smart Gun project were not members of the SNL Field Intelligence Element, the DOE Intelligence Procedures were applicable to the conduct of the project. The DOE Intelligence Procedures apply to all DOE Management and Operating contractors, their subcontractors and employees engaged in intelligence-related Work for Others. In this regard, the project was conducted by employees of the SNL M&O contractor. In addition, Smart Gun was an intelligence-related WFO project, as confirmed by one official from the Office of Energy Intelligence, because the project was work (1) for which the Director of Intelligence was the cognizant technical DOE Headquarters official at the time the project was accepted by DOE, and (2) from a law enforcement agency requesting technical assistance through the Special Technologies Program.

Conclusions

We found that SNL had obtained approval of six projects involving human subject research that had been identified and processed using SNL-developed procedures. We also found, however, that SNL had initiated human subject research in two of these projects prior to obtaining required human subject approvals. As a result, SNL expended Federal funds without satisfying requirements of 10 CFR 745 and did not act in accordance with the DOE Intelligence Procedures.

Recommendation:

We recommend that the Manager, Albuquerque Operations Office:

7. Review procedures at the Sandia National Laboratories that educate employees in recognizing and conducting projects that involve human subject research and direct revision of the procedures, as necessary.

In commenting on a draft of this report, the Acting Area Manager, Kirtland Area Office, Albuquerque Operations Office, concurred with this recommendation. He stated SNL had reviewed procedures that educate employees in recognizing and conducting projects that

involve human subject research, and had determined that the procedures should be revised to ensure that all investigators had a "clear awareness of them." As a result, the Acting Area Manager stated that SNL had undertaken the following: (1) disseminated in March 1995 a Human Studies Board (HSB) pamphlet to enhance Principal Investigators' awareness of regulations and the need to contact the HSB prior to beginning research; (2) draft and distribute by November 30, 1995, a document to increase managerial awareness of HSB requirements; and (3) brief executive management on HSB requirements by January 31, 1996.

In commenting on a draft of this report, the Director, Health Effects and Life Sciences Division, Office of Health and Environmental Research, concurred with this recommendation. He added that "a great deal of effort has been expended at . . . SNL . . . to comply with 10 CFR 745 since its adoption in 1991. [SNL has] created a standard by which other offices and laboratories have been measured."

C. Office of Nonproliferation and National Security Did Not Fully Implement Procedures for Identifying Human Subject Research

We found that the Office of Nonproliferation and National Security (NN) did not fully implement the procedures they had developed to identify human subject research projects. As a result, selected project records did not identify all NN-funded projects and intelligence and intelligence-related Work for Others projects that involved human subject research. Additionally, as a result, the Office of Intelligence approved three intelligence-related WFO projects involving human subject research that were not conducted in accordance with the "Department of Energy Procedures for Intelligence Activities."

Responsibilities to Identify Human Subject Research Projects

DOE Order 1300.3, "Policy on the Protection of Human Subjects," states that Program Secretarial Officers or their designees have the responsibility to "Review all proposals and applications to identify research involving human subjects."

The NN "National Environmental Policy Act (NEPA) and Human Subjects Procedural Manual," dated November 1994, contains the following responsibilities:

- Director, Office of Nonproliferation and National Security: "Ensure that all project managers['] proposals are reviewed to identify research involving human subjects."

- NN Human Subjects Point-of-Contact (POC): "Compile a list of all human subjects projects/programs in NN."
- Program Human Subjects Points-of-Contact within the offices of NN: (1) In coordination with project managers, "review projects/programs to identify those involving human subjects." (2) "Coordinate all human subjects projects/programs with" the NN Human Subjects Point-of-Contact. (3) Provide the NN Human Subjects Point-of-Contact annually with "an updated listing of all human subjects projects."

The draft manual, which was used by the Office of Nonproliferation and National Security prior to November 1994, contained similar responsibilities.

NN Records Identified Some Human Subject Research Projects

The NN Human Subjects POC discussed with us the list of human subjects projects/programs that he had compiled on NN-funded projects and on intelligence and intelligence-related WFO projects reviewed and approved by the Office of Energy Intelligence. Based on a survey he had conducted of the six program offices in the Office of Nonproliferation and National Security, he said that he did not believe the Office was funding any project that involved human subject research. Regarding the WFO projects, the NN Human Subjects POC has the responsibility to review "all Office of Energy Intelligence work-for-others projects for Human Subjects approval." He provided us documentation on one active and five inactive/closed intelligence-related WFO projects identified in the intelligence and intelligence-related WFO project records as being human subject research projects.

NN Records Did Not Identify All Human Subject Research Projects

Project records in the Office of Nonproliferation and National Security did not identify all NN-funded projects and intelligence and intelligence-related WFO projects that involved human subject research. As stated previously, information on the Facial Recognition project, SNL 9303, which was funded by the Office of Safeguards and Security, was contained in the Human Subject Research Records maintained by the Office of Health and Environmental Research. According to these records, the project was initially approved by the Sandia National Laboratories Human Studies Board and the Program Manager, Human Research Subject Activities, Office of Health and Environmental Research, in March 1993, and was reapproved by them in March 1994. The project manager for Facial Recognition, who was in the Planning and

Technology Development Branch, Office of Safeguards and Security, told us that his project records, however, did not identify the project as a human subject research project. He said that he did not know the project had been identified and approved as a human subject research project by the SNL Human Studies Board and the Program Manager, Human Research Subject Activities. The Chief, Planning and Technology Development Branch, also told us that he had not known that the Facial Recognition project had been approved as a human subject research project.

During our review of active intelligence and intelligence-related WFO project records, we noted seven projects that were not identified in the project records as being human subject research projects. These seven projects were designated as DOJ 006, DOJ 007, DOJ 008, DOJ 021, DOD 1071, and DOD 1072, which contained two projects. We later determined that the seven projects involved human subject research. Information on DOJ 021 (Smart Gun) and the three DOD projects was contained in the Human Subject Research Records maintained by the Office of Health and Environmental Research. As previously discussed, DOJ 006 (Barrier Strip), DOJ 007 (Airbag Restraint System), and DOJ 008 (Tagging System) had not been identified, prior to our review, as projects involving human subject research.

NN Procedures for Identifying Human Subject Research Not Fully Implemented

Officials in the Office of Nonproliferation and National Security discussed with us their procedures for identifying human subject research projects. The project manager for the Facial Recognition project, SNL 9303, said that he depended upon the laboratories to identify and inform him of human subject research projects that they were conducting. He told us, however, that he had not established procedures for the laboratories to provide him such information. The project manager also said he would not have thought that the Facial Recognition project was a human subject research project. In addition, he said that he did not know that such projects had to be reported to the NN Human Subjects Point-of-Contact. The Chief, Planning and Technology Development Branch, said that he had also not recognized that the Facial Recognition project involved human subject research.

The NN Human Subjects POC told us that he reviewed proposed intelligence and intelligence-related WFO projects' statements-of-work in order to identify whether the projects involved human subject research. He said that if he believed a project possibly involved human subject research, but had not been identified as such, he: (1) asked the Program Manager, Human Research Subject Activities, Office of Health and Environmental Research, for her

opinion of the project and (2) requested additional information from the applicable Operations Office. He also said, however, that identification of human subject research projects was often difficult because project statements-of-work were often not clear enough for him to identify such research.

In this regard, the Program Manager, Human Research Subject Activities, also told us that statements-of-work for proposed intelligence and intelligence-related WFO projects were often not clear enough for her to identify whether the projects involved human subject research. We discussed with her the statements-of-work for 17 projects noted during our review of WFO project records in the Office of Energy Intelligence, which we believed possibly involved human subject research. The 17 projects, however, were not identified as human subject research projects in the project records. The Program Manager, Human Research Subject Activities, said that the statements-of-work for nine of the 17 WFO projects were not clear enough for her to determine whether the projects involved human subject research. We later determined, as previously stated, that four of these nine projects involved human subject research: the Barrier Strip, Airbag Restraint System, Tagging System, and Smart Gun projects.

Approved WFO Projects Were Not Conducted in Accordance with the DOE Intelligence Procedures

The Office of Energy Intelligence approved three intelligence-related WFO projects involving human subject research that were not conducted by the Idaho National Engineering Laboratory and the Sandia National Laboratories in accordance with the DOE Intelligence Procedures. As stated previously, we found that INEL and SNL had not satisfied requirements of 10 CFR 745 in conducting the intelligence-related WFO projects identified as the Barrier Strip, Airbag Restraint System, and Smart Gun projects. Also as stated previously, we had noted that the three projects were not identified in the intelligence and intelligence-related WFO project records as being human subject research projects.

The NN Human Subjects POC told us that his review of WFO projects to identify human subject research was part of the overall process in the Office of Energy Intelligence for reviewing and approving all intelligence and intelligence-related WFO proposals. DOE Order 4300.2B, "Non-Department of Energy Funded Work (Work for Others)," with Change 3, which was in effect at the beginning of this review, stated that all intelligence-related WFO projects were to be reviewed and approved by the Director, Office of Intelligence, for conformance with EO 12333. DOE Order 4300.2C, Work for Others (Non-Department of Energy Funded Work)," dated December 28, 1994, which superseded DOE Order 4300.2B, requires

that all "Intelligence-related activities will be conducted in accordance with [EO] 12333" DOE Order 4300.2C states that the Director, Office of Energy Intelligence, has the responsibility to review and approve proposed intelligence-related WFO projects. As stated previously, the DOE Intelligence Procedures were adopted pursuant to EO 12333.

The NN Human Subjects POC told us that the lack of clarity in the three projects' statements-of-work had hindered his ability to identify them as human subject research projects. He said that, therefore, the Director, Office of Intelligence, had reviewed and approved the projects without knowing that they involved human subject research.

Conclusions

We found that the Office of Nonproliferation and National Security did not fully implement the procedures they had developed to identify human subject research projects. As a result, selected project records did not identify all NN-funded projects and intelligence and intelligence-related WFO projects that involved human subject research. Additionally, as a result, the Office of Energy Intelligence approved three intelligence-related WFO projects involving human subject research that were not conducted in accordance with the DOE Intelligence Procedures.

Recommendations:

We recommend that the Director, Office of Nonproliferation and National Security, in coordination with the Associate Director for Health and Environmental Research:

8. Establish procedures that will assist the Office of Nonproliferation and National Security in identifying applicable DOE-funded and Work for Others projects that involve human subject research.

We recommend that the Director, Office of Energy Intelligence:

9. Provide applicable agencies with instructions to cite in their statements-of-work for proposed Work for Others projects, as applicable, that human subject research will be conducted in the projects or that humans will be used in conducting the projects.

In commenting on a draft of this report, the then Acting Director, Office of Nonproliferation and National Security, concurred with these recommendations. Regarding the eighth recommendation, he stated that the "Office of Energy Intelligence has an ongoing

effort with the Office of Energy Research to develop a general education program that the Office of Nonproliferation and National Security can use. This course will be presented along with a Human Subjects brochure to enhance human subjects research awareness within the nonproliferation office." He further stated that the Office of Energy Research has provided briefings to intelligence Work for Others personnel on human subject research and will continue this "education" at future intelligence and non-intelligence Work for Others meetings. In addition, the then Acting Director stated that the Office of Energy Intelligence and the Office of Energy Research "are continuing their dialogue concerning utilization of a separate data base for all classified as well as intelligence-related projects [that] . . . will provide an additional human subject research check on projects within the Office of Nonproliferation and National Security." He also stated that the Office of General Counsel is now "reviewing every intelligence related [WFO] project to ensure compliance with" EO 12333, which includes human subject research restrictions.

Officials in the Office of Nonproliferation and National Security provided subsequent comments regarding the eighth recommendation. The Audit Liaison, Office of Nonproliferation and National Security, stated that the dialogue between the Office of Energy Intelligence and the Office of Energy Research will allow the Office of Energy Research (ER) to identify all human subject research projects approved by ER, which are being conducted by an organization monitored by the Office of Nonproliferation and National Security. He also stated that the efforts between the two offices to develop a general education program has resulted in the publication of brochures that enhance human subject research awareness within the Office of Nonproliferation and National Security. The NN Human Subjects POC stated that as a result of their dialogue, the Program Manager, Human Research Subject Activities, Office of Health and Environmental Research, is providing him documentation on human subject research projects that she has approved and that indicate involvement of the Office of Nonproliferation and National Security.

In commenting on a draft of this report, the Program Manager, Human Research Subject Activities, provided additional information regarding the eighth recommendation. She stated that the general education program developed by her office and the Office of Energy Intelligence enhances human subject research awareness within all of DOE as well as the Office of Nonproliferation and National Security. The Program Manager also stated that she is working with the Office of Nonproliferation and National Security to create, by May 1996, the separate database for classified human subject research projects, should any such projects be identified in the future.

Regarding the ninth recommendation, the then Acting Director, Office of Nonproliferation and National Security, stated that the Office of Energy Intelligence "has: (1) increased its training for sponsoring organizations emphasizing human subject testing and safety of [DOE] employees and, (2) requested sponsoring organizations to consider, and incorporate as appropriate, human subject testing in their statements of work." He further stated that the brochure . . . developed by the Office of Energy Research will be provided to each sponsor. In addition, the Director, Office of Energy Intelligence, provided us a memorandum that provided addressees with instructions regarding human subject research information to be included in their statements-of-work for proposed Work for Others projects. Members of the Intelligence Community were among the addressees.

In commenting on a draft of this report, the Director, Health Effects and Life Sciences Division, Office of Health and Environmental Research, concurred with these recommendations. He stated that communication "within NN offices does need to be strengthened, so that the cognizant individual [NN Human Subjects POC] gets informed properly." The Director also stated that "a great deal of effort has been expended at . . . NN . . . to comply with 10 CFR 745 since its adoption in 1991." He stated that NN procedures for processing human subject research projects are "well implemented" if the NN Human Subjects POC is aware of the projects.

D. Familiarization Training Not Conducted

We found that the Director, Office of Energy Intelligence, had not ensured that DOE Management and Operating contractors, who were not members of a DOE Field Intelligence Element but were engaged in intelligence-related Work for Others projects, had received required training to familiarize them with Executive Order 12333, "United States Intelligence Activities," and the "Department of Energy Procedures for Intelligence Activities." As a result, the Director, Office of Energy Intelligence, issued a memorandum to the Directors of each Field Intelligence Element which stated they were responsible for ensuring that all employees involved in intelligence-related activities received appropriate training on Executive Order 12333 and the DOE Intelligence Procedures.

The DOE Intelligence Procedures state that, "Each DOE Intelligence Component shall familiarize its personnel with the provisions of Executive Order 12333, these Procedures, and any instructions implementing these Procedures which apply to the activities of such component." According to the DOE Intelligence Procedures,

the Director, Office of Energy Intelligence, "shall ensure that training is conducted to achieve the requisite familiarity."

The DOE Intelligence Procedures apply to all DOE Intelligence Components, which includes Field Intelligence Elements (FIEs), and DOE M&O contractors engaged in intelligence-related WFO projects.

Non-FIE Members Who Had Not Received Training Engaged in Projects

Six employees of the Sandia National Laboratories M&O contractor, who were not members of the SNL Field Intelligence Element, said that they had been engaged in WFO projects that we knew were intelligence-related. They also said that they (1) did not know that the projects were intelligence-related; (2) did not know that the DOE Intelligence Procedures were applicable to the projects; and (3) had not received training on EO 12333 and the DOE Intelligence Procedures. The six employees were the projects' principal investigators, their supervisors, and a senior manager who was responsible for three of the projects.

In addition, two employees of the Idaho National Engineering Laboratory M&O contractor told us that employees of the M&O contractor, who were not members of the INEL Field Intelligence Element, were engaged in three intelligence-related WFO projects. The Manager of National Security Programs, who was also the Director of the INEL Field Intelligence Element, told us that INEL employees could be temporarily assigned to the FIE when they were required to work on intelligence-related projects. He said that he provided familiarization training on EO 12333 and the DOE Intelligence Procedures to such employees. The Manager also said, however, that he had not yet provided familiarization training to employees engaged in the three intelligence-related WFO projects because he had just recently been assigned the projects. The Project Manager/Principal Investigator for two of the projects confirmed that she had not received the familiarization training.

Responsibility for Providing Familiarization Training Established

The Director, Office of Energy Intelligence, acknowledged to us in a meeting on February 22, 1995, that he was responsible for providing the required familiarization training to M&O contractors who conducted intelligence-related WFO projects, but were not members of a Field Intelligence Element. Stating in the memorandum that the "DOE Inspector General has raised this issue in past intelligence . . . inspections," the Director, Office of Energy Intelligence, subsequently issued a March 13, 1995, memorandum regarding training on EO 12333 and the DOE Intelligence Procedures. The memorandum stated:

"Executive Order 12333, 'United States Intelligence Activities,' and the DOE 'Procedures for Intelligence Activities' apply to all DOE employees, detailees, contractor and subcontractor employees assigned to or acting on behalf of a DOE Intelligence Component or Field Intelligence Element at any time. This includes individuals engaged, even on a temporary or sporadic basis, in any intelligence-related work"

The memorandum further stated that the Director of each Field Intelligence Element has "the duty . . . to ensure that all employees involved in intelligence-related activities receive appropriate training on the Executive Order and the DOE Intelligence Procedures."

Conclusions

We found that the Director, Office of Energy Intelligence, had not ensured that DOE M&O contractors who were conducting intelligence-related WFO projects, but were not members of a DOE Field Intelligence Element, had received required familiarization training on EO 12333 and the DOE Intelligence Procedures. The DOE Intelligence Procedures apply to all DOE M&O contractors engaged in intelligence-related WFO projects as well as to DOE Intelligence Components, which includes DOE Field Intelligence Elements. As a result, the Director, Office of Energy Intelligence, issued a memorandum to the Directors of each Field Intelligence Element which stated they were responsible for ensuring that all employees involved in intelligence-related activities received appropriate training on EO 12333 and the DOE Intelligence Procedures.

Recommendation:

We recommend that the Director, Office of Energy Intelligence:

10. Assist Directors of each Field Intelligence Element, as needed, in ensuring that all employees of applicable Management and Operating contractors, who are involved in intelligence-related Work for Others projects, receive familiarization training on Executive Order 12333 and the "Department of Energy Procedures for Intelligence Activities."

In commenting on a draft of this report, the then Acting Director, Office of Nonproliferation and National Security, concurred with this recommendation. He said that the "Office of Energy Intelligence will continue its ongoing program to provide training on the various aspects of Executive Order 12333. In memoranda to

the field, Directors of Field Intelligence Elements were reminded to ensure temporarily assigned personnel, certain support personnel, and members of the Federal establishment are properly trained and not wait for annual Headquarters sponsored training."

VI. CONCLUSIONS

We found that officials at the Idaho Operations Office and the Idaho National Engineering Laboratory did not comply with Federal regulations and DOE directives because the officials did not recognize that three intelligence-related Work for Others projects that they had approved and conducted involved human subject research. The Program Manager and the Project Manager/Principal Investigator for the projects said that they thought research on human subjects involved activities such as radiation testing or "sticking needles" in a human subject. Officials in the Idaho Operations Office told us that the "prevailing culture" at the Operations Office and at INEL was that human subject research involved the use of radiation. As a result of our review at INEL, the Program Manager, Human Research Subject Activities, Office of Health and Environmental Research, issued the Idaho Operations Office a stop work order on the three projects until the conduct of the projects came into compliance with provisions of 10 CFR 745. Within approximately three months, the Idaho Operations Office had taken corrective actions and had received approval from the Office of Health and Environmental Research to conduct the human subject research.

We found that the Sandia National Laboratories had obtained approval of six projects involving human subject research that had been identified and processed using SNL-developed procedures. We also found, however, that SNL had initiated human subject research in two of these projects prior to obtaining required human subject approvals. As a result, SNL expended Federal funds without satisfying requirements of Title 10 Code of Federal Regulations Part 745 and did not act in accordance with the "Department of Energy Procedures for Intelligence Activities."

We found that the Office of Nonproliferation and National Security did not fully implement the procedures they had developed to identify human subject research projects. As a result, selected project records did not identify all NN-funded projects and intelligence and intelligence-related WFO projects that involved human subject research. Additionally, as a result, the Office of Energy Intelligence approved three intelligence-related WFO projects involving human subject research that were not conducted in accordance with the DOE Intelligence Procedures.

We found that the Director, Office of Energy Intelligence, had not ensured that DOE Management and Operating contractors who were conducting intelligence-related WFO projects, but were not members of a DOE Field Intelligence Element, had received required familiarization training on Executive Order 12333 and the DOE Intelligence Procedures. The DOE Intelligence Procedures apply to all DOE M&O contractors engaged in intelligence-related WFO projects as well as to DOE Intelligence Components, which includes DOE Field Intelligence Elements. As a result, the Director, Office of Energy Intelligence, issued a memorandum to the Directors of each Field Intelligence Element which stated they were responsible for ensuring that all employees involved in intelligence-related activities received appropriate training on EO 12333 and the DOE Intelligence Procedures.

THREE INTELLIGENCE-RELATED WORK FOR OTHER PROJECTS at INEL

The Statement of Work for the "Airbag Restraint System for Patrol Vehicles" (Airbag Restraint System) stated, in part,

"The principal task objective is to design and fabricate an airbag device which can be mounted in the rear seat compartment of a patrol vehicle and which can be remotely deployed by the driver of the vehicle. The airbag will inflate at a rate sufficient to quickly physically restrain an individual passenger who has suddenly become violent and will remain inflated, at the driver's discretion, with a force sufficient to prevent harmful action by the passenger but not with a force that will result in injury.

"The only apparent safety concern seen by NIJ is the possibility that a passenger restrained by the airbag could inadvertently be suffocated. An important requirement for the airbag therefore will be that such an inadvertent event have a low likelihood of occurrence."

An objective of this project was to determine the effects of an inflated airbag restraining device on humans, which in our opinion, possibly indicated research to obtain data on human subjects through intervention with them, i.e., manipulation of their environment for research purposes.

The Statement of Work for the "Retractable Spiked Barrier Strip" (Barrier Strip) stated, in part,

"[This] project . . . will build upon the study currently being done by INEL on potential methods to halt fleeing vehicles . . . [which had as a] principal focus . . . to determine what mechanical systems or human factors if disrupted could cause a vehicle to be stopped safely by a pursuing police vehicle [The] project will have as its focus the design and fabrication of a device for puncturing the tires of the fleeing vehicle to effect a safe stop. This approach may not be ideal, particularly because it requires officers to be able to place the device in front of the path of the fleeing vehicle, but it is more straightforward than techniques under consideration that would be activated from a pursuing vehicle and it is fraught with far fewer potential safety and health risks than current techniques to physically stop fleeing vehicles."

The principal focus of this project was to determine in part what human factors, if disrupted, could cause a vehicle to be stopped safely by a pursuing police vehicle, which in our opinion, also possibly indicated research to obtain data on human subjects through intervention with them, i.e., manipulation of their environment for research purposes.

The Statement of Work for the "Fleeing Vehicle Tagging System" (Tagging System) stated, in part,

"The principal task objective is to design and fabricate a projectile launcher that can emplace a tagging device onto the surface of a fleeing vehicle from a pursuing law enforcement officer's patrol vehicle One major requirement or specification is that the projectile not pose asafety [sic] hazard to any pedestrian that may be inadvertently struck should the fleeing vehicle be missed when the projectile is fired."

This project also built upon the study done by INEL on potential methods to halt fleeing vehicles which had as a principal focus, "to determine what mechanical systems or human factors if disrupted could cause a vehicle to be stopped safely by a pursuing police vehicle"

Project Officials Discuss Use of Human Subjects

The Program Manager for the three projects told us that humans had been involved in the conduct of the Airbag Restraint System and Barrier Strip projects, but had not yet been involved in the conduct of the Tagging System project. He said that work on the Tagging System project was still in the research stage, but that he had planned originally to involve humans in driving the "fleeing vehicle."

Regarding the Airbag Restraint System project, the Project Manager/Principal Investigator said that the airbag had been inflated "less than a dozen times" on a human in a mockup prototype, and the effects of the inflated airbag on the human were monitored. Regarding the Barrier Strip project, she told us that the strip was remotely activated to puncture the tires of a moving vehicle to cause a slow leak, and the driver's ability to control the vehicle was then monitored. The Project Manager/Principal Investigator said that two drivers were used to conduct a series of tests that increased the vehicle's speed five miles per hour (mph) every iteration and culminated with the vehicle being driven over the barrier strip at 55 mph.

The Project Manager/Principal Investigator told us that she had consulted with the contractor's Human Factors Engineering Group regarding design criteria of the Airbag Restraint System and the Barrier Strip projects. She said that a Safety Engineer reviewed the two projects to determine potential harm to humans who would participate in project tests. She also said that the Safety Engineer had deemed the projects "safe" for testing on humans.

The Safety Engineer consulted by the Project Manager/Principal Investigator also told us that he had deemed the Airbag Restraint System and the Barrier Strip projects "safe" for testing on humans. He described the scenarios he had been shown regarding the use of humans in both projects. His descriptions, however, did not indicate that he had been shown the full extent of how human subjects were used in the two projects as described to us by the Project Manager/Principal Investigator. We discussed with the Safety Engineer how human subjects had been used in the two projects, as described to us. He said that such scenarios had not been shown or described to him. The Safety Engineer added that regarding safety issues, he would have further "questioned . . . the use of humans in the projects" if such scenarios had been shown or described to him.

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