Q&A regarding human radiation experiments

Q: The Advisory Committee on Human Radiation Experiments (ACHRE) has recommended to the President that the Government apologize to those experiment subjects that participated in human radiation experiments (HREs) without giving informed consent. Several Federal Agencies have already stated that it would be very difficult to locate the majority of these subjects. Why is it so difficult to locate these individuals given the vast resources at the command of the Government?

A: Many of the experiments that the ACHRE has found to involve questionable informed consent took place as long as forty years ago. Information that would identify participants in these experiments has been destroyed long ago in accordance with standard record destruction procedures. In other cases, the limited information that is available does not provide identifying information such as names, social security numbers, military identification numbers, dates and places of birth or other such data.

A major source of information, and one which we are counting on to assist us in the difficult task of identifying experiment participants, are public inquiries. With the help of letters, questionnaires, and other documentation submitted by the public, the Government will conduct in-depth research to determine participation in experimental research. The Government is committed to make every effort to contact participants in questionable experiments.

Q: What will the Government do to ensure that the present high-profile effort to allow the public access to information related to HRE will continue after the ACHRE has been disbanded?

A: In December 1993 the President immediately enacted steps to determine the degree of Governmental involvement in HREs. This commitment to determining the facts has been carried out by the agencies. Senior government officials, such as Secretaries O'Leary, Perry and Brown, are dedicated to a complete accounting of the Government's role in this issue. Each agency will continue to conduct research related to the many thousands of inquiries from the public that have been received. This research is an on-going effort.

Q. Did the DoD establish any expedited processes for document declassification?

A. Guidance for declassification procedures is provided by DoD Directive 5200.1-R Chapter III. DoD's purpose was to be consistent with the guidance issued by the Secretary of the Cabinet on 19 January 1994, which directed agencies to "institute procedures consistent with existing statutes and regulations, for making records on human radiation experiments . . . available to the public." However, we also understood the urgency and priority of our task, therefore in his 31 January 1994 Memorandum, Dr. Smith explicitly stated that every effort must be made to expedite the declassification process.

In early 1995, Dr. Smith provided a memorandum to accompany all requests for mandatory declassification review of documents identified as pertinent to the HRE review. This memorandum explained the urgency of declassifying records as completely as national security concerns allow, and as expeditiously as possible. Approximately 1,200 records have been declassified as a direct result of the HRE review. These records have been provided to the ACHRE.

Q: To date the Government has declassified thousands of documents related to the HRE review. Will declassification of pertinent documents remain a high-priority for the Government?

A: Documents that are located as a result of additional research related to public inquiries will be reviewed for declassification with the same significance as those documents reviewed since January 1994. The Government, from the President on down, is committed to operating in a more open and accountable manner. For example, recently Executive Order 12958 was issued that requires that within 5 years from the date of the order, all national security information contained in records that are more than 25 years old and that have been determined to have permanent historical value shall be automatically declassified whether or not the records have been reviewed. This effort is in line with the administration effort to maximize openness in government.

Q: Several times over the past year and a half the Government has revealed that documents related to important aspects of the HRE review had been destroyed. Why were these documents destroyed and what is going to be done to ensure that this problem will not be encountered in the future?

A: In January 1994 the agencies placed an immediate stop to the destruction of records that could possibly be related to HREs. Since then, no pertinent records have been destroyed. However, until that time, normal destruction routine was followed. The Government created hundreds of millions (or tens of millions) of records during the Cold War. Because of this massive volume of records it is necessary to destroy records each year to allow the storage of more current information.

While it would be impossible to retain all these documents, specific procedures are currently in place to guide records managers and archivists in determining what records are of historical value. Unfortunately, it is difficult to determine what future needs will be. The ACHRE has made several recommendations related to records management

Q: What types of experiments has the DoD identified during its HRE review?

A: The DoD has identified approximately 2,600 possible HREs that were either conducted or sponsored by the DoD. In order to comply with the guidance to err on the side of inclusion when reviewing experiments, most of the experiments identified appear to be

diagnostic or therapeutic research.

Q. Is the DoD now conducting any experiments involving human subjects that are classified?

A. No classified human radiation experiments are currently being conducted by the DoD.

Q. What Federal statutes cover DoD research using human subjects, and what sanctions or penalties can be applied for violation of these statutes?

A. The major provisions of federal law and regulations applicable to DoD research using human subjects are: (a) 10 USC Section 980, which generally provides that DoD funds may not be used for research involving a human being as an experimental subject without the informed consent of the subject (or in certain cases the legal representative of the subject); (b) 32 CFR Part 219, DoD's implementation of the Federal Policy for the Protection of Human Subjects (the "common rule"), adopted pursuant to 42 USC Section 300V-1(b), which established agency responsibilities regarding recommendations of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Research; and (c) 21 CFR Part 50, the Food and Drug Administration's regulation on protection of human subjects in clinical investigations subject to the Federal Food, Drug and Cosmetic Act. Possible sanctions for failure to comply with these requirements depend on the context. For contractors and grantees, noncompliance could result in a termination of the contract or grant. For DoD personnel, a range of disciplinary measures could be taken under both civil service or military personnel systems.

Q. When soliciting volunteers, are any other inducements offered, such as commendations, promotions, or other benefits not available to non-volunteers?

A. No inducements are offered to active duty military personnel or civilians that are not available to non-volunteers, with two exceptions. Active duty soldiers may be compensated a nominal amount for blood contributed for scientific analysis, but not for transfusion. Other private citizens may enter into an independent contractual relationship and participate for compensation. However, the amount of compensation is determined by the burden of time required of the subject for participation. In all cases, the proposed dollar values are evaluated by the research review committees, so that the amount is justly compensatory, but not coercive. The issue of the coercion of subjects is taken extremely seriously. DoD views the protection of the human subject as a major responsibility.

Q: How many HRE inquiries has the DoD received to date and how many additional HRE-related inquiries can the DoD expect?

A: To date the DoD has received and responded to over 7,000 inquiries on HRE. The future

influx of inquiries is contingent upon the media and Congressional interest. Currently, the RECC is receiving approximately 5 new inquiries per week.

Q: How many Congressional actions have been received?

A: As of 15 September 1995, 233 Congressional actions have been received. The frequency of Congressional inquiries has increased recently.

Q: How many Freedom of Information Act (FOIA) requests have been received?

A: As of 15 September 1995, 19 FOIA requests have been received. However, as with the Congressional inquiries, the frequency of such requests is increasing. Recent FOIA requests are asking for the availability of RECC information on the Internet or other public access vehicles.

Q: What are the concerns on answering FOIA requests *vis a vis* the Privacy Act?

A: Extreme care is being taken to ensure that information protected by the Privacy Act is redacted from any information being released by the RECC. Concurrently, the RECC is taking reasonable steps to ensure that any Privacy Act protected information that is being released is being sent to the individual about whom it concerns. In the case of this individual being deceased, communication with documented family members is occurring. General release of any such information to the public at large is not currently permitted.

Q: What type of records has DoD located related to HREs?

A: During the first half of 1994, the DoD focused on searching for records related to HREs that had been identified. Since June of 1994, the DoD focused on locating records on the development of DoD policy on the use of humans in experimental research and the historic organizational structure of DoD's research and development efforts during the Cold War.

This search has resulted in the identification, and when necessary declassification, of agendas, meeting minutes and transcripts, reports, policy papers, correspondence, memoranda, letters, research reports, bibliographies and contracts. This information has been provided to the ACHRE.

Q. Where were the records located that DoD reviewed?

A. A Memorandum of January 31, 1994, from the ATSD(AE), Dr. Smith, directed DoD agencies and departments to identify organizations that might have conducted or sponsored human radiation experiments from 1944 to the present. This directive includes

predecessor organizations.

Records were located at a variety of repositories, some controlled by DoD and some by other Agencies. These repositories include archives, libraries, record centers, laboratories, contractor organizations, government agencies, university facilities, medical centers, and military installations. Some of the locations identified include the Federal Records Center, Suitland, Maryland; Federal Personnel Records Center, St. Louis, Missouri; Naval Medical Research Institute, Bethesda, Maryland; Naval Hospital, San Diego, California; Dugway Proving Ground, Utah; the Army Training and Doctrine Command, Fort Monroe, Virginia; and Armstrong Laboratory, Brooks Air Force Base, Texas and Wright-Patterson Air Force Base, Ohio. Another illustration of the search's scope is that one reporting agency identified 33 sites where records were reviewed.

Q. What did the DoD do to ensure uniformity of standards in how records pertaining to radiation experiments were collected and reviewed to determine what will be publicly disclosed?

A. In line with the 19 January 1994 White House Memorandum, the Human Radiation Interagency Working Group and other Federal departments and agencies coordinated to develop common procedures for record retrieval and inventory.

Within the Department, to supplement existing policies on declassification, the Freedom of Information Act, and records management, several procedural and organizational initiatives were implemented. Early in January 1994, directions were issued to stop the routine destruction of documents related to human radiation experiments, and guidance was issued on types of documents to retain. Subsequently, a 31 January 1994 Department Memorandum from ATSD(AE) provided detailed guidance on locating, identifying, reviewing, and declassifying records pertaining to human radiation experiments.

The memorandum also contained a standard format for organizations to report the results of their review. The results were reported in two parts. In Part I, the agency was required to report each organization under its control that may have conducted experiments; the location(s) where records might be stored; a description of the efforts undertaken to confirm that records exist at the location(s) identified; and if records were found. Part II required a description of each experiment identified as a result of activities described in Part I. Each experiment was to be described as follows: identification of experiment or possible experiment; where and when it took place; name of primary researcher(s); DoD organizations, grantees, or contractors involved in the experiment; number of human subjects (including available information on subjects); summary of experiment; records location; estimated nature and quantity of records; and whether the records were classified, and, if so, what actions had been or would be taken to review the classification.

These external and internal initiatives in conjunction with current Department policies are in place to provide mechanisms to ensure uniformity of collection standards and for reviewing information released to the public.