

CURRENT AGENCY ACTIVITIES RELATING TO IMPROVING HUMAN SUBJECTS RESEARCH PROTECTIONS

The following are specific activities that have been undertaken by agencies involved in the human radiation experiments effort in relation to, or as a result of, their review of current human research in light of the Advisory Committee recommendations.

The Department of Energy

- Revised and updated the *DOE Human Subjects Research Handbook (2nd Edition)*. The handbook specifically addresses issues raised by the Advisory Committee on informed consent and classified research as well as all other areas of human subjects protections and provides regulations, resources, and models. The manual has been distributed throughout DOE and to other parts of the government as well.
- Has begun a program of regular site visits to its facilities performing human subjects research, for education and review. Each site will be visited approximately once every 3 years. Five laboratories and three field offices were visited by a team in 1996.
- Requested all DOE laboratories to provide a sample of current informed consent documents. These were reviewed to improve and monitor the quality of these documents and a similar request will be made in late 1997.
- Has begun drafting three model informed consent documents that will be sent to all sites to adapt and use, one for genetic research, one for biomedical research, and one for human factors research.
- Requested all laboratories to provide plans that detail local education activities to improve the human subjects research review system. This request will be updated during FY 1997.
- Put DOE's Fiscal Year 1995 and 1996 Human Subjects Database on the Internet.

- Updated the DOE Human Subjects Research Home Page with access to all DOE information, contacts, and resources. These include information about educational workshops and conferences related to generic human subjects research issues. (www.er.doe.gov/production/oher/humsubj/index.html)
- Continued the twice-yearly meetings of DOE-wide human subjects working group. The DOE human subjects research newsletter, *Protecting Human Subjects*, is widely distributed twice-yearly both inside and outside the agency.
- Sponsored a large, interagency human subjects workshop to highlight the ACHRE report and other bioethical issues. This ongoing series is undertaken every other year. The meeting in June 1997 is on “Human Subjects and Genetics Research: The Changing Landscape.”
- Is joining NIH and VA in co-sponsoring a research program on the informed consent process.

The Department of Defense

- Reviewed in detail existing DOD policies and procedures for the protection of human research subjects and has undertaken extensive revision of DOD Directive 3216.2, “Protection of Human Subjects in DOD Supported Research.”
- Implemented changes to current policies that:
 - Adopt investigator assurances of familiarity with the Nuremberg Code, the Belmont Report, the Common Rule, and related requirements;
 - Incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals;
 - Include specific language in the revised directive that would emphasize the expedited review process for certain categories of minimal risk research that are detailed in the Common Rule (32 CFR 219);
 - Require education in human subjects regulations at the executive level of training for commanders and senior civilians who may be involved in human subjects research and for individual investigators, IRB members, research administrators, and support personnel; and

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- Ensure that officers and senior NCOs (non-commissioned officers) in the chain of command not be present during research recruitment briefings of personnel under their command, and that an ombudsman be present at group recruitment briefings.

The National Aeronautics and Space Administration

- Established an external Bioethics Policy Task Force to review all NASA human use research policies and procedures, chaired by Baruch Brody, Ph.D., Leon Jaworski Professor of Biomedical Ethics and Director of the Center for Ethics, Medicine and Public Issues at Baylor College of Medicine. The final report of the Task Force was provided on February 14, 1996. In collaboration with the Task Force, NASA enhanced the conduct of human subjects research so that it satisfies the requirements both of the Federal Common Rule and of the highest principles of research ethics.
- Updated the NASA Management Instruction (NMI) on the conduct of Human Research, issued on August 8, 1995, to reflect the Federal Common Rule and incorporate the relevant recommendations reflected in the Advisory Committee's *Final Report*. NASA Headquarters has also established a process for oversight and assurance. An Agency Authorizing Official has been named for the authorization of human research and the protection of human subjects. Documentation of assurance of human subjects protection is required every 5 years, from all nine NASA Field Installations and the Jet Propulsion Laboratory, if the Center is conducting human subjects research. Centers not conducting such research must recertify by letter every year.
- Conducted internal reviews at Headquarters, Johnson Space Center, and Ames Research Center to ensure that elements of the Common Rule and Advisory Committee recommendations were incorporated into agency and center instructions.
- Because much of its future space research will be conducted with its partners on the International Space Station, has conducted the first in a series of forums to inform NASA's international biomedical community on issues related to the ethics of human subjects research. These workshops will effect a transnational understanding of the sensitivity to ethical issues in human research and ensure that all international partners support common ethical principles regarding the protection of human subjects. A common consent form for use on the International Space Station was agreed upon and will undergo periodic review.
- Initiated ethics forums on the Common Rule and protection of human subjects for its domestic biomedical research community.

The Central Intelligence Agency

- Obtained the services of a prominent ethicist from the academic community to become a permanent voting member of the Agency's Human Subjects Research Panel (HSRP).
- Revised agency regulations to indicate that all research carried out or sponsored by the Agency that utilizes human subjects shall be brought to the HSRP for approval. The Chairman must certify as exempt or approve a research proposal before it can proceed; final approval rests with the Agency Director.
- Disseminated an agency bulletin to all employees specifying the rationale and function of the panel and necessity of referring human subjects research to it for approval.
- Revised the Agency's Contracting Manual to guarantee that HSRP approval is obtained prior to approval of any contract involving human subjects research.

The Department of Health and Human Services

- Coordinates Interagency Request for Applications from researchers, to develop new knowledge related to the informed consent process.
- Expanded technical assistance to IRBs at institutions receiving DHHS research funds, by means of 12 to 24 site visits per year.
- Increased activities to improve the procedures for protecting human subjects. For example, CDC is developing an online education system in research integrity and ethics that will be mandatory for investigators.
- Provides administrative support for NBAC.

The Food and Drug Administration

- Has the largest IRB oversight program of any Federal agency and the only Federal program for oversight of radioactive drug research committees.
- Performs periodic on-site inspections of all IRBs that are known to review FDA-regulated studies. In cases of serious non-compliance, FDA suspends approval of new studies and accrual of new subjects into ongoing studies. Such sanctions are imposed on over 20 IRBs per year.

- Has recently expanded the scope of its on-site inspection program of radioactive drug research committee (RDRC) to include evaluation of the quality of the drugs and the scientific and medical justification of radiation use.
- Is revising the RDRC regulations to strengthen the safeguards to human subjects.

Other Agencies

- VA has planned IRB site visits to review procedures and their Office of Research and development is reviewing its policy manual to identify any needed revisions.
- The Department of Education anticipates reporting to NBAC on ongoing training activities, and efforts to disseminate information through guidance documents and establish networks within that Department.
- The Environmental Protection Agency (EPA) is updating an internal order on human research subjects to implement the Common Rule.
- The Consumer Product Safety Commission is updating and changing its internal documents and policies.