PROTECTING HUMAN SUBJECTS

U.S. DEPARTMENT OF ENERGY • OFFICE OF BIOLOGICAL AND ENVIRONMENTAL RESEARCH

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Contents

Lessons from the Past; Challenges for the Future

Human Subjects Conference 1995

On October 2–3, 1995, noted researchers, ethicists, and others concerned with research involving human subjects and the protection of human subjects convened at the National Institutes of Health's National Library of Medicine for *Lessons from the Past: Challenges for the Future*. Sponsored by the U.S. Department of Energy's (DOE) Office of Health and Environmental Research (OHER) and the Human Subjects Research Subcommittee of the National Science and Technology Council, the interagency conference coincided with official release of the *Final Report of the Advisory Committee on Human Radiation Experiments* (ACHRE), which the Committee presented to President Clinton on October 3.

The conference brought together 135 representatives of 16 Federal agencies, 9 national laboratories, and 10 universities/research centers, many of whom had assisted ACHRE in its quest to evaluate the impact of radiation research conducted from 1944 to 1974 on the human subjects involved.

Participants previewed the outcomes of ACHRE's work, listened to presentations and discussions of critical issues in human subjects research, and voiced their own concerns about the conduct of contemporary and future research.

Among the issues addressed were historical records collection, nonprotocol studies (also known as compassionate-use or single-use protocols), ethical issues related to repositories and gene research, children as research subjects, informed consent in emergency room research, equipment testing as human subjects research, audits of research to ensure regulatory compliance, occupational surveillance, and the assurance process.

Dr. Susan Rose, manager of the human research subjects program for DOE's Office of Energy Research, and Dr. Joan P. Porter, currently on loan from the National Institutes of Health to the Presidential Advisory Committee on Gulf War Veterans' Illnesses, organized and hosted the conference.

Results of DOE Openness Initiative

In December 1993, Secretary of Energy Hazel R. O'Leary released documents related to human radiation experiments conducted in the 1940s. She promised that the Department would collect and review historical data about these experiments and release as much information to the public as legally possible. Because seven other Federal agencies were potentially involved in similar experiments, President Clinton created the Human Radiation Interagency Working Group in January 1994, composed of the respective cabinet level secretaries. One of the Working Group's tasks was to coordinate the Federal response on past human radiation experiments—a response that would require a Government-wide records search.

At the same time, the President established an independent Advisory Committee on Human Radiation Experiments (ACHRE) to provide expert advice and recommendations on the human radiation studies uncovered by the records search. He directed each agency represented on the Human Radiation Interagency Working Group to provide relevant historical records and other pertinent information to ACHRE so that the Committee could fulfill its independent mission.

DOE's Special Office

In March 1994, in response to these official directives, DOE set up the Office of Human Radiation Experiments (OHRE) to take responsibility for the records search, provide information to ACHRE, answer written and telephone inquiries from the public, and, ultimately, make DOE records available to the public as part of the Federal openness initiative. At the interagency conference on October 2, Dr. Roger Anders, the project's Chief Historian, said that DOE had been very aggressive in seeking out and organizing historical records on human radiation experiments despite the fact that some 3.2 million cubic feet of paper files exist in locations all across the country. OHRE devised a 9-step strategy for describing what is where. A summary of this strategy appears in Chapter One of *Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records* (DOE/EH 0445, February 1995), commonly referred to as the DOE *Roadmap*.

DOE/OHRE on the Internet

When interviewed, Ms. Elly Melamed, Acting Director of OHRE, said that to date DOE is the only Federal agency to publish a guide to its historical records collection on human radiation experiments. She added that the U.S. Department of Defense (DOD) is working on a guide—using DOE's roadmap as a model—to locate records of past DOD human radiation experiments.

OHRE has also placed DOE's historical records related to human radiation experiments on the Internet (http://www.hss.energy.gov/HealthSafety/ohre/). Having succeeded in placing its historical data online, DOE/OHRE is collaborating with the other seven agencies to put on line documents they collected in response to ACHRE requests.

On October 3, President Clinton directed the Human Radiation Interagency Working Group to prepare responses to certain ACHRE recommendations. According to Ms. Melamed, OHRE will actively participate in preparing DOE's responses.

Federal Outreach, Local Control Advocated

In his address to the conference, Dr. Gary B. Ellis, Director of the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), challenged all Federal agencies to use their most powerful and cost-effective tool to improve the protections afforded to human subjects. That tool, he said, is education.

Dr. Ellis declared that OPRR and the other organizations represented at the conference share a commitment to protect citizens who contribute to the common good by volunteering for research studies. The Government, he said, is the steward of a trust agreement between researchers and volunteers. Because this trust has been weakened by past abuses, Federal agencies must strengthen their educational outreach efforts as a form of preventive maintenance.

Federal Policy and Leadership


Dr. Gary B. Ellis

Federal regulations governing the protection of human subjects continue to evolve, Dr. Ellis observed. The current Federal Policy for the Protection of Human Subjects[2], also known as the "Common Rule," was adopted in 1991. In part, the "Common Rule" is the culmination of work done by past national commissions and advisory boards. Future regulations, he said, may well be shaped by the findings and recommendations of the newly chartered National Bioethics Advisory Commission.

Federal leadership on the complex issue of protecting human subjects starts with the National Science and Technology Council chaired by the President. The Council's Subcommittee on Human Subjects Research coordinates implementation of the "Common Rule" across 16 Federal departments and agencies. Dr. Ellis' office, OPRR, chairs and staffs the subcommittee.

Local Oversight

The "Common Rule" requires institutions to establish an Institutional Review Board (IRB). According to Dr. Ellis, the local IRB is the cornerstone of the U.S. system of protecting human subjects. Each IRB must approve all new and continuing research that involves human subjects. Agencies bound by the "Common Rule" may fund no human subjects research without IRB approval of the study protocol.

Countering calls by several noted ethicists for a national IRB, Dr. Ellis pointed out some of the strengths of the current, locally based IRB system: Each IRB has a minimum of five members—including at least one scientist, one nonscientist, and someone not affiliated with the research institution. No IRB member may be directly involved in the research study under review. IRB members carefully review each protocol to ensure that it satisfies specific criteria, for example, that it provides for equitable selection of subjects and it minimizes risks to those subjects.

Dr. Ellis emphasized that the individuals serving on local IRBs are in the best position to know the local situation: the site, the resources, the investigators, the community values, the subject population. He questioned how a national IRB based in Washington, DC, could look after the welfare of the research subjects in a community better than a local IRB. Instead of a national IRB, Dr. Ellis favors a national body composed of private citizens who would carefully consider the bioethical issues arising from research on human biology and behavior.

Decision Chain

Errors are possible, Dr. Ellis acknowledged, in any endeavor based on human judgment. The U.S. system of protecting human subjects is built on a series of judgments. Among the first and most important judgments is informed consent on the part of the volunteer. The decision chain also involves research investigators, IRB members, scientific reviewers, Federal agencies charged with protecting human subjects, and Congress.

Producing the ACHRE Report

Addressing the conference 24 hours before official release of the Final Report of the Advisory Committee on Human Radiation Experiments, Dr. Jeffrey Kahn described the challenges ACHRE faced and offered a glimpse of the report's findings. Associate Director of ACHRE and Director of Graduate Studies at the Center for the Study of Bioethics, Medical College of Wisconsin, Dr. Kahn spoke as the representative of ACHRE chair Dr. Ruth Faden.

The Challenge to ACHRE

As explained by Dr. Kahn, ACHRE had three charges: (1) to tell the story of what happened with human radiation experiments between 1944 and 1974, (2) to tell the American people why it happened, and (3) to recommend what should be done to protect human subjects in the future. Gathering the data ACHRE needed to address these charges proved to be an enormous paper chase.

Dr. Kahn said that even with the cooperative efforts of Federal agencies and sites across the nation, which helped locate and submit data to ACHRE during its 18 months of work, the mere act of collecting historical records was daunting.

The task of examining the records proved equally daunting. Committee members knew they could not look at every experiment conducted during the 30-year time frame, so they agreed to limit their studies to representative cases from eight categories of experiments.

ACHRE also wrestled with the task of establishing moral principles for actions taken 40 or more years ago, said Dr. Kahn. Members confronted two issues: First, are there universal tenets of morality that are timeless whether it's 1995 or 1945? And second, can we hold people who lived then responsible for what we believe now? ACHRE wanted to know whether and how the principle of informed consent–mandated by current Federal regulations–operated from 1944 to 1974. The Final Report includes the Committee's ethical framework for judging past experiments.

Current Human Subjects Research

ACHRE evaluated current human subjects research by conducting various studies. One was an audit of the process by which IRBs review proposed research. Committee members conducted their own review of a random sample of current projects (Research Proposal Review Project/RPRP). Dr. Kahn emphasized that only a paper audit was possible because ACHRE did not have access to records of conversations between Principal Investigators and local IRBs or between the investigators and their human subjects.

Is It Fair? Should It Go Further?

Responding to questions about the fairness of the Committee's process for carrying out the RPRP and for ranking some current research protocols (on a scale of 1 to 5), Dr. Kahn said that the Final Report does not

classify any current research as "unethical." Some protocols, however, are categorized as "raising ethical concerns." The institutions that submitted documents for the RPRP, he remarked, were allowed to respond to the Committee's evaluation, but the responses had no impact on the rankings and do not appear in the Final Report. The responses will, however, be housed in the National Archives.

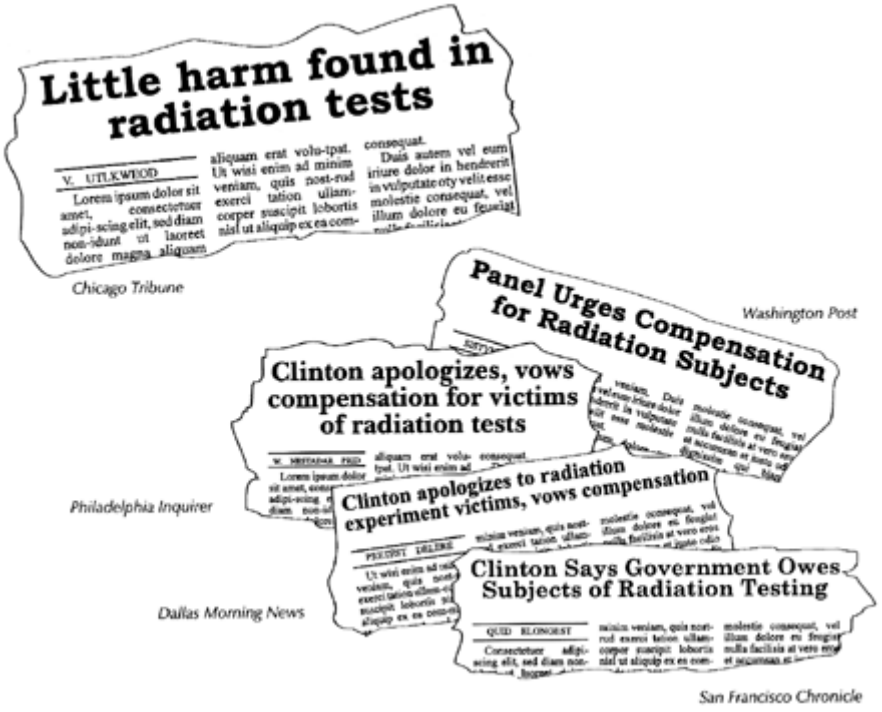
In closing, Dr. Kahn noted that some believe the work started by ACHRE should continue. He cited a brief statement by ACHRE member Dr. Jay Katz, which appears in the report. The statement is a call to "go further" on certain issues than the Committee's Final Report has done.

"Extra! Extra! Read All About It!"

In brief remarks to the conference, Pat Glynn, J.D., of the U.S. Department of Justice (DOJ), predicted that press reports on the Advisory Committee on Human Radiation Experiments (ACHRE) Final Report would focus on "compensation" and "victims" because these issues sell papers. Unfortunately, he remarked, this kind of publicity would overshadow the facts uncovered by the investigation, which concluded that only a very small number of people were involved in radiation experiments between 1944 and 1974 and not very many of them were put at risk or injured.

Mr. Glynn's prediction held true. A review of the headlines of related articles published in the days following release of the ACHRE Final Report shows that, of 20 articles found in 19 major newspapers, only one (in the *Chicago Tribune*) announces "Little harm found in radiation tests."

Of the 19 other headlines, 10 mention "pay" or "compensation" (as in, "Panel Urges U.S. to Apologize for Radiation Testing and Pay Damages" [*New York Times*]).



ACHRE: The Outcome

On October 3, 1995, Ruth R. Faden, Ph.D., M.P.H., Chair, presented the *Final Report of the Advisory Committee on Human Radiation Experiments (ACHRE)* to President Clinton. Publication of the 925-page report was the final act in an 18-month effort on the part of the independent Committee, which had been chartered in January 1994 to—

- Review human radiation experiments carried out or sponsored by the U.S. Government from 1944 to May 30, 1974. The review was to include determining the ethical and scientific standards and criteria by which to evaluate the experiments.
- Evaluate the extent to which human radiation experiments were consistent with applicable ethical and scientific standards (as determined by the Committee).
- If required to protect the health of individuals who were subjects of radiation experiments (or their descendants), recommend to the Human Radiation Interagency Working Group that an agency notify particular subjects of any potential health risk or need for medical follow up.
- Recommend further policies to ensure compliance with recommended ethical and scientific standards for human radiation experiments.
- Carry out such additional functions as the Interagency Working Group might request.

Appointed by the President, ACHRE was composed of 14 members from the disciplines of bioethics, law, radiation oncology, psychiatry, history, epidemiology, radiation biochemistry, radiology, public health, radiation therapy, and statistics. One member was a citizen representative. The Committee had assistance from a staff of about 40 part- and full-time professionals. In addition, hundreds of people informed and advised ACHRE during interviews and public hearings.

Report Highlights—The Past
Nearly three-quarters of the ACHRE Final Report is devoted to radiation research conducted from 1944 to 1974. Early on, the Committee cautions readers that not all of the historical records were found, and for many of those that were, only the barest descriptions remained. Moreover, the Final Report represents only a fraction of the documents collected.

One chapter of the report explains how ACHRE judged the "ethics" of human radiation experiments carried out prior to 1974. ACHRE agreed to apply three kinds of standards to selected groups of experiments:

1. Basic ethical principles that are widely accepted and generally regarded as so fundamental as to be applicable to the past as well as the present.
2. The policies of Government departments and agencies at the time.
3. Rules of professional ethics that were widely accepted at the time.

In an endnote to the first standard, the Committee said it "is aware that questions such as precisely what ethical principles should be considered 'basic,' . . . are among the most controversial and difficult in moral philosophy." ACHRE ultimately agreed to apply the six principles set out below to past radiation experiments:

- One ought not to treat people as mere means to the ends of others.
- One ought not to deceive others.

- One ought not to inflict harm or risk of harm.
- One ought to promote welfare and prevent harm.
- One ought to treat people fairly and with equal respect.
- One ought to respect the self-determination of others.

ACHRE concluded that most of the 4,000 radiation experiments in its database were not harmful to the human subjects involved. The majority involved radioactive tracers administered in amounts likely to be similar to those used in research today. Most of these tracer studies used adult subjects and were unlikely to have caused physical harm. The report also says that the human radiation experiments between 1944 and 1974 contributed significantly to advances in medicine and thus to the health of the public.

ACHRE did, however, uncover past practices that are considered unacceptable now. For example, the Committee found that Government officials and researchers are blameworthy for not having had policies that protected the rights and interests of humans subjects used in research from which they could not possibly receive any medical benefit.

Although ACHRE "was not expressly charged with considering issues relating to remedies, including financial compensation," the Final Report recommends limited financial compensation in a few specific cases.

Report Highlights—The Present

As for contemporary research, the Final Report acknowledges the significant advances in the protection of the rights and interests of human subjects since 1974. It notes, however, that some research areas have greater safeguards than others and recommends tighter Federal monitoring and disciplinary practices. ACHRE recommended changing the role of the IRB in five important areas. The report also states that certain procedures for protecting human subjects are still deficient. For example, written information may sometimes confuse patient-subjects about the difference between research and therapy (medical care).

The Committee arrived at these conclusions after—

- Completing a paper audit of Federal policies and oversight practices.
- Reviewing a random sample of 125 projects—84 of them radiation related—from thousands involving human subjects (FY 90-FY 93).
- Conducting brief interviews with almost 1,900 patients in the waiting rooms of clinics nationwide and longer interviews with 125 patient-subjects to determine their attitudes and beliefs regarding human subjects research and their participation.
- Exchanging correspondence with 41 chairs of IRBs and 40 chairs of radiation safety committees at institutions around the country.

This bulletin presents a summary of the ACHRE findings and recommendations on current/future human subjects research.

Copies of the ACHRE Final Report (stock number 061-000-00-848-9, $44.00) as well as the 36-page *Executive Summary and Guide to Final Report* (stock number 061-000-00849-7, $2.75) may be purchased from the U.S. Government Printing Office, telephone (202) 512-1800.

On October 3, President Clinton officially established the National Bioethics Advisory Commission (NBAC) to grapple with the ethical problems raised by the ACHRE Final Report, help set new policies regarding research in human biology, and review ongoing Government research projects. Federal agencies have been directed to review their current research policies using human subjects and to report findings directly to NBAC.

Human Subjects Protection: Current and Future

Set forth here is a summary of the Advisory Committee on Human Radiation Experiments' (ACHRE) "Findings for the Contemporary Period" and its "Recommendations for the Protection of the Rights and Interests of Human Subjects in the Future." For the full text, see Part IV of the Final Report, where the contemporary findings are set out in Findings 20–23, and the recommendations for the future appear as Recommendations 9–18. The recommendations are advisory, rather than regulatory in impact.

Findings for Today

ACHRE published four findings for contemporary research:

- More safeguards are in place for human subjects research involving radioisotopes than for most other areas of human subjects research. There are no apparent differences between the treatment of human subjects involved in radiation research and those involved in other biomedical research.
- It is appropriate at times to conduct human subjects research in secret and to classify results, but the provisions of the "Common Rule" still apply.
- Significant advances have been made in the policies and procedures in place today to protect the rights and interests of human subjects; however, some serious deficiencies still exist.
- Intentional releases of radiation could still take place in secret under current environmental laws and regulations.

Recommendations for Tomorrow

ACHRE made 10 recommendations for the future:

- Make a national effort to ensure the centrality of ethics in the conduct of scientists whose research involves human subjects.
- Change the Institutional Review Board component of the Federal system for protection of human subjects in at least five critical areas. Put mechanisms in place to ensure that—
    - IRBs have adequate time to review studies that pose more than minimal risk to human subjects.
    - Potential subjects receive information that (1) clearly distinguishes research from treatment, (2) realistically portrays any possible medical benefit to the subject for participating, and (3) clearly explains any potential discomfort or pain associated with participation.
    - Potential subjects receive information identifying the agency or agencies supporting the research and the purpose of the research.
    - Potential subjects receive information identifying the financial implications of participating (or not participating) in the research.

    - IRBs have the responsibility to determine that the science is of a quality to warrant imposing a risk or inconvenience on human subjects and, when a project has purported medical benefits to a subject, to determine that research subjects have at least as great a chance of securing that benefit as others who do not participate.
- Establish the mechanism of an open and public forum for the continuing interpretation and application of ethics rules and principles for conducting human subjects research.
- Improve three elements of the current Federal system for the protection of the rights and interests of human subjects: oversight, sanctions, and scope.
- Review the area of compensation for federally funded research, and create a mechanism for the satisfactory resolution of this long-standing issue.
- Adopt a Federal policy—not subject to waiver or exemption—requiring the informed consent of all human subjects of classified research, and adopt a separate policy requiring that classified research involving human subjects be permitted only after review and approval by an independent panel of appropriate nongovernmental experts and citizen representatives.
- Improve the protections of the public's rights and interests with respect to intentional releases.
- Ensure the continued application of the lessons learned from the efforts to organize the Nation's research records and make them accessible to the public and the Government.
- At a minimum, take four steps to improve existing protections of the rights and interests of military personnel with respect to human subjects research:
    - Review applicable policies and procedures to ensure that they state that research is voluntary, and that they clearly distinguish research (voluntary) activities from other (obligatory) activities, such as training maneuvers and medical interventions intended to protect troops.
    - Ensure that all officers and investigators who may be involved in decisions regarding human subjects research are aware of and understand the applicable regulations.
    - Define situations in which (1) officers and noncommissioned officers should be excluded from human subjects research recruitment sessions, and (2) an ombudsman should be present to ensure that the voluntary nature of participation is stressed and information provided about the research is adequate and accurate.
    - Establish and maintain U.S. Navy and Air Force registries of all volunteers in human studies and experiments conducted under research and development programs. The registry maintained by the U.S. Army could serve as a model.
- Review the record-keeping system of the Central Intelligence Agency (CIA) to ensure records are accessible upon legitimate request from the public or governmental sources, and make all records of the CIA bearing on programs of secret human research top priority for declassification review.

Old and Emerging Bioethical Issues in Research on Atoms and Genes

The provocative closing presentation on October 2 was given by Professor George J. Annas of Boston University's Health Law Department, School of Public Health. He prefaced his remarks on bioethical issues by insisting that the vocabulary used to discuss human subjects research be accurate and precise, and by warning that the ethical debate has been hindered by the misuse of six key terms—"research" and "therapy," "scientist" and "physician," "human subject" and "patient." **Research**, he said, is not synonymous with "therapy." (Research is not medicine or innovative treatment.) A **scientist** (or researcher) is not a "physician," and a **human subject** must not be confused with a "patient."

Gene Research
Prof. Annas spoke at more length about genetics, which currently has a very high profile in the popular and research press. Gene research is proceeding in a cultural environment he characterized as dominated by hype and commercialism. The research itself raises two concerns: (1) the potential for physically enhancing future generations, and (2) even more pressing, the potential for repairing genetic diseases in people living today. The public wants to take immediate advantage of these "repairs," but researchers are not yet ready to advise general use because their hypotheses have not been adequately tested. Physicians, however, are pressing for the "best treatments" now because their patients are urging them to find something that might help. Rushing to try new therapies before they are ready muddies the distinction between research and medicine.

New Safeguards Needed
Prof. Annas noted that the human subjects research community cannot afford to ignore the standards set out in the 1947 Nuremberg Code, which for years was somewhat overshadowed by the World Medical Assembly's Declaration of Helsinki in 1964. Based on "universal" principles, the Nuremberg Code is today being accepted as the benchmark for judging human subjects involvement in research, as evidenced by the work of the Advisory Committee on Human Radiation Experiments (ACHRE). In Prof. Annas' view, informed consent, justice, and fairness are not being taken seriously enough in the area of genetics research. Neither the Nuremberg Code nor current Federal regulations address genetic research directly; therefore, new safeguards are needed. Human subjects involved in gene research face potential medical and social risks if confidentiality is not maintained.

Other Recommendations
Prof. Annas offered additional recommendations:

- The term "therapeutic research" should not be permitted in research protocols. Either physicians are doing therapy or researchers are following protocols—the two cannot be mixed without creating unacceptable confusion in the minds of both subjects and researchers.
- Every research subject should have a personal physician to act as his or her advocate because patients continue to see themselves as patients even if they volunteer to be part of a research protocol. Their own physicians cannot act as advocates if they are doing the "research."
- Informed consent should be the **same** whether it is given in a medical context or a research context.
- Terminally ill subjects with less than 6 months to live should be disqualified from human subjects research. Desperate and, therefore, too vulnerable, they are unable to distinguish research from treatment.

Prof. Annas closed by suggesting reforms to current Federal regulations, among which were establishing a National Human Research Agency, strengthening the Institutional Review Board role in protecting human subjects, and rewriting current regulations to clarify the roles of the scientist, the subject, and research.

Commenting briefly on atomic research, Prof. Annas mentioned past projects involving radiation, many of which gave radiation research a bad name. He wholeheartedly supported independent reviews of past and current projects involving human subjects. Reviews such as the ACHRE study help restore confidence in scientific research and help clarify complex issues.

Dateline Washington

- DOE's Education/Outreach Efforts: During brief introductory remarks at the human subjects conference, Dr. Ari Patrinos, Associate Director, Office of Health and Environmental Research (OHER), cited with pride OHER's recent outreach efforts—the online database of current human subjects research, the revised human subjects research handbook (in press), and the human subjects Internet home page.

  Dr. Patrinos also announced that in FY 95 the Office of Energy Research will begin education/site visits to all DOE facilities performing human subjects research. Each site will be visited approximately every 3 years. DOE will be the first Federal agency to conduct such visits on a regular, noncomplaint-driven basis.

- **FDA Seeks Exceptions to Informed Consent in ER**: On September 21, 1995, the Food and Drug Administration (FDA) published a proposal in the *Federal Register* (FR) to amend FDA's current informed consent regulations on emergency room (ER) research. The same FR notice stated that the U.S. Department of Health and Human Services (HHS) intended to harmonize future HHS and FDA regulations on this matter.

  HHS and FDA now differ on the conditions for waiver of, or exception to, informed consent. HHS does not permit research activities, even in an emergency, for example, without prior IRB review and approval. HHS also requires that the research involve no more than minimal risk to the subjects. In contrast, FDA permits exceptions to informed consent rules, principally for one-time emergency uses of a drug or device as treatment for a patient in a life-threatening situation (rather than for research purposes) when no alternative recognized therapy is available. In some cases, IRB approval must occur within 5 working days after the ER use of the test drug/device.

  IRB and research communities have expressed frustration with the difficulties of interpreting the conflicting regulations. From their perspective, a common position by FDA and HHS would make it easier to evaluate ER research protocols, especially when protocols are subject to both the HHS and the FDA conditions. The period for public comment on FDA's proposed amendment ended November 6, 1995.

- **Dr. Susan Rose and Dr. Joan Porter** would like to thank the following individuals for sharing their experience and wisdom with all the other participants at the October 1995 interagency conference on human subjects research:

  Roger Anders, DOE; **George Annas**, Boston University; **Fred Bonkovsky**, HHS; **Dan Brown**, U.S. Air Force; **Gary Chadwick**, FDA; **Deborah Collyar**, San Francisco Advocacy Core; **Sherry Davis**, Pacific Northwest National Laboratory; **Helene Deramond**, U.S. Department of Education; **F. William Dommel**, HHS; **Gary Ellis**, HHS; **John Ensign,** FDA; **Earl Ferguson**, National Aeronautics and Space Administration; **Pat Glynn**, DOJ; **Jeffrey Kahn**, ACHRE (Medical College of Wisconsin); **Patricia Kvochak**, HHS; **William LeFurgy**, DOE; **Robert Levine**, Yale University; **Melody Lin**, HHS; **Deborah Maresca**, Brookhaven National Laboratory; **Curtis Naser**, Fairfield University; **Ari Patrinos**, DOE; **Stuart Plattner**, National Science Foundation; **Tom Puglisi**, HHS; **Karen Rothenberg**, HHS; **Clifford Scharke**, HHS; **Paul Seligman**, DOE; **Ada Sue Selwitz**, University of Kentucky; **Dale Vander Hamm**, DOD; and **John Wooley**, DOE.

Newsletter Information

This bulletin is designed to facilitate communication among those involved in human subjects research and to inform persons interested in human subjects research activities.

DOE Human Research Subjects Program

- **Program Manager**: *Dr. Susan L. Rose*
- **Editor**: *Jane Otto*
- **Graphic Designers**: *David Hoff and Carolyn McHale*
- **Reviewers**: *Dr. Martha Firestine and Rita Trapani*

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Dr. Susan L. Rose
Office of Biological and Environmental Research, SC-72
U.S. Department of Energy
19901 Germantown Road
Germantown, MD 20874-1290

PHONE: (301) 903-5468
FAX: (301) 903-8521
E-mail: kim.laing@science.doe.gov or joanne.corcoran@science.doe.gov