301-601-9915
Contractor fax
Attn: Daphne
Attn Elly McLaurel

Nicholson Aerospace RPT.

JOHNS HOPKINS
UNIVERSITY

The Bioethics Institute
624 N. Broadway
Hampton House 511
Baltimore MD 21205-1996
(410) 955-3018 / FAX (410) 614-9567

Ruth R. Faden, Ph.D., M.P.H., Director
Philip Franklin Wagley Professor of Biomedical Ethics

January 8, 1997

Elizabeth Drye
Domestic Policy Council
The White House
OEOB Rm 213
Washington, DC 20052

Dear Elizabeth:

As promised - copies of the journal issues deovoted to ACHRE. For what its worth, my article in the Hastings Center Report includes some (still punitive) thoughts about presidential commissions - I'd appreciate your reactions.

Best,

Ruth

Ruth R. Faden, Ph.D., M.P.H.
Director
Philip Franklin Professor
of Biomedical Ethics

JOHNS HOPKINS
UNIVERSITY

The Bioethics Institute - Pediatrician

624 N. Broadway
Hampton House 511
Baltimore MD 21205-1996
(410) 955-3018 / FAX (410) 614-9567

Ruth R. Faden, Ph.D., M.P.H., Director
Philip Franklin Wagley Professor of Biomedical Ethics

December 20, 1996

TO: Elizabeth Drye

FROM: Ruth Faden

Thought you'd like to see these; we're doing okay!

Warmly,

Ruth

cc: SAMA

FINAL REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

620 pp. New York, Oxford University Press, 1996. $39.95.
ISBN 0-19-510792-6.

THE last time I devoted my summer holiday reading to a single book was when *War and Peace* was assigned in high school. In addition to bulk, the similarities between the *Final Report of the Advisory Committee on Human Radiation Experiments* and Tolstoy's classic include a large cast of characters and a more than occasional tone of moral indignation. The action in both takes place in war and peace.

The *Final Report* is the work of a distinguished panel appointed by President Bill Clinton in 1994, mostly comprising academics in the medical and radiation sciences, law, ethics, and other disciplines and chaired by Ruth Faden, director of the Bioethics Institute at Johns Hopkins University. Some 50 staff members assisted the panel. It reviewed experiments conducted between 1944 and 1974 that involved exposing humans to ionizing radiation from various sources. The experiments, some intentional and some accidental, had a wide range of formats and covered a variety of research topics, medical and nonmedical.

The report begins with a primer on radiation, radioactivity, and effects of radiation and a historical perspective on the ethics of research on human subjects. It proceeds with case studies that I would group in three categories: studies of the health effects of the Manhattan Project, assessments of the psychological and somatic effects of putative nuclear warfare, and clinical investigations involving radionuclides. The panel distinguishes among these categories, but grouping them all under the rubric of "human radiation experiments" has some confounding consequences. In the case of the Manhattan Project and nuclear warfare, the chief concern should be acts committed in the name of national security, with their attendant secrecy; as for clinical investigation, the principal interests are parity in the patient–doctor relationship, experimentation on vulnerable populations, and informed consent.

The book has a central premise, perhaps a dogma — that certain ethical principles are so basic that they are not temporally limited and should have been applied throughout the period under study, independently of evolving standards. These principles are the six "one oughts": not to treat people as mere means to an end, not to deceive others, not to inflict harm or a risk of harm, to promote welfare and prevent harm, to treat people fairly and with equal respect, and to respect others' right to self-determination. Judged against these six principles, many of the experiments described in the *Final Report* fail or falter.

Yet, except for the most egregious examples, the authors do not unduly castigate and seem more intent on informing than on scolding. And they provide considerable information, including addresses such as the informed-consent requirements laid down by the Weimar Republic's Ministry of the Interior in 1931 for therapeutic and nontherapeutic medical research and the 1953 top-secret memorandum of Secretary of Defense Charles Wilson, reiterating the Nuremberg Code and requiring that informed consent be written and witnessed. A copy of Wilson's memorandum was sent to the Joint Chiefs of Staff, but initially it was disseminated no lower than the three secretaries of the armed services because of its security classification. Informed consent is the banner held aloft throughout the *Final Report* and reemphasized by Jay Katz, a panel member who keenly believes that the matter has not been sufficiently addressed in evaluating current behavior. Katz also points out that the dignity of the subjects, rather than physical injury, should be our principal concern in reviewing past practices. Indeed, most instances cited in the *Final Report* seem to have caused little physical harm.

The panel's staff members themselves conducted two experiments. In the first they examined contemporary proposals for research (using radiation or not) with regard to the level of risk, the degree to which the subjects understood the research, the factors likely to affect their voluntary participation, and the inclusion of those with a limited ability to make decisions. All these were issues in experiments conducted between 1944 and 1974. Among the panel's findings was that research using radiation is more risky or ethically problematic than research that does not use radiation; actually, research using radiation may be controlled more strictly than other research, because of the double review by institutional review boards and radiation-safety committees. But the panel also found substantial deficiencies in the current system with regard to the protection of human subjects. In the second study by the panel, 1900 patients were interviewed. Among the conclusions was the following:

> . . . nearly 40 percent of the patients we talked with either believed they were or had been subjects of research . . . almost all of these patients said they had enrolled in research because they thought it was their best chance of personal medical benefit — [but] patients also said that they had participated in research to help others.

The panel concludes with 23 findings and 18 recommendations. Some are technical, and others are and are beyond contention. But whether one agrees with all of them or not, this thick book tells a cautionary tale. The great knowledge of disease processes, powerful diagnostic methods, and useful treatments derived from the radioactive materials that became available after World War II came at a price that with greater wisdom and thoughtfulness might have been avoided.

S. JAMES ADELSTEIN, M.D., PH.D.
Harvard Medical School
Boston, MA 02115

COMPREHENSIVE HUMAN PHYSIOLOGY: FROM CELLULAR MECHANISMS TO INTEGRATION

Edited by R. Greger and U. Windhorst. 2527 pp. in two volumes, illustrated. New York, Springer-Verlag, 1996. $135.
ISBN 3-540-58109-X.

THIS two-volume textbook of human physiology is indeed comprehensive. The editors and the 102 other contributors have produced an excellent treatise that inte-

Atomic Bomb Poetry

Outcry From the Inferno: Atomic Bomb Tanka Anthology, edited and translated by Jiro Nakano (special double issue of *Bamboo Ridge, The Hawaii Writers Quarterly*, Nos 67 & 68, summer/fall 1995). 101 pp, paper, $10. ISBN 0-910043-38-8; Bamboo Ridge Press, PO Box 61781, Honolulu, HI 96839-1781 (808) 599-4823; 1995.

Outcry From the Inferno is a collection of *tanka* (a five-line Japanese poetic form) that were written by survivors of the atomic bombing in Hiroshima. These *tanka* were compiled as *Hiroshima Tanka Anthology* by Seishi Toyota in 1954. Such *tanka* are a major literary form in Japan but have limited exposure elsewhere.

Jiro Nakano, MD, former professor of pharmacology and associate professor of medicine at the University of Oklahoma, selected the 100 best *tanka* from the anthology and translated them for this book.

The accompanying posthumous poem is reprinted from *Outcry From the Inferno* by permission of the publisher.

Tonight again,
the only light to aid me
as I write my nursing notes—
the luminous flames
from the burning of the corpses.

人を焼く
焔の明りを
たよりとし
こよひも看護の
メモをしたたむ

hito wo yaku
honoho no akari wo
tayori to shi
koyoi mo kango no
memo wo shitatamu

FUMIKO FUJII
藤井文子

Radiation

Advisory Committee on Human Radiation Experiments: Final Report, October 1995, by Ruth R Faden, chair, and Kenneth R Feinberg, Eli Glatstein, and Jay Katz, et al. 925 pp, paper, $44, stock No. 061-000-00-848-9, Washington, DC, US Government Printing Office, 1995 (telephone orders Superintendent of Documents, US Government Printing Office, 202-512-1800, fax 202-512-2250; mail orders: US Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954).

The Human Radiation Experiments: Final Report of the President's Advisory Committee, by Ruth R. Faden, chair, and Kenneth R. Feinberg, Eli Glatstein, and Jay Katz, et al, 620 pp, $39.95, ISBN 0-19-510792-6, New York, NY, Oxford University Press, 1996. (This is the same report as above; it also includes an index.)

Executive Summary of Final Report of the Advisory Committee on Human Radiation Experiments, Ruth R. Faden, chair, 38 pp, paper, $2.75, stock No 061-000-00849-7, Washington, DC, US Government Printing Office, 1995 (telephone orders: Superintendent of Documents, US Government Printing Office, 202-512-1800, fax 202-512-2250; mail orders: US Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954).

When the Advisory Committee on Human Radiation Experiments was created by President Clinton in January 1994, commentators posed three critical questions. First, was there sufficient surviving documentary evidence to enable the committee to analyze the radiation research conducted in the United States between 1942 and 1974; would the record be complete enough to enable it to determine "the ethical and scientific standards by which to evaluate the pre-1974 experiments and the extent to which these experiments were consistent with such standards"? Second, was it worth the expenditure of millions of dollars to uncover and analyze the record? Third, would a committee appointed by the White House with a membership that was almost evenly divided between bioethicists and physician-scientists inevitably issue a final report that reflected political and intellectual compromise; would the report recount the history in compelling detail and then offer conclusions that blurred the lessons to be learned? Now that the report has been issued, it is apparent that the answer to all three questions, with appropriate qualifications, is yes.

With the cooperation of many government agencies, particularly the Department of Energy, the advisory committee collected and examined several thousand research protocols. The roster includes the experiments involving plutonium (mainly on patients with a diagnosis of terminal illness); radioisotopes (particularly on children); total body irradiation (on advanced cancer patients); testes radiation (on prisoners); and intentional releases into the environment of radiation (in various communities). The evidentiary record now available is, from the vantage point of historians accustomed to working with lacunae, remarkably complete and filled with surprises. Historians and public policy analysts owe an enormous debt to the archivists, agency administrators, and advisory committee members and staff for their exceptional diligence.

What do we know that we did not know before? Perhaps the single most important and unexpected finding is just how aware government officials and researchers were in the 1950s and 1960s of the Nuremberg Code in particular and of the principles of research ethics, including informed consent, in general. Although the attention that the public and medical press had paid to the Nuremberg Code was minimal, leaders in the Department of Defense (DOD), the Armed Forces, and the Atomic Energy Commission (AEC) were fully cognizant of both its specific provisions and broader implications. In fact, their very sensi-

Edited by Harriet S. Meyer, MD, Contributing Editor, Jonathan D Eldredge, MLS, PhD, University of New Mexico, Health Sciences Center Library, Journal Review Editor, adviser for new media, Robert Hogan, MD, San Diego

tivity suggests that the provisions of the code were not so much a novel departure as a restatement of long-established and recognized precepts in medical ethics. The report puts to rest the dubious but often-heard claim that research ethics in the 1950s and 1960s were substantially different from those of the 1980s and 1990s.

As early as 1947 the AEC appreciated that human radiation experiments had to have a potential "therapeutic effect" in order to be ethical, and they had to be "susceptible of proof that, prior to treatment, each individual patient, being in an understanding state of mind, was clearly informed of the nature of the treatment, and its possible effects, and expressed his willingness to receive the treatment." Thus, when the AEC and the DOD were concerned about the risk to airplane crews posed by nuclear-powered engines and considered using prisoners to test effects of exposure levels, Shields Warren of the AEC commented: "It's not very long since we got through trying Germans for doing exactly the same thing." Another investigator, Joseph Hamilton, remarked that the proposed research "would have a little of the Buchenwald touch." Such expressions prevented the research from being conducted. Moreover, the documentary record reveals that a large number of administrators insisted that investigators obtain consent from subjects and that at least some researchers followed this practice. In all, the Nuremberg Code was not as obscure as many of us had believed, and the idea of informed consent, as many of us had heretofore insisted, had a secure place in the ethics of human experimentation well before the 1970s.

Because of the advisory committee efforts we also know how large the gap was between ideas and practices, between stated principle and actual deed. The report is replete with dispiriting examples of administrators failing to implement the ethics they espoused. The DOD, for example, incorporated the Nuremberg Code into its regulations and then, amazingly, proceeded to classify the document "top secret" and not distribute it within its own network. Yes, the AEC ruled out nontherapeutic radiation research, but it did nothing to enforce the standard even among its contract research organizations.

By the same token, officials resisted suggestions, generally emanating from agency lawyers, on the need for congressional legislation on the conduct of human experimentation. Some were fearful of "unfavorable publicity"; others worried that "[t]o commit to writing a policy on human experimentation would focus unnecessary attention on the legal aspects of the subject" and narrow the discretion that researchers enjoyed.

Perhaps most disheartening, the advisory commission report sets forth the details of clinical research that patently sacrificed the well-being of its subjects and illuminates the lengths to which researchers and government officials were willing to go in order to maintain secrecy. Thus, Ebb Cade, a 53-year-old "colored male" who was hospitalized following an auto accident but was otherwise in good health, was injected with 5 μg of plutonium at the Oak Ridge Army Hospital; he was, without his knowledge or consent, part of a research project to study the effects of plutonium on workers. Cade, the report documents, was one of "at least twenty-two patients [who] were administered long-lived isotopes in experiments." Nor were all of these subjects terminally ill, a criterion invoked to justify the research on the grounds that they would not be harmed by long-term negative effects. The advisory committee properly notes that terminal illness does not bring with it a waiver of rights.

When the AEC considered declassifying some of these research reports, its declassification officer concluded that such a step was unthinkable:

> The document appears to be most dangerous since it describes experiments performed on human subjects, including the actual injection of plutonium into the body. . . . It is unlikely that these tests were made without the consent of the subjects, but no statement is made to that effect and the coldly scientific manner in which the results are tabulated and discussed would have a very poor effect on the public.

The advisory committee could find no justification for the officer's assumption that consent had actually been obtained. Further, all of the plutonium protocols violated the AEC prohibition on nontherapeutic research. As the report aptly concludes: "Concerns about adverse public relations and legal liability do not justify deceiving subjects, their families, and the public."

Having documented the widespread knowledge of ethical principles and standards in research among agency directors and investigators, the inadequate efforts to distribute, let alone to enforce, these standards, the many experiments that violated the basic rights and well-being of subjects, and the systematic and extensive efforts at cover-up to avoid liability or censure, the advisory committee goes on to place these stunning findings in a frame that is often lackluster and lifeless. In the detailed analyses and case studies of particular protocols, its language and judgments are forthright. But the summary statements back off from a resolute declaration of findings. The tone is one of excessive caution, complicating issues that are really not so complicated.

Much of it is a matter of style. The language of the report is unusually arid. Nothing uncovered seems to shock the conscience, provoke dismay, or threaten democratic principles. Whether the case is that of retarded children at Fernald State School, Waltham, Mass, being fed radioisotopes under protocols that lied to their parents, or AEC officials hiding information to protect themselves and their investigators from well-deserved public criticism, the report all too typically adopts a posture of disengagement, distance, almost abstraction.

But there are also matters of interpretation. The report is most critical of research of a nontherapeutic character conducted without subjects' knowledge or consent. However, it suggests that failures to respect subjects' autonomy are less reprehensible when the research had a prospect, however faint, of therapeutic benefit. To justify this conclusion, it notes that many investigators followed this practice and that medical paternalism and discretion was more entrenched then than now. But such arguments ignore the fact that most of the normative statements on research ethics did not distinguish in principle between therapeutic and nontherapeutic experiments. Although, as one commentator suggested, it might be more difficult to get consent from sick patients, that does not make it any the less necessary. Nor is it right to reduce culpability because of the number of people who violated the precepts.

In this same compromising spirit, the report totters on the verge of allowing ends to justify means. Although explicitly disavowing such a proposition, it is too eager to remind readers that the research, however ethically dubious, produced important findings. All the while, the report does not hold up to embarrassment or consider what might be appropriate censure for a researcher or government official who had breached ethical principles or public trust. To be sure, this charge was not part of the advisory committee mandate; however, a more forceful report might have discussed the admittedly complex question of whether or how to respond to past transgressions. Acts are dubbed wrongful, but actors are never implicated.

These criticisms notwithstanding, the advisory committee efforts have much to commend them. The committee has built an archive that will be o

Adding to the Canon

The Final Report

by Eric M. Meslin

Final Report: White House Advisory Committee on Human Radiation Experiments. (061-000-00-848-9). Washington, D.C.: U.S. Government Printing Office, 1995. 925 pp.

When the first stories of the plutonium experiments, conducted on eighteen hospital patients between 1945 and 1947, were revealed in Eileen Welsome's stories in the *Albuquerque Tribune*, it appeared that another story was to be added to the research ethics curriculum and to our list of "classic cases." When President Clinton announced the formation of the Advisory Committee on Human Radiation Experiments the status of this case was upgraded from one of an interesting footnote to one that gained the attention of the executive branch of the U.S. government, a status achieved only by a select group of previous national advisory committees and commissions.[1] The resulting 925-page report, produced after eighteen months of work by a fourteen-person committee (including one "citizen" member) and a staff of fifty-six is now in the public domain for review and study.[2]

The committee was charged with the following tasks in an executive order by President Clinton: (1) learn and explain the history of human radiation experiments between 1944 and 1974; (2) examine specific cases of known research involving the exposure of humans to radiation (both of environmental releases of radiation and ionizing radiation to their bodies); (3) evaluate the degree to which these experiments were ethically acceptable and scientifically valid; and (4) make specific recommendations for improving (if necessary) the current system for protecting human subjects in research. The resulting document is an intriguing read: part cold war history, part careful review of voluminous files, part commentary on the status of human subjects research historically and in the contemporary period, and part illustration of the state of bioethics research methodology as applied to public policy.

The report is divided into four parts, the first of which provides a historical perspective on radiation experimentation conducted and/or funded by the U.S. government between 1944 and 1974. One is immediately struck not so much by the extent to which ethical issues were discussed in research at that time, but rather how easy it was to administratively dismiss the moral (if not legal) requirements for obtaining informed consent from individuals. Although the historical accounts are the most gripping, the most challenging chapter of Part I is the last, "Ethics Standards in Retrospect." This chapter carefully addresses a problem readily appreciated by anyone who is asked to discuss the ethical integrity of an activity that pre-dates one's experience, or more specifically, the legal and ethical standards enjoyed at the moment.

The committee is able to make its case for the validity of this activity by describing an ethical framework consisting of two types of moral judgments: those that examine the "moral quality of actions, policies, practices, institutions and organizations" and those that examine the "praiseworthiness or blameworthiness of individual agents" (pp. 198-99). The framework describes three kinds of ethical standards: basic ethical principles, government policies, and professional rules (pp. 199-200), which the committee applies retrospectively to the 1944-74 period and demonstrates that some of the research was unethically conducted and some government agencies blameworthy. The grounds for these assertions lie in the presence of certain government and/or department policies relating to the conduct of research and to existing professional guidelines regarding the care of patients. The case for retrospective judgment is made more forcefully using these standards,[3] however, than using the principle-based standards. Of particular interest to those protagonists in the now tiresome debate about the place of ethical principles in bioethical deliberation, this is a sensible, albeit conservative use of the several tools of applied ethics available to scholars. For example, the committee adopts the somewhat mainstream approach that "there is broad agreement about and acceptance of basic ethical principles . . . such as principles that enjoin us to promote welfare and to respect self-determination."[4] But it also recognizes the all-too-obvious point that ethical pluralism is based not only on these principles alone (or at all), but rather on other sources of moral norms including government policies and professional norms and practices.

The committee found that the history is complex and detailed, weaving through various branches of the U.S. government. It traces, as best as possible, the standards used to assess human experimentation. But, like any story, it was incomplete. Documents were missing, old, or occasionally inaccessible. Still, approximately 4,000 instances of human radiation experiments were identified. The committee could not review all of these experiments; instead it identified eight case studies that were representative of the studies conducted. Part II reviews the types of experiments conducted. This casuistic exercise serves two purposes: it provides the content for understanding the general categories of radiation experiments examined by the committee and it focuses the reader's attention in a way that would never be accomplished by the (no doubt) monotonous review of all 4,000 studies. For example, the committee found that the plutonium infusion experiments described by Welsome may very well have been the most egregious examples of unethical research uncovered; had these experiments been treated alongside thousands of others some of the important and perhaps subtler messages might have been lost.

Individual chapters in the report are devoted to each case study. Chapter 5 examines experiments in which sick patients were injected with plutonium as part of the Manhattan Project; Chapter 6 examines the Atomic Energy Commission's system for distributing radioisotopes used in human research. As the committee notes, "in studying [this area] . . . we sought to learn the ground rules that governed the conduct of the majority of human radiation experiments, most of which have received little or no public attention" (p. 229). Chapter 7 describes twenty-one cases of research on children, including the studies co-sponsored by the Quaker Oats Company at the Fernald School in Massachusetts where mentally retarded boys were given oatmeal containing radioactive iron and calcium. In another study at the Wrentham State School, mentally retarded children were administered radioactive iodine. Chapter 8 focuses on total-body irradiation studies, partially sparked by the studies that raised some controversy at the University of Cincinnati. Chapter 9 reviews research conducted on prisoners, one notable example being the research on the effect of ionizing radiation on testicular function.

Chapter 10 describes the use of human subjects in a different context: research done in connection with the testing of nuclear weapons. Although the current research ethics lexicon might exclude these participants from a list of research subjects, this case study convincingly argues for revising what we commonly hold to be a straightforward definition of a "subject" or "participant," and what ought to count as "research" or "experimentation." Complicating this issue is the fact that the "participants" were members of the military. As the committee noted, "having heard from many atomic vets and their family members . . . the real offense to many is the belief the risk was unacceptable and that they or their loved ones may suffer illness unnecessarily as a consequence" (p. 487).

Chapter 11 focuses on another type of "experiment" not typically discussed in research ethics circles: the intentional release of radioactive material into the air to determine how radioactive gases resulting from the production of atomic weapons behave in the atmosphere. The final case study (Chapter 12) relates the committee's assessment of observational research conducted by the U.S. government on three different populations exposed to radiation hazards: uranium miners in the western United States who worked in underground mines with inadequate ventilation; the inhabitants of the Marshall Islands in the South Pacific who were prematurely returned to their island following the detonation of nuclear weapons at Bikini Atoll between 1946 and 1954; and a group of Alaskans (Caucasians, Eskimo, and Indians) who, between 1956 and 1957, were subjects of a study in which iodine[131] was administered to determine the effect on the thyroid gland of extreme cold. The committee concluded that, of the three groups discussed in this chapter, the uranium miners were "the single group that was put most seriously at risk of harm, with inadequate disclosure and with often-fatal consequences" (p. 604).

The committee's historical research is soberingly placed in the context of secrecy. In Chapter 13, we are reminded that the committee knows what they know because they obtained access to some, but not all, files:

> The story we have told in this report could not have been told if the government did not keep records that could be retrieved. By the same token, the story is often disturbingly fragmentary; seemingly contradictory statements of principle or policy abound, and the trail from policy to practice is often hard to discern. The story is complex, but it is also hard to reconstruct because . . . many documents appear to have been long since lost or destroyed. (p. 646)

Following its historical review, Part III details a set of contemporary projects the committee conducted to determine how the current system of protecting human subjects is working. The scope of these three projects was considerable and is discussed in Chapters 14 through 16: a review of current guidelines and policies governing human subjects research to determine whether the problems identified between 1944 and 1974 had been remedied; a mock review of selected contemporary research protocols (the Research Proposal Review Project) to determine the extent to which subjects are currently being protected; and the Subject Interview Study, which insightfully shares the experiences of participants and their families involved in radiation experiments. This latter project is emotionally moving, particularly when you take the time to read the endnotes, which contain more interview data.

Part IV summarizes the committee's findings and recommendations. Seventeen findings and eighteen recommendations are discussed at length in Chapters 17 and 18, respectively.

One of the difficulties in preparing this review was trying to keep separate the various accounts of the committee's work as a *product* of bioethics scholarship from the final report as a piece of scholarship itself. One cannot help but blur these. With this caveat, there are several (potentially) enduring outcomes of this report. I have described these "legacies" in metaphorical terms: architectural renovation, updated cartography, and evolutionary branching.

Architectural Renovation. The history of research ethics in the United States has been updated, refurbished, and remodelled as a result of the committee's work. By dusting off the records, we can now see that several of the most important stories in contemporary research ethics continue to have explanatory and heuristic power. Adding the cold war radiation experiments to Nuremberg, Tuskegee, and Willowbrook adds a brick to the edifice that philosophers, theologians, lawyers, health care professionals, and historians have constructed to inform and warn about opportunities and dangers in science. In addition to reinforcing the power of these stories, there is an opportunity to repair some well-worn steps in the research ethics structure: the standard story that informed consent came into the lexicon in 1957 following *Salgo* must now be revised. Veatch, writing recently in the *Hastings Center Report*, and citing his and others' work, reflected that the history of consent reveals that it

is a relatively recent phenomenon.[5] Indeed, Faden and Beauchamp's seminal work on the history and theory of informed consent[6] takes the cold war period to be the origin of consent. The committee confirmed that consent was discussed as early as 1944.

If the National Commission provided the foundation for two decades of discussion ranging from theoretical questions involving the proper role of ethical principles in debate to more practical problems of involving persons incapable of consent in research, the Advisory Committee report constructs an edifice on that foundation that will surely support fruitful debate for another two decades.

Updated Cartography. Many bioethics reports exist. The report on bioethics in public policy of the now-defunct OTA noted in 1993 that nearly forty national commissions in almost thirty countries had produced reports on a variety of bioethics topics. Rarely do these commissions thoroughly describe the method used to fulfill their mandate and construct a road map for obtaining the original sources and documents used to develop their reports.[9] Unlike the *Belmont Report* (or any of the major bioethics public policy deliberative bodies in the United States since 1974), the Advisory Committee not only constructed the map describing where and how it was going to go (methodologically), it left enough breadcrumbs on the path to allow others to follow and find their way. For example, the final appendix, "A Citizen's Guide to the Nation's Archives—Where the Records Are and How to Find Them," is very helpful.

Not only is this evidence of scientific integrity (since sharing of primary research data is an obligation binding on all researchers), it is also evidence of concern and care for those individuals and families who wish to bring closure to events in their lives. By archiving materials and making them accessible in either hard copy or through various websites on the Internet, the committee has made a positive contribution to the cartographic project.

Evolution of Bioethics Methodology. The methods used to conduct the research in this report reflect the evolution of bioethics scholarship. In one report, we see conceptual, public policy, and jurisprudential analysis. Perhaps most interestingly, we see in-depth use of various quantitative and qualitative empirical methods. Casuistic and narrative methods are used with success. It is probably the most comprehensive use to date by a federal commission of the multiple methods bioethics has to offer to investigate and analyze moral problems in health care. As such, the report is itself a case study.

The history of human research ethics in North America has some familiar stories that the community now recites as comfortably as a storyteller in passing an oral history on to the next generation. It has followed a path that travels past familiar signposts that flag certain seminal documents (Nuremberg, Helsinki), regulatory initiatives (the U.S. *National Research Act;* 45 CFR 46, the Federal Common Rule), and cases (Willowbrook, Tuskegee, the Jewish Chronic Disease Hospital). The pedagogy used to teach about this history tends to be equally well-worn: a comprehensive documentation of the cases of abuse, with the assumption that we can learn from history by simply avoiding past injustices. Although genetic research may ultimately force a rethinking of the way we review, conduct, oversee, and report on human subjects research, the stories emerging from the human radiation experiments conducted in the United States, Canada, and Europe may also play a role in research ethics reform.

References

1. U.S. Congress, Office of Technology Assessment, *Biomedical Ethics in U.S. Public Policy—Background Paper,* OTA-BP-BBS-105 (Washington, D.C.: U.S. Government Printing Office, June 1993).

2. The Final Report has also been published by Oxford University Press: Advisory Committee on Human Radiation Experiments, *The Human Radiation Experiments: Final Report of the Advisory Committee on Human Radiation Experiments* (New York: Oxford University Press, 1996).

3. A somewhat more elegant argument is made by Allen Buchanan in his recent article "Judging the Past: The Case of the Human Radiation Experiments," *Hastings Center Report* 26, no. 3 (1996): 25-30.

4. Advisory Committee, *The Human Radiation Experiments,* p. 203.

5. Robert M. Veatch, "Abandoning Informed Consent," *Hastings Center Report* 25, no. 2 (1995): 5-12.

6. Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986).

7. OTA, *Biomedical Ethics,* pp. 16-17.

8. The Department of Energy produced a comprehensive listing of the DOE records of this research in *Human Radiation Experiments: The Department of Energy Road Map to the Story and the Records* (Washington, D.C.: Department of Energy, February 1995).

Waiver of informed consent minimal risk studies only

identity of sponsoring agency " " "

Exempt from common rule

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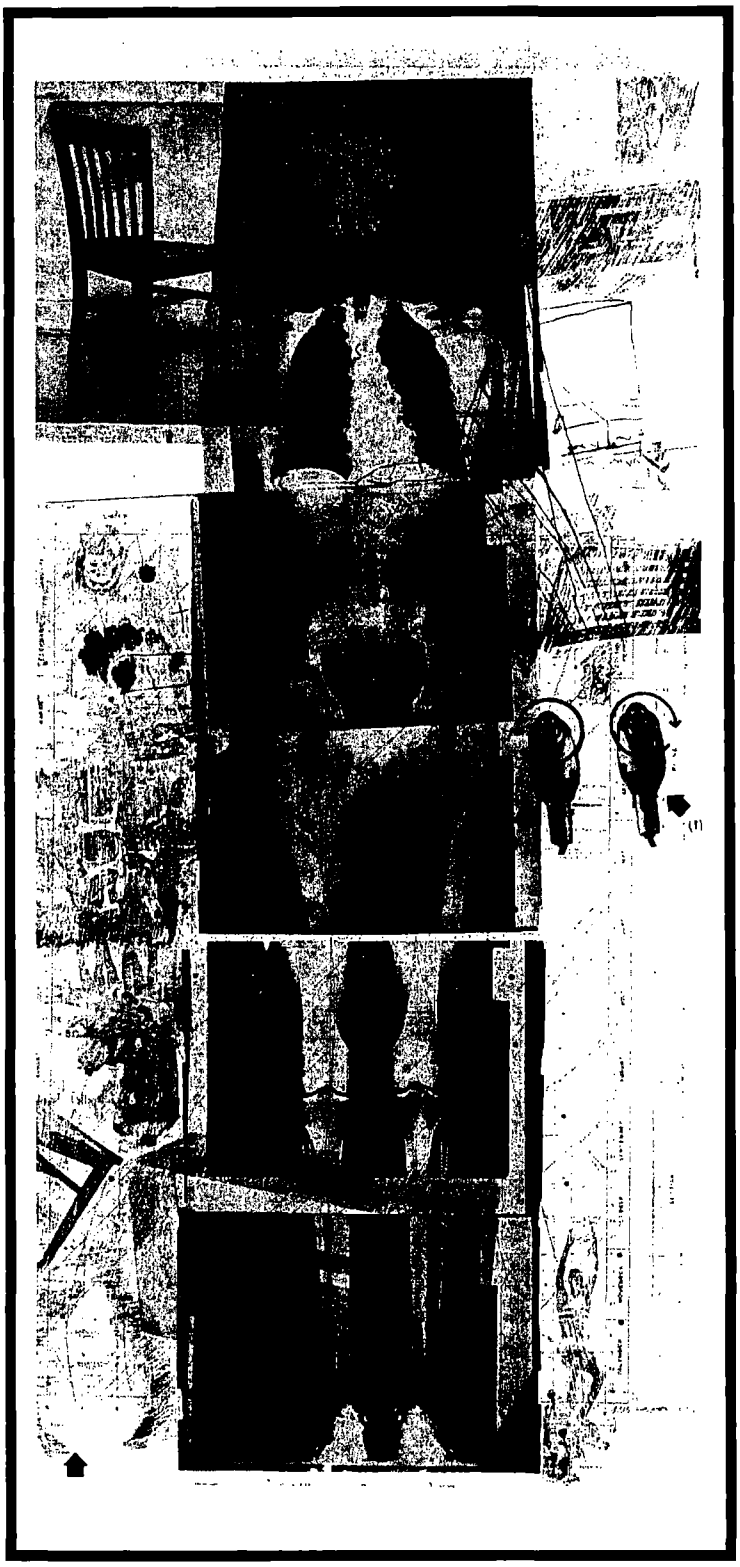

TRUSTING SCIENCE

Nuremberg and the Human Radiation Experiments

Robert A. Burt
Ruth Faden
Nancy E. Kass
Jonathan D. Moreno
Monica Schoch-Spana
Jeremy Sugarman