

HQ 200a (11-73)

NO. 7-2501 LOGGING DATE Dec. 28, 1973**AEC SECRETARIAT**

TO:  COMMISSIONER  GEN. MANAGER  DIR. REGULATION  PLAN. & ANAL.  GEN. COUNSEL  INFO. SERVICES  SECRETARY

DATE: 12/28

INCOMING FROM: Frank Church  
United States Senate  
Special Committee on Aging

DATE: December 21, 1973

SUBJECT: Annual Report by committee summarizing  
developments related to Federal policy and  
actions affecting older Americans

 PREPARE REPLY FOR SIGNATURE OF:

- CHAIRMAN  
 COMMISSIONER  
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 FOR APPROPRIATE ACTION FOR INFORMATION FOR RECOMMENDATION

REMARKS: \_\_\_\_\_

FOR THE COMMISSION: \_\_\_\_\_

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THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE  
WASHINGTON, D. C. 20201

TO:

NOV 6 1972

Honorable James R. Schlesinger  
Chairman

U. S. Atomic Energy Commission  
Washington, D. C. 20545

Dear Jim:

Thank you for your letter of October 16 concerning collaboration of the National Institutes of Health and the Atomic Energy Commission on research projects of mutual interest. I was pleased to hear your opinion on the excellent and productive relationships that have been established and maintained.

Looking at the two proposed strategies which would permit DHEW to make grants to the AEC, the first, seeking statutory change, might be more burdensome than is necessary. The alternate proposal, changing our regulations to permit grants to profit-making institutions, appears more feasible and thus deserves our most serious consideration. My staff will explore this matter further and will advise you at an early date as to what might be done.

You may be interested in knowing that the Commission on Government Procurement, in several conferences with our staff, expressed similar concern that profit-making institutions are not eligible for DHEW research grants. Your letter emphasizes the need for us to expedite our review of this question.

In the meantime, I applaud what I understand from you and the NIH to be an excellent working relationship.

With kindest regards,

Sincerely,

Secretary



UNITED STATES  
ATOMIC ENERGY COMMISSION  
WASHINGTON, D.C. 20545

OCT 16 1972

Honorable Elliott Richardson  
Secretary of Health, Education  
and Welfare

*Elliott*  
Dear Mr. Richardson:

The AEC and various Institutes of the National Institutes of Health have collaborated on research projects of mutual interest for many years. In addition, the AEC has conducted for the Institutes, from time to time, research of primary interest to the Institutes, which most effectively can be carried out at the AEC laboratories. The Commission has been very pleased at these opportunities to collaborate and to be of assistance to NIH. It hopes to be able to continue the relationships in the most effective manner.

As you know, the facilities at the AEC laboratories are operated for AEC by contractors under cost-reimbursement type contracts. Most of these operating contractors are non-profit universities or associations of universities; one of the major laboratories, the Oak Ridge National Laboratory, is operated by a profit-making contractor, Union Carbide Corporation.

The National Institutes are well aware of the unique research capabilities of these laboratories, and of the assistance they can provide in support of the missions and objectives of the Institutes. These capabilities include specialized facilities, diverse scientific and engineering talent, and support personnel which make the AEC laboratories a unique multidisciplinary national resource. Since the solution to many of the complex problems that confront man and the nation today requires expertise from more than one scientific or engineering specialty, the AEC laboratories, with their broad capabilities, are ideally constituted and highly qualified to attack problems in the biological, medical, environmental, agricultural and physical sciences' research and development areas with a high probability of attaining solutions to these problems in a reasonable period of time.

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OCT 16 1972

To assure the continued success of the collaborative research programs of AEC and NIH, the Commission would appreciate your consideration of certain suggestions to remove restrictions which prevent the AEC, or the profit-making contractors which are operating its laboratories, from receiving research grants. The research conducted at ORNL by Union Carbide Corporation has been supported by interagency agreements between AEC and NIH which use NIH's contract funds. However, NIH representatives have recently indicated that they have considerably more funds available for grant-supported research than for contract-supported research and that funds earmarked for grants or contracts are not interchangeable. They have also indicated that they would prefer to use the peer review process which is used to review grant-supported research for the work to be conducted at ORNL. Thus, NIH would rather support a number of the ongoing or recently proposed projects at ORNL with grant funds instead of contract funds.

However, HEW's regulations governing eligibility to receive the Institute research project grants now provide that Federal agencies not specifically authorized by law, and profit-making institutions, are ineligible for grant awards (42 CFR, Part 52, Sec. 52.11). AEC is not specifically designated by law to receive research project grants (as are the hospitals of a number of other agencies specified in the Public Health Service Act, Section 507 (42, U.S.C. Sec. 225 a.)), and thus possible arrangements for grant programs at laboratories, such as ORNL, which happen to be operated by profit-making contractors are handicapped.

Grants have been made by NIH to non-profit contractors operating AEC's laboratories, such as Associated Universities, Inc., which operates the Brookhaven National Laboratory. However, whether a grant is made to AEC or one of its contractors, the research would be conducted within the scope of the AEC operating contract and covered by the overall administrative mechanism governing the conduct of research at the laboratory. It would thus be more direct and administratively uncomplicated if there were no bar to a grant directly to AEC for research to be performed by a contractor operating an AEC laboratory.

Notwithstanding the foregoing problems, the overall relationship between the Commission and the Institutes has been excellent. In that spirit the Commission would like to offer a

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suggestion regarding a change of the Public Health Service Act or, if a statutory change is not feasible, a change of administrative regulations which could facilitate the Institutes' support of research at any of AEC's laboratories by the use of grants. These suggestions were discussed at a meeting of AEC staff with Dr. R. W. Lamont-Havers, Associate Director, Extramural Programs, NIH; Dr. Thomas Malone, his successor; and Dr. R. P. Akers, Policy and Procedure Officer, Extramural Programs.

If the Public Health Service Act were amended to permit grants to be made to AEC for research at any of its Government-owned, contractor-operated laboratories, the Institutes could exercise greater discretion in selecting the appropriate method of support. For example, an Institute could then determine in the case of each individual project if a contract or grant should be used, based upon such factors as the availability of contract or grant funds and whether it deemed the contract or grant procedures more suitable for reviewing the project application.

If a statutory change is not deemed feasible at this time, AEC would also appreciate your considering the desirability of an amendment of the regulations governing eligibility to receive Institute grants, to enable our operating contractors to qualify for the receipt of grants for work at AEC laboratories irrespective of whether the particular operating contractor happens to be a for-profit entity.

The Commission would appreciate your consideration of these suggestions because it believes that the outstanding capabilities at the AEC laboratories should be made available to the Institutes, when they wish to use them, with as little administrative difficulty as possible.

You may be interested in knowing that AEC has received some grants from the National Science Foundation that would be similar to grants it could receive from NIH if the changes suggested above take place.

- bcc: Chairman (2)
- Comm. Ramey
- Comm. Larson
- Comm. Doub
- Comm. Ray
- GM (2)
- Secy (2)
- DBER (3)

Sincerely,

Signed by

Chairman

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OFFICE	AGMR	OGC	DBER	EAGM	GM
PERSONNEL	EDeRenzis/sjb SSEnglish	JReich	JRTotter	JRyan	R. E. F

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# United States Senate

## SPECIAL COMMITTEE ON AGING

(PURSUANT TO S. RES. 51, 93D CONGRESS)

WASHINGTON, D.C. 20510

December 21, 1973

WILLIAM E. ORIOL, STAFF DIRECTOR  
 DAVID A. AFFELDT, CHIEF COUNSEL  
 JOHN GUY MILLER, MINORITY STAFF DIRECTOR

Dixy Lee Ray, Ph.D.  
 Chairman  
 Atomic Energy Commission  
 Washington, D. C. 20545

Dear Dr. Ray:

Each year, the Senate Special Committee on Aging prepares an annual report summarizing developments related to Federal policy and actions affecting older Americans.

I have enclosed a copy of our most recent report. You will note, in Appendix One, statements from Federal units which are concerned in one way or another with aging.

These presentations, it seems to me, serve an important function. They enable departments and agencies to report directly on matters which should receive public attention.

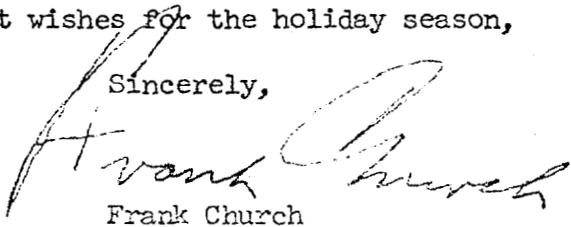
I would very much like to have, therefore, a paper from your office summarizing major activities on aging during 1973 and your plans for follow-up efforts during 1973.

We plan to go to press by mid-February. Your reply should reach us by January 30 for study and for publication. Please enclose a carbon copy of your reply and a duplicate copy of any other material you may wish to send.

If you have questions, please get in touch with Mr. William E. Oriol at this office (180-5364).

With thanks and best wishes for the holiday season,

Sincerely,



Frank Church  
 Chairman

Enclosure

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12-21-73

NO. 74-2183 LOGGING DATE December 14, 1973

# AEC SECRETARIAT

TO:  COMMISSIONER \_\_\_\_\_ DATE: 12/14/73  
 GEN. MANAGER BER  GEN. COUNSEL  INFO. SERVICES  
 DIR. REGULATION  PLAN. & ANAL.  SECRETARY  
 \_\_\_\_\_

INCOMING FROM: Casper W. Weinberger  
HEW

DATE: December 12, 1973  
SUBJECT: Re Proposed Federal Policy for Protection of  
Human Subjects, in Federally supported and  
conducted research

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  - COMMISSIONER
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  - CHAIRMAN
  - COMMISSIONERS
  - SECRETARY

- FOR APPROPRIATE ACTION
- FOR INFORMATION
- FOR RECOMMENDATION

REMARKS \_\_\_\_\_  
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FOR THE COMMISSION: Wanna

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UNITED STATES  
ATOMIC ENERGY COMMISSION  
WASHINGTON, D.C. 20545

DEC 19 1973

Chairman Ray

THRU: General Manager

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SUPPORT OF RESEARCH BY THE NATIONAL INSTITUTES OF HEALTH  
CONDUCTED AT AEC LABORATORIES

Enclosed is a proposed letter for your signature to the Honorable Caspar W. Weinberger, Secretary of HEW. The letter endorses current efforts on the part of HEW to broaden their legislative authority permitting research grants to be awarded to all Government agencies and private institutions. Although HEW could, by changing regulations, make it possible for ORNL to receive research grants, they are seeking a much broader authority which would be of very great benefit to all parts of the AEC.

A year ago, the problems posed to ORNL by the inability of HEW to award grants to private parties were discussed and pointed out in the enclosed letter from former Chairman James Schlesinger to former Secretary Elliott Richardson. At that time, Mr. Richardson felt that the alternative strategy of changing regulations to permit grants to profit-making institutions would be sufficient for HEW's needs. Since that time, the HEW has apparently decided that Congressional action to permit a much broader authority is the desirable course of action. These proposed changes to Section 507 of the Public Health Services Act would permit HEW to award grants directly to private institutions, corporations, and all governmental agencies.

Representatives of the National Institutes of Health are vigorously pushing for these changes following several meetings during the past months between AEC and NIH staff. At present, the request for Congressional action has been transmitted to the Assistant Secretary

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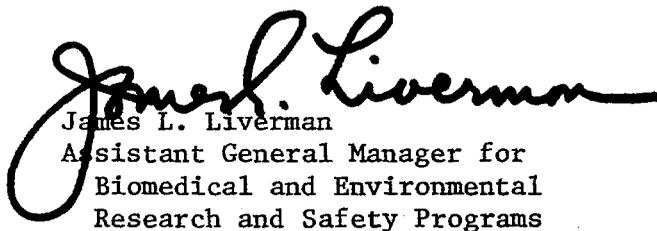
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Chairman Ray

- 2 -

of HEW for legislation, has been approved by that office, and is now on Secretary Weinberger's desk for transmittal to the proper Congressional committee. A letter from you to Secretary Weinberger endorsing these developments would be most helpful in obtaining the necessary action.

  
James L. Liverman  
Assistant General Manager for  
Biomedical and Environmental  
Research and Safety Programs

Enclosures:

1. Proposed ltr to Secy. Weinberger
2. 11/6/72 ltr to Schlesinger frm  
Richardson
3. 10/16/72 ltr to Richardson frm  
Schlesinger

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THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE  
WASHINGTON, D. C. 20201

DEC 12 1973

Dr. Dixy Lee Ray  
Chairman, Atomic Energy Commission  
Washington, D.C. 20545

Dear Madam Chairman:

The desirability of developing a uniform comprehensive Federal policy providing for the protection of human subjects involved in Federally-supported and Federally-conducted research is, I believe, evident. A clearly enunciated uniform policy and a means to guarantee as fully as possible the protection of the rights and welfare of any American citizen who is asked to serve as part of a research project are needed so that public confidence in the scientists and scholars of this country will continue.

I believe there is general agreement among those most concerned with this issue that, while much of the early stages of medical, psychological and sociological research can and should be carried out using animals, man remains the subject of necessity if new diagnostic, therapeutic, preventive or rehabilitative techniques are to be shown effective and safe for human application. A prohibition of research in which humans play a role would seriously impede if not halt the Government's continuing efforts to improve the quality of professional care in the United States. Therefore, I am convinced that it is both important and appropriate that the initiative in safeguarding the rights of human subjects be maintained by the Federal Government.

The Department of Health, Education, and Welfare now funds about seventy percent of the Federal research activities involving human subjects. Early in 1953, we began to develop internal policy for the protection of subjects in biomedical research at the National Institutes of Health. Through the years, protective policies have continued to be developed and extended. Most recently, on October 9, 1973, I published a notice of proposed rule-making in the Federal Register proposing regulations to govern all Departmental

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Reply: 1-10-74

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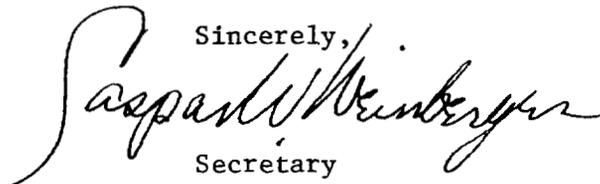
grant and contract programs. Many of the policies contained in that notice were developed with the help of sister Departmental agencies and are already in place on a voluntary basis in programs of the Department of Agriculture, the Agency for International Development, and portions of the Department of Defense, the Atomic Energy Commission and the Environmental Protection Agency.

Enclosed with this letter is a first attempt at developing an explicit government-wide policy and procedure for ensuring the protection of human subjects. I would appreciate your reaction to this draft and the opportunity to work with you and your staff to develop it further. ~~It would be very helpful if you will designate a representative to work with us.~~ I have asked Dr. Charles C. Edwards, Assistant Secretary for Health, to lead this effort for me; please provide him with the name of your designee by January 15, 1974, if possible. I am also enclosing a list of other Departments and agencies to which I have sent a similar request.

Preliminary policies dealing specifically with the special problems of research involving children, prisoners, and the institutionalized mentally ill and mentally retarded have been drafted; I would consider these to be the next logical extension of Federal policy for us to consider. Similar guidelines for research performed by Departmental employees are being drafted which also could be considered as possible Federal policy.

The issues surrounding the participation of human subjects in research projects are complex and challenging. I look forward to cooperating with you in the development of a Federal policy to meet those issues.

Sincerely,



Secretary

2 Enclosures

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PROPOSED  
FEDERAL POLICY  
FOR  
PROTECTION OF HUMAN SUBJECTS

Purpose:

To establish reasonable and uniform Federal standards for the protection of human subjects at risk in research, development, or related activity conducted by Federal employees or supported by Federal agencies.

II. Proposed Federal Policy:

- a. It is the policy of the Federal Government that no funds appropriated for use by a Federal agency shall be used to conduct or support research, development, or related activity involving human subjects, unless a responsible official advised by a convened committee composed of appropriately qualified and knowledgeable individuals, has reviewed and determined: either that these subjects will not be placed at risk or that risk is involved and that:
  1. The activity has scientific merit, will provide sound information and requires the participation of human subjects;
  2. The sum of benefit to the subject, the importance of the knowledge to be gained, and the expected outcome of the appropriately designed experiment justifies a decision to permit subjects to be asked to accept risk;
  3. The rights and welfare of any such subject will be adequately protected;
  4. The subject's freely given informed consent is to be obtained by adequate and appropriate methods;

5. The conduct of the activity will be reviewed at timely intervals;
  6. Suitable records or summaries are kept to permit later follow-up if new findings may require it;
  7. No study will be undertaken in which the expected outcome is the death or serious injury of the subject;
  8. The subject retains complete freedom to withdraw from the experiment at any time.
- B. This policy is applicable to all Federally supported research, development, test, and evaluation where humans are the subjects of the investigation. It is not concerned with the ordinary risks of public or private living nor with recognized occupational hazards.
- C. No individual supported by Federal funds may act as a project director or in a similar investigative capacity involving human subjects at risk unless he is affiliated with an agency or organization which reviews human subject use as described in A above. No member of a committee shall be involved in either the initial or continuing review of an activity in which he has a conflicting interest, except to provide information requested by the Committee.

### III. Definitions:

- A. "Activity" means any research, development, or related project, program, study, task, test, experiment, or similar organized function.
- B. "Agency" means any department or independent agency of the Federal Government authorized to conduct research, development, or related activities, or to enter into agreements to support such activities with appropriated funds.

- C. "Organization" means any non-Federal public or private institution or entity (including State and local government entities) found by an agency to be authorized and qualified by professional and other relevant competence to administer research, development, or related activities involving human subjects.
- D. "Subject at Risk" means any individual who may be exposed to the possibility of harm--physical, psychological, sociological, or otherwise--as a subject in any research, development, or related activity which goes beyond the application of those established and accepted procedures necessary to meet his needs.
- E. "Informed Consent" means the consent of a person, or his legal representative, so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, or other form of constraint, coercion, or undue or improper inducement. The information to be given to the subject should include the following basic elements:
1. A fair explanation of the procedures to be followed, including an identification of any which are experimental;
  2. A description of any attendant discomforts and risks reasonably to be expected;
  3. A description of any benefits reasonably to be expected;
  4. A disclosure of any appropriate alternative procedures that might be advantageous for the subject;
  5. An offer to answer any inquiries concerning the procedures; and
  6. An instruction that the subject is free to decline entrance into a project or to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice.

In addition, the agreement entered into by such person or his legal representative, shall include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights, or to release the organization or its agents from liability, including liability for negligence.

IV. Responsibilities:

- A. The Cabinet Committee on Health will formulate Federal policy for the protection of human subjects and will review subsequent implementation of the Federal policy. When this subject is on the agenda, the following departments and agencies will be added to the Cabinet Committee: Departments of State, Justice, Interior, Agriculture, Transportation, the Atomic Energy Commission, Environmental Protection Agency, the National Aeronautics and Space Administration, the National Science Foundation, and the Smithsonian Institution.
- B. The head of each Federal agency will be responsible for execution of these policies within his agency.
- C. The Assistant Secretary for Health of HEW or his representative will head an interagency ad hoc working group composed of representatives of all Federal agencies which use human subjects in research to assist the Cabinet Committee on Health in developing its policies and review procedures.
- D. The Secretary of HEW will designate a single office within DHEW to serve as staff to the working group.

V. Federal Review of Proposals:

In consultation with other Federal agencies, the Federal Policy Council shall develop policies and procedures for the internal review by Federal agencies of proposals and agreements for the support of research, development, and related activities involving human subjects. Such policies and procedures shall be reasonable and, insofar as possible, uniform.

VI. Federal Review of the Conduct of Direct Operations:

In consultation with Federal agencies, the Federal Policy Council shall develop policies and procedures for the review of new and ongoing research, development, and related activities performed on humans by Federal employees. Such policies and procedures shall prescribe reasonable and, insofar as possible, uniform procedures to be applied to all such Federally supported activities.

VII. Organizational Review of Agreements:

In consultation with other Federal agencies, the Federal Policy Council shall develop policies and procedures for initial and continuing review of activities conducted under agreements entered into between Federal agencies and non-Federal organizations for the support of research, development, and related activities involving human subjects.

VIII. Federal Agency Participation:

Each Federal agency which conducts or supports from appropriated funds research, development, or related activities shall designate an individual with whom the Federal Policy Council and the ad hoc working group staff will interact in the coordination, development, and implementation of these guidelines and policies.

Enclosure #2

Department of State  
Department of Defense  
Department of Justice  
Department of the Interior  
Department of Agriculture  
Department of Transportation  
Atomic Energy Commission  
Environmental Protection Agency  
National Aeronautics and Space Administration  
National Science Foundation  
Smithsonian Institution  
Veterans Administration

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