

memorandum

DATE: OCT 13 1992

REPLY TO
ATTN OF: ER-72

SUBJECT: Animal Care and Usage in Department of Energy (DOE) Facilities, Including Those Performing Work for Others (WFO)

TO: Distribution

A. Background

Paragraphs 10.h (1) and (3) of DOE Order 4300.2B give specific authority and responsibilities to the Director of Health and Environmental Research (HER), Office of Energy Research, regarding the use of animal subjects in Non-Department of Energy Funded Work (WFO). These paragraphs require that within DOE, the Director of Health and Environmental Research, Office of Energy Research:

10.h (1) "Establishes and implements a system to review all proposed research involving human and animal subjects for conformance with established regulations for protection of these subjects."

10.h (3) "Determines adequacy of laboratory assurance for animal subject research and provides that determination and project approval to the cognizant Secretarial Officer(s) and appropriate Heads of Field Elements. Work on such projects shall not proceed without this approval."

The system presented in this memorandum addresses these responsibilities and applies to the care and use of animals in all DOE facilities, including those conducting WFO research.

B. Regulations and Requirements for Protection of Animal Subjects

Before research involving animal subjects can be initiated at a DOE facility, the Director of HER shall be assured that the research will conform to the following requirements:

1. The research will be conducted in a facility that either:
 - a) has a current National Institutes of Health (NIH) assurance number for animal care and usage, or
 - b) is currently accredited for animal care and usage by an appropriate organization such as the American Association for Accreditation of Laboratory Animal Care, Inc. (AAALAC),
or
 - c) has a DOE Assurance Plan Number.

To obtain a DOE Assurance Plan Number, a facility that lacks an NIH assurance number or AAALAC accreditation must submit to HER a description of their animal care and use program, including significant deficiencies, and a definitive plan for addressing the deficiencies. The plan should include the goal of satisfying requirements of either paragraphs 1.a or 1.b above. The animal care and use program and assurance plan will be reviewed by DOE/HER. Those found to be satisfactory will be given a DOE Assurance Plan Number. Such facilities must demonstrate reasonable annual progress toward the goals of the plan.

2. The facility at which research involving animal subjects is to be conducted must have an officially constituted "Animal Care and Use Committee" (Public Health Service Policy on Humane Care and Use of Laboratory Animals, Revised September 1986). The responsibilities of the Committee shall include reviewing all animal care and usage at that facility and assuring that animals are kept, treated, and used in a humane and lawful manner. Research projects involving animal subjects must be reviewed and approved by the Animal Care and Use Committee before being submitted to DOE for approval (in the case of WFO research) or funding (in the case of DOE-sponsored research).

3. The DOE facility at which the research is to be conducted must be listed by the U.S. Department of Agriculture (USDA), and comply with their regulations governing animal care and usage.

4. The facility shall comply with all other relevant local, State, and Federal regulations concerning animal care and usage.

C. Facility Assurance for Research Involving the Use of Animal Subjects

1. Review of Individual Projects

- a. Each WFO proposed research project that is submitted to DOE for approval must include a section documenting that the research will comply with the requirements in Section B, 1-4, above.

The responsibility to review WFO proposals to assure that they contain the required documentation is hereby delegated to the DOE Field Offices. Based on that review, and unless notified otherwise by the Director of HER, the DOE Field Office may approve the use of animal subjects in WFO research projects.

- b. Each proposed research project or field task proposal involving animal subjects that is presented to DOE Headquarters for funding must include a statement that the research will comply with requirements in Section B, 1-4 (above), and include the NIH assurance number, AAALAC accreditation number, or DOE Assurance Plan Number.

2. Annual Assurance Report

The Director of each DOE facility (laboratory or institute) that conducts research involving animal subjects must assure the Director of HER that the research will be done in a manner that conforms to the Section B, 1-4 requirements above. This shall be done by submitting an annual report of assurance from the Facility Director to the Director of HER with a copy to the appropriate DOE Field Office.

The annual assurance report shall be submitted no later than December 15 of each calendar year and shall include the following information:

- 1) The NIH assurance number, AAALAC accreditation number, or the DOE Assurance Plan Number. In the case of facilities having a DOE Assurance Plan Number, the report shall delineate progress made during the preceding year toward meeting the goal of the plan and remaining significant deficiencies. It will also contain a statement that the facility complies with DOE requirements concerning animal care and use.
- 2) A list of all research projects involving animal subjects, including date of approval by animal care committee, the name of the principal investigator, and an indication as to whether the individual projects are in progress, or were completed in the preceding year.
- 3) A statement signed by the facility director certifying that the facility is listed by the USDA and that it conducts research involving animal subjects in a manner that conforms to all local, State, and Federal laws governing the care and use of research animals.

D. Adequacy of Assurance

To determine the adequacy of laboratory assurance for animal subject research, HER staff will periodically conduct on-site verifications of animal use and care programs. They may be done in concert with scientific and technical reviews of DOE research programs. They may also be done independently on an as needed basis.

Questions pertaining to the use of animal subjects may be directed to Dr. James Beall (301-903-4507) of my staff.

William Happer
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Director
Office of Energy Research