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SUBJECT PROTECTION OF HUMAN AND ANIMAL RESEARCH SUBJECTS — 19

1. PURPOSE. To establish policies and procedures implementing DOE regulations and nationally recognized standards designed to protect human and animal test subjects utilized in research.
2. APPLICABILITY. The provisions of this directive apply to SAN administered agreements including, but not limited to DOE funded grants and contracts supporting research and development, and non-DOE funded work at DOE owned, controlled or leased facilities. It also applies to those DOE contractors in which an agreement exists between SAN and another Operations Office whereby SAN provides EH or S oversight services to another DOE contractor e.g. Sandia, Livermore.
3. REFERENCES.
  - a. 10 CFR 745 - Protection of Human Subjects
  - b. 9 CFR 1-199 - Animals and Animal Products
  - c. 51 FR 20204, June 3, 1986, Proposed Model Federal Policy for the Protection of Human Subjects
  - d. Guide For the Care and Use of Laboratory Animals-NIH Pub.No.80-23
  - e. DOE 4300.2 - Non-Department of Energy Funded Work
  - f. SAN MD 4300.2
  - g. Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, mandated by Public Law 99-158.
4. POLICY. It is the policy of SAN that the rights and welfare of human subjects be protected and that any research involving the use of animals be conducted in a humane manner.
5. DEFINITIONS
  - a. Animal. Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.
  - b. Approved Assurance. A document approved by DOE or the Secretary or the Administrator of the Department of Health, Education, and Welfare, which indicates that an organization has an acceptable Institutional Review Board and complies with the provisions of the proposed Model Federal Policy for Protection of Human Subjects.
  - c. Multi-Project Assurance (MPA). An Approved Assurance which entitles the contractor to initiate three or more human subject research studies per year.

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COLLECTION Env. & Safety Support Div.

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FOLDER 1300.3.d Human Subjects  
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- d. Human Subject. A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for <sup>the act of</sup> obtaining the information to constitute research involving human subjects.
- e. Institutional Review Board (IRB). A committee charged with responsibility for review of research activities involving human subjects conducted at or sponsored by the institution. Composition and duties of the IRB are described in references (a) and (b).
- f. Animal Care Committee (ACC). A committee charged with responsibility for review of research activities involving animals conducted at or sponsored by the institution. Composition and duties of the ACC are described in reference (g).
- more to p 3 after f. (g.) DOE contractors are responsible for:
- (1) Establishing and maintaining approved IRB's and ACC's.
  - (2) Complying with DOE and funding agency requirements and the provisions of this MD.

## 6. RESPONSIBILITIES AND AUTHORITIES

- a. The Manager, (TBD)
- b. The Director, Contracts Management Division, is responsible for assuring approval by cognizant SAN management (institutional, program, or project manager), of all proposals involving human or animal research prior to authorizing funding.
- c. The Director, Energy Research Division, has overall responsibility for:
  - (1) Interpreting DOE policies on the protection of human and animal subjects and providing guidance to SAN management as needed.
  - (2) Developing SAN policies and procedures for the review, coordination, and authorization of proposals involving human or animal research.
  - (3) Providing the primary interface between SAN, SAN contractors and the Office of Health & Environmental Research (OHER), DOE-HQ.
  - (4) Approving or disapproving all proposals involving human or animal research; receiving concurrence from OHER on all approved proposals.
  - (5) Performing the functions of an institutional, program, or project manager when no other SAN employee has been assigned the function because of circumstances dictated by the research location or the funding agency.
- d. Institutional, Program or Project Managers are responsible for recommending to the Director, ER, approval or disapproval of all proposals involving human or animal research. Any recommended disapp-

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roval shall first be communicated to the affected contractor for possible resolution.

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- e. The Director, SAN Site Offices, is responsible for:
  - (1) Performing the functions of the Institutional Manager.
  - (2) Assuring that contractor IRB's and ACC's hold current NIH approval.
  - (3) Participating in reviews conducted by DOE/HQ or the funding agency.
- f. The Director, ESQA Division, is responsible for:
  - (1) Assessing risks associated with proposed human or animal research when requested by cognizant line management.
  - (2) Reviewing the published minutes of contractor IRB's and ACC's.
  - (3) Investigating any complaints or suspected improprieties associated with human or animal research.
  - (4) Maintenance of a file of current regulations.

g. DOE Contractors

## 7. PROCEDURES AND REQUIREMENTS

### a. SAN Contractors

- (1) Any contractor intending to engage in research involving animals or human test subjects shall first establish an IRB and/or an ACC which shall be approved by the funding agency and DOE. Approvals granted by the Department of Health and Human Services (OPRR) are automatically approved by DOE.
- (2) Principal Investigators, <sup>or</sup> Project or Program Managers and others interested in conducting research which may involve animals or human test subjects shall first obtain the approval of the IRB and/or the ACC as applicable.
- (3) One copy of all proposals is submitted to the DOE Site Office, if present, or the Director of Energy Research Division when there is no Site Office, together with the approval granted by the IRB and/or the ACC. In the case of non-funded proposals, an additional copy is submitted to DOE/SAN Contract Management Division in accordance with refs e. and f.
- (4) Any human or animal research proposed to be conducted under contract by an outside laboratory or other organization shall require approval of the outside organization's IRB or ACC as well as the contractor's IRB and/or ACC.
- (5) Any proposed research involving human subjects who are employees of another organization or animals belonging to another organization shall require approval of the outside organizations IRB or ACC as well as the contractor's IRB or ACC.
- (6) All research involving human subjects shall meet or exceed the provisions of the DOE approved proposed Model Federal Policy for Protection of Human Subjects.(ref.c).
- (7) All research involving animals shall meet or exceed the provisions of references b,d, and g.
- (8) Any facility designed for animal holding and/or research shall be registered with the US Dept. of Agriculture in accordance with the Animal Welfare Act (ref. b).

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- (9) When requested, results of any committee action (IRB and/or ACC meeting minutes) shall be made available to DOE.
  - (10) The DOE Site Office shall be notified of any accident/incident or complaint related to human or animal research in accordance with SAN MD 5484.1 CH I&II.
- b. Site Office Directors, Institutional, Program or Project Managers:
- (1) Receive and evaluate contractor proposals involving human or animal research.
  - (2) Immediately consult with the contractor when disapproval of a proposal appears warranted.
  - (3) Forward all approved proposals to the Director, Energy Research Div.
  - (4) Consult with the Office of ESQA when a proposal suggests an element of risk to any person, the public, or the environment.
  - (5) Receive and forward any accident/incident notification, including any complaints, in accordance with SAN MD 5484.1 CH I&II.
- c. The Director, Energy Research Division:
- (1) Approves or disapproves, after appropriate consultation, all proposals involving human or animal research. Receives the concurrence of OHER on all approved proposals.
  - (2) Notifies Contract Management Division of all decisions reached on non-DOE funded proposals.
- d. The Director, Office of Environment, Safety, and Quality Assurance:
- (1) Provides consultation, when requested, to any SAN Division relative to factors of risk or applicable regulations.
  - (2) Receives accident/incident notifications and recommends the initiation of investigations as necessary.
  - (3) Conducts overview audits or appraisals to verify compliance with applicable regulations.