1. INTRODUCTION

Battelle Energy Alliance, LLC (BEA) has institutional responsibility for reviewing the rights and welfare of human subjects of research. This charter establishes Idaho National Laboratory's (INL) policy for complying with federal, state, and local laws applying to human research subjects.

2. POLICY

It is INL's policy that the rights and welfare of human subjects involved in research supported or sanctioned by the Department of Energy (DOE) be protected in accordance with 10 CFR 745, and in accordance with the special policies for protection of vulnerable groups, as defined in 45 CFR 46.

INL policy includes the emphasis of minimized risk to human subjects and an informed consent process that allows the subject to freely choose to participate without any deceit, duress, or coercion.

BEA has established the Institutional Review Board (IRB) and granted the authority to approve or disapprove, or suspend or rescind previous approval of human research for protecting the rights and welfare of human subjects. No individual or committee at INL may approve a research project that has been disapproved by the IRB.

Initiation of any research involving human subjects without prior IRB approval is in violation of this policy.

3. SCOPE

The requirement of this instruction applies to research involving human subjects that:

- Is sponsored by the prime contractor, BEA, at INL.
- Is conducted by or under the direction of any employee of BEA performing work under contract at INL in connection with the employee's assigned responsibilities.
- Involves subcontractor use of property or facilities of DOE at INL or work funded by INL. Research involving human subjects being conducted at institutions funded by INL may not begin until the INL IRB approves the protocol. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the INL IRB, under separate letter to the funded institution and the principal investigator. A copy of this approval will be retained in the INL IRB official files.
  Non-compliance with any provision of this clause may result in withholding of funds and/or the termination of the award.

- Involves the use of any INL contractor or private data to identify or contact human research subjects or prospective subjects.

Note that individuals who volunteer to be research subjects may or may not be INL employees.

4. DEFINITIONS

Human Subject. A living individual about whom an investigator conducting research obtains:

- Data through intervention or interaction with the individual,
- Identifiable private data or information.

Intervention. Includes both physical procedures by which data are gathered (e.g., 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.

Research. A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

5. RESPONSIBILITIES

INSTITUTIONAL OFFICIAL

- Is authorized to act for the institution and assumes on behalf of the institution the obligations in the Assurance
- Sets the tone for an institutional culture of respect for human subjects
- Is responsible for appointing the IRB chair
- Provides IRB with necessary resources and staff
- Supports IRB decisions
- Ensures effective institution-wide communication and access to human subject information
- Encourages participation in human subject educational activities.

INSTITUTIONAL REVIEW BOARD

- Reviews and approves, requires modification to, or disapproves all research activities, including proposed changes in previously approved human subject research

- Conducts continuing review of approved research at intervals appropriate to the degree of risk, but not less than once a year

- Has authority to suspend or terminate previously approved research not being conducted in accord with the IRB's requirements or that has been associated with unexpected serious harm to subjects

- Unresolved and important risk issues relating to the health and safety of human subjects participating in research activities being funded by INL/BEA, involving INL/BEA staff, or conducted at INL shall be properly tracked to closure using an approved laboratory issues management tracking system. An important risk issue is defined to be an item of safety, noncompliance, poor quality, or other problem where the severity of consequences could be catastrophic or critical (i.e., death, severe injuries or illness, mission interruption, or environmental damage). Every effort is made to capture risk issues by conducting periodic reviews of issues being tracked, and ensuring frequent communication between IRB office personnel and the applicable Management System Lead to review areas of concern and associated mitigative actions.

- Must be familiar with:

    1. Ethical principles of human subject research

    2. Requirements of federal regulations

    3. Applicable state laws

    4. Institution's Federal-Wide Assurance

    5. Institutional policies and procedures for the protection of human subjects.

- Must have effective knowledge of:

    1. Subject populations

    2. Institutional constraints

    3. Differing legal requirements

4. Other factors that may contribute to a determination of risks and benefits to subjects and subjects' informed consents.

Note that the IRB process does not preempt any of BEA's environment, safety, and health (ES&H) requirements or responsibilities.

IRB CHAIR

- Is the knowledgeable point of contact for DOE
- Is responsible for appointing IRB members
- Ensures that the IRB carries out its responsibilities
- Conducts expedited review of protocols
- Keeps institutional official informed
- Educates IRB members and investigators.

IRB ADMINISTRATOR

- Receives all research protocols and communicates IRB decisions to investigators
- Often makes preliminary determinations regarding exemptions and eligibility for expedited review
- Schedules IRB meetings
- Prepares and distributes the agenda and review material for IRB members
- Records the minutes of IRB meetings
- Ensures that IRB decisions and requirements for modifications are promptly conveyed to investigators in writing
- Maintains the IRB records and arranges access to the records when requested by federal authorities
- Acts as designated institutional contact for receipt of communication from federal or other policymakers concerning human subject research issues

- Reports promptly to the appropriate institutional officials, DOE OBER, and other sponsoring federal department or agency heads:

    1. Any unanticipated injuries or problems involving risks to subjects or others

    2. Any serious or continuing noncompliance with the regulations or requirements of the IRB

    3. Any suspension or termination of IRB approval for research.

PRINCIPAL INVESTIGATOR

- Has primary responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of their institution's Federal-Wide Assurance.

- Must be familiar with:

    1. Ethical principles of human subjects research

    2. Requirements of federal regulations

    3. Applicable state laws

    4. Institution's Federal-Wide Assurance

    5. Institutional policies and procedures for protection of human subjects.

- Conducts all research according to the IRB-approved protocol and complies with all IRB determinations.

- Ensures that each potential subject understands the nature of the research and of the subject's participation and takes whatever steps are necessary to gain that comprehension.

- Provides a copy of the IRB-approved informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement.

- Retains all signed consent documents for the life of the Battelle contract (but not less than 3 years beyond completion of the research).

- Promptly reports proposed changes in previously approved human subject research activities to the IRB.

- Does not initiate changes without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

- Reports progress of approved research to the IRB, as often as and in the manner prescribed by the IRB on the basis of risks to subjects, but not less than once a year. Submits an electronic report to the DOE Protecting Human Subjects database on an annual basis.

- Promptly reports to the IRB any unanticipated injuries or problems involving risks to subjects or others.

INDIVIDUAL SUBJECTS

- Understand and complete necessary consent forms prior to participating in human research studies.

- May cease participation at any time.

- Report any suspected adverse effects to the principal investigator and the IRB chair.

6. RELATED INFORMATION

Source documents:

- Title 10 CFR Part 745, “Protection of Human Subjects”

- Title 45 CFR Part 46, “Protection of Human Subjects”

- DOE P 443.1A, “Policy on the Protection of Human Subjects”

- DOE O 443.1A, “Protection of Human Subjects.”