

**OAK RIDGE SITE-WIDE INSTITUTIONAL REVIEW BOARD
STANDARD OPERATING PROCEDURES**

January 2014

7/2/14

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CHAPTER 1: PURPOSE, SCOPE, AND OWNERSHIP

Purpose

The purpose of this manual is to establish the operating procedures of the Oak Ridge Site-wide Institutional Review Board (ORSIRB), hereinafter referred to as the IRB, or the Board. The function of the IRB is to assure that risks to human subjects are minimized and reasonable in relation to the anticipated benefit, and to protect the rights and welfare of research subjects in accordance with applicable federal regulations, state laws, Department of Energy (DOE) directives, and institutional policies.

“Research” is defined as a systematic investigation, including pilot projects, designed to contribute to generalizable knowledge. Human subjects are considered to be involved: if humans are asked to participate physically in an activity or to donate bodily material (e.g., blood); if information about humans is sought directly (e.g., through an interview or questionnaire) or indirectly (e.g., by observation); or if individually identifiable information about humans is requested from a person or a databank. Collaborative studies (materials or information collected at another institution and shared with researchers at an institution covered by this IRB) are included, as are projects in which the investigator is the only subject of the research.

Ownership

Oak Ridge Associated Universities (ORAU) administers the IRB, constituted and operated under a Federalwide Assurance (FWA) with the Office of Human Research Protection (OHRP) of the U.S. Department of Health and Human Services (DHHS). By direction of the DOE Oak Ridge Operations Office (DOE/ORO), the ORSIRB reviews proposed or continuing studies involving human participants conducted by employees or agents of ORAU, Oak Ridge National Laboratory (ORNL), the Y-12 facility, and **other facilities as determined by DOE/ORO**. By direction of DOE, the ORSIRB also serves as the cognizant site-specific IRB for research conducted by other entities sponsored by DOE or the DHHS, i.e., the Centers for Disease Control (CDC) or the National Institute of Occupational Safety and Health (NIOSH), involving current or former workers at the sites within the DOE/ORO purview. ORAU, therefore, provides the central focus for researchers, the IRB, and administrators in processing protocols, arranging IRB review, keeping records and reporting, and communicating pertinent information about human subjects research.

Scope

This manual applies to all activities of the IRB and pertains to all research activities that involve human subjects (even if the research team are the only subjects):

- Conducted or sponsored by participating institutions; conducted or directed by any employee or agent of these institutions in connection with his or her institutional responsibilities.
- Conducted or directed by any employee or agent of these institutions using any property or facility of these institutions; involve the use of information by these institutions to identify or contact human research subjects or prospective subjects.
- Involve the use of information compiled for present/former employees of DOE, its contractors and predecessors at facilities within ORO purview, by non-affiliated

institutions sponsored by DOE, NIOSH, or other government agency (federal, state, local), for which this IRB provides site-specific institutional review.

- Human terrain mapping (HTM) projects - DOE Order 443.1B, Protection of Human Research Subjects, Section 4a(2), dated March 17, 2011, outlines DOE requirements for HTM activities. DOE limits engagement of its Laboratories in HTM projects to: 1) development of models and software for use by the Department of Defense (DoD) and other Federal agencies in their analyses of collected HTM data; and 2) analysis of de-identified as defined in the definitions section of this Standard Operating Procedure (SOP) or publicly available data. It is DOE's policy that, prior to initiation, such projects be approved by DOE Headquarters, the DOE or NNSA human subjects protection and if intelligence-related, also IN-10). DOE Headquarters will engage the ORSIRB, and potentially, the DOE laboratory principal investigator (PI), in confirming that the intention of the PI is to work only with de-identified or publicly available data. Once the project is initiated, the recognized DOE IRB is the only entity authorized to determine whether the HTM data received by the PI after project initiation meets the DOE criteria for de-identification. The ORSIRB, therefore, will be responsible for working with certain DOE laboratory PIs to: 1) discuss the datasets received from the sponsor and/or any other data to be used to ensure they are sufficiently de-identified for the PI to begin work; and 2) complete and sign a data security agreement with the PI using the DOE-provided template. DOE also expects that the ORSIRB will periodically (not less than once a year) follow up with the PI to check on progress and scope of the work being conducted. Any modifications in scope would require both Headquarters and ORSIRB approval.**Generalizable*** studies in human environments (e.g., occupied homes and offices, classrooms, and transit centers like subway systems and airports) that use tracer chemicals, particles, and/or other materials, such as perfluorocarbons, to characterize airflow.
- **Generalizable*** studies in occupied homes and/or offices that:
 - manipulate the environment to achieve research aims, e.g., increasing humidity and/or reducing influx of outside air through new energy-saving ventilation systems.
 - test new materials (e.g., sequentially changing the filter materials in the HVAC system while monitoring the effects on air quality and energy use).
 - involve collecting information on occupants' views of appliances, materials, or devices installed in their homes or their energy saving behaviors through surveys and focus groups. Some surveys may be online surveys administered through providers such as Amazon Mechanical Turk and Survey Monkey.

CHAPTER 2: INTRODUCTION AND OVERVIEW OF IRB FUNCTIONS

Numerous federal statutes set forth the requirements and expectations for IRB performance. The root of all these requirements is the fundamental desire that all human research subjects be treated with respect, dignity, and an assurance that risk will be held to the lowest achievable level consistent with the goals of the research. The principles that underlie the protection of human subjects today are found in three main documents:

- [The Nuremberg Code](#)
- [The Declaration of Helsinki](#)

- [The Belmont Report](#)

Basic Ethical Principles

The ORSIRB is guided by the ethical principles set forth in the report of the [National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research](#), entitled “Ethical Principles and Guidelines for the Protection of Human Subjects in Research” (the *Belmont Report*). These three principles are autonomy, beneficence, and justice.

Autonomy means “respect for persons.” It requires that potential subjects be given the information they need, in language they understand, to decide whether or not to participate in a study, as well as the time and opportunity necessary to make that decision without any pressure to participate. Autonomy further requires protection of subject privacy, confidentiality of data, and increased protection for vulnerable populations.

Beneficence requires that researchers (and their institutions) do no harm. This includes minimizing the nature, probability, and magnitude of risk while maximizing potential benefits.

Justice requires that the benefits and burdens of research be distributed fairly. Subjects should be recruited based on their relation to the problem being studied rather than their easy availability, their compromised position, or their malleability. Investigators should base inclusion/exclusion criteria on those factors that most effectively and soundly address the research problem. For example, subjects should not be denied access to a study simply because they may not speak English.

In addition, the requirements set forth in [45 CFR 46](#) of the Code of Federal Regulations [10 CFR 745](#) and [21 CFR 56](#) will be met for all applicable research regardless of the funding source. The reporting information will be as required by the funding source, and by DHHS and DOE if these are not the funding source.

Recommended Institutional Policy

Institutions submitting proposals to the IRB are expected to acknowledge and accept their responsibilities for protecting the rights and welfare of human subjects in research covered by this assurance.

These institutions are expected to establish policies that all research involving human participants will be reviewed for approval by the ORSIRB which has been established under an assurance of compliance negotiated with DHHS. The involvement of human subjects in research covered by these policies should not be permitted until the Board has reviewed and approved, or determined as exempt, the research protocol and informed consent has been obtained in accordance with and to the extent required by 45 CFR 46.116. Furthermore, review of research on a continuing basis will be conducted by the IRB at least once per year. Unless informed consent has been specifically waived by the Board, no investigator should involve any human being as a subject in research unless he or she has obtained legally effective informed consent from the subject or the subject’s legally authorized representative using a consent instrument reviewed and approved by the Board within the previous 12 months, or less, as the Board requires.

These institutions are expected to assure compliance with federal, state, or local laws as they may relate to research covered by the assurance with DHHS.

These institutions are expected to comply with the policies set forth in 45 [CFR 46 Subpart B](#), which provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization.

These institutions are expected to comply with the policies set forth in [45 CFR 46 Subpart C](#), which provide additional protection for prisoners involved in research.

These institutions are expected to comply with the policies set forth in [45 CFR 46 Subpart D](#), which provide additional protections for children involved in research, and in addition will consider additional safeguards in research when that research involves those individuals institutionalized as mentally disabled and other potentially vulnerable groups.

These institutions are expected to comply with the requirements set forth in [45 CFR 46.114](#) regarding cooperative research projects. When research covered by the assurance is conducted at or in cooperation with another entity, all provisions of the DHHS assurance remain.

CHAPTER 3: BOARD AUTHORITIES AND RESPONSIBILITIES

Institutions

ORAU has established and will maintain the Oak Ridge Site-wide IRB in accordance with 45 CFR 46 and 10 CFR 745. This Board shall have the responsibility and authority to review, approve, withhold approval, or request changes in any of the participating institutions’ research activities involving human subjects.

These institutions are, and will continue to be, represented on the Board by institutional representatives (one per institution) with delegated authority from each institutional official to serve as liaisons between the Board and the institutions.

ORAU has provided and will continue to provide meeting and records keeping space for the Board, and sufficient staff and technical resources to support the Board in carrying out its duties and meeting responsibilities under the DHHS assurance.

Protecting the subjects of research is a shared responsibility involving institutional officials, research investigators, IRBs, and research subjects.

IRB PROTOCOL REVIEW STANDARDS	
Minimal regulatory requirements for IRB review, discussion and documentation in the meeting minutes	
Regulatory review requirement	Suggested questions for IRB discussion
1. The proposed research design is scientifically sound & will not unnecessarily expose subjects to risk.	(a) Is the hypothesis clear? Is it clearly stated? (b) Is the study design appropriate to prove the hypothesis? (c) Will the research contribute to generalizable knowledge and is it worth exposing subjects to risk?

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result.	(a) What does the IRB consider the level of risk to be? (b) What does the PI consider the level of risk/discomfort/inconvenience to be? (c) Is there prospect of direct benefit to subjects?
3. Subject selection is equitable.	(a) Who is to be enrolled? Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)? Seriously-ill persons? Healthy volunteers? (b) Are these subjects appropriate for the protocol?
4. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.	(a) Are appropriate protections in place for vulnerable subjects, e.g., pregnant women, fetuses, socially- or economically-disadvantaged, decisionally-impaired, prisoners or workers?
5. Informed consent is obtained from research subjects or their legally authorized representative(s).	(a) Does the informed consent document include the eight required elements? (b) Is the consent document understandable to subjects? (c) Who will obtain informed consent (PI, nurse, other?) & in what setting? (d) If appropriate, is there a children's assent? (e) Is the IRB requested to waive or alter any informed consent requirement?
6. Risks to subjects are minimized.	(a) Does the research design minimize risks to subjects? b) Would use of a data & safety monitoring board or other research oversight process enhance subject safety?
7. Subject privacy & confidentiality are maximized.	(a) Will personally-identifiable research data be protected to the extent possible from access or use? (b) Are any special privacy & confidentiality issues properly addressed, e.g., use of genetic information?
Additional considerations	
1. Ionizing radiation.	If ionizing radiation is used in this protocol is it medically indicated or for research use only?
2. Collaborative research.	Is this domestic/international collaborative research? If so, are FWAs or other assurances required for the sites involved? Is there a CRADA?
3. FDA-regulated research	Is an IND or IDE involved in this protocol?

Office of Research Administration (ORA)

As the parent institution responsible for the ORSIRB, ORAU maintains an Office of Research Administration (ORA). The ORAU president appoints a Chair who supervises the IRB Administrator.

Institutional Official (IO)

The President or Director of each participating institution is responsible for human subjects protection at their site. This Institutional Official (IO) has the following responsibilities:

- Sets the “tone” for institutional culture of respect for human subjects.
- Certifies compliance with federal policies to DOE Headquarters (HQ).
- Ensures that no research involving human subjects is initiated without IRB approval.
- Ensures that solicitations or proposals for research, studies, tests, surveys, surveillance, or other data collection are reviewed to identify research involving human subjects.
- Encourages and promotes communication among staff and management as a means of maintaining a high level of awareness regarding protecting the rights and welfare of human subjects.
- Encourages participation in human subjects educational activities.
- Supports IRB authority and decisions.
- Appoints Chair of the IRB

Human Studies Coordinator (HSC)

Each participating institution may appoint an HSC at their site or defer to the IRB Administrator for guidance. The HSC or the IRB Administrator is responsible for reviewing proposals submitted by the institution’s PIs for completeness and compliance with 45 CFR 46 and 10 CFR 745. The HSC or the IRB Administrator returns to a PI proposals that are not complete and/or not compliant for revision and works with the PI to revise proposals. The complete proposal package is submitted to the IRB Administrator with an initial recommendation for the appropriate type of review. The HSC serves as the official contact with DHHS/OHRP, and the [DOE Office of Human Studies](#) for the participating institution.

IRB Administrator

The IRB Administrator is responsible for the day-to-day activities of the IRB and is the primary point of contact. The IRB Administrator also has the following responsibilities:

- Acts as point of contact and subject matter expert concerning the ORSIRB with DOE, other federal agencies, and the OR research community.
- Manages the administrative and record-keeping requirements of the IRB.
- Assists the IRB to ensure that research conducted by the staff of OR facilities and human subject research performed at OR facilities and other institutions is conducted in accordance with all applicable regulations, policies, procedures, institutional requirements, and agreements.
- Ensures documentation of IRB activities is generated and maintained.
- Develops, along with the Chair and Vice-Chair, policies and standard operating procedures. Minor changes and updates are carried out as necessary. Major changes shall have the concurrence of a simple majority of members of the Board.
- Develops and facilitates education in compliance with federal agency and institutional requirements.
- Receives proposals submitted by each institution, reviews them for completeness and compliance, and forwards them to the IRB chair with an initial recommendation for the appropriate type of review.

- Participates in the [DOE Human Subjects Working Group \(HSWG\)](#).
- Attends professional meetings and appropriate training as required to maintain certification as an IRB Administrator.
- Serves as the Secretary of Record for the Board in accordance with 45 CFR 46.115.
- Prepares and submits an annual report to the [DOE Human Subjects Research Database](#)
- Serves as a voting representative on the Board.
- Notifies DOE of any new human participants research projects involving:
 - o An institution without an established IRB.
 - o A foreign country.
 - o The potential for significant controversy (e.g., negative press or reaction from stakeholder or oversight groups).
 - o Research subjects in a protected class.
 - o The generation or use of classified or sensitive unclassified information.

IRB Chair

The IRB Chair is responsible for ensuring that the Board carries out its responsibilities. The Chair also has the following responsibilities:

- Determines the type of review required (Full Board, Expedited, Exempt).
- Conducts expedited reviews or appoints expedited review subcommittees from the voting members of the Board.
- Acts as liaison with the institutional officials.
- Reports promptly to DOE/HQ and institutional officials any injuries to human subjects, any unanticipated problems involving risks to human subjects or others, any serious or continuing noncompliance with the requirements or determinations of the IRB, and any suspensions or terminations of IRB-approved research.
- Does not vote unless there is a tie of the membership vote.
- Supervises the IRB Administrator

Principal Investigator (PI)

The Principal Investigator (PI) on a project submitted to the IRB for review has primary responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of federal law and any requirements of the ORSIRB. Each PI must be familiar with the ethical principles of human subjects research and the requirements of federal regulations, DOE directives, and applicable state laws. PIs are required to successfully complete training as prescribed by the IRB and use the electronic tracking system for submission.

In addition, each PI shall:

- Justify the need to involve human subjects.
- Assure that risks to subjects are minimized and benefits are maximized.
- Secure director-level approval of research proposals prior to IRB review.
- Ensure that each potential subject understands the nature of the research.
- Provide a copy of the IRB-approved informed consent document to each participant at the time of consent unless the IRB has specifically waived this requirement.

- Assure that subject privacy and data confidentiality are protected in so far as allowed by law.
- Promptly report any proposed changes in previously approved research to the IRB, and not initiate changes without IRB review and approval.
- Report progress of approved research to the IRB as often as, and in the manner prescribed by the IRB, but not less than once a year.
- Promptly report to the IRB any unanticipated injuries or problems involving risks to subjects or others.
- Notify the IRB when the project is complete or needs to be inactivated. upon completion a closure request form must be submitted in the electronic submission and management system.
- Notify the Food and Drug Administration (FDA) and the Board whenever it is anticipated that an investigational new drug (IND) or device exemption (IDE) will be required.

PIs are encouraged to consult with the IRB early in the development of their proposals to ensure that (1) their studies are scientifically sound (worthy of involving human subjects), (2) the rights and welfare of subjects are fully considered in the study design, and (3) the study has a high likelihood of meeting the criteria for IRB approval. PIs shall prepare a protocol giving a complete description of the scientific and ethical aspects of proposed research including provisions for the adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed. This is required even in situations in which the research is exempt under [45 CFR 46.101](#). The proposal review package must include the following and shall be submitted using electronic management system as directed ([Attachment A](#)).

- A completed IRB Application Form e-signed by the PI and his or her Director
- A complete research proposal, including provisions for the protection of human subjects in accordance with all applicable laws and regulations, and any related paperwork (e.g., advertisements, recruitment materials, questionnaires, survey instruments).

Investigators shall include with the protocol a draft of all applicable informed consent documents that address all the elements of informed consent as prescribed in [45 CFR 46.116 \(a\) and \(b\)](#) and other elements recommended by this IRB to be routinely included in a consent form. PIs are responsible for ensuring that legally effective informed consent shall:

- Be obtained using a consent form that has been reviewed and approved by the IRB within the previous 12 months or less as previously prescribed by the IRB.
- Be obtained from the subject or the subject's legally authorized representative.
- Be in non-technical language understandable to the subject or his/her representative.
- Clearly state that participation is voluntary.
- Be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate.
- Not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the PI, the sponsor, the institution or its agents from liability for negligence.

Unless otherwise authorized by the Board, PIs at a minimum shall provide the following information to each subject:

- The names, affiliation, addresses of the principal and any co-investigator(s), the sponsor (funding source), and location at which the research will be conducted.
- A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation; a description of the procedures to be followed as they involve human subjects, and identification of any procedures that are experimental.
- A description of any benefits to the subject or to others that may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be available.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and identifying the individuals (by title), institutions, and/or agencies that may routinely use or access the records.
- For research involving more than minimal risk, explanations as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- A statement describing how and in what form the data will be used, stored and maintained, and how and to whom the results of the research will be reported to assure the privacy of the subject and the confidentiality of the subject's personally sensitive information.
- An explanation of whom to contact for answers to pertinent questions about (a) any research-related injury to the subject, and (b) the research and research subjects' rights and responsibilities; this shall include identification of "the Chair, ORSIRB" as an alternate source of information about subjects' rights.
- A statement that participation is voluntary and refusal to participate or discontinue participation at any time will not result in any penalty or loss of benefits to which the subject is otherwise entitled.
- A statement of the action, if any, to be taken by the subject if he/she decides to withdraw from the research before its completion and of the disposition of the subject's data compiled up to the time of withdrawal.
- A statement that the PI may decide to withdraw the subject from the research and the sponsor might terminate funding, without notification.
- A statement to be signed and dated by the subject assuring his/her consent to participate in the research with full knowledge of the objectives, methods, procedures, risks/benefits, alternatives to, and voluntary participation.
- A statement to be signed and dated by the individual obtaining the consent, assuring that the consent has been obtained in accordance with this policy and assurance the subject has had all questions and concerns addressed to his/her satisfaction.
- When required by the Board, the PI also shall provide one or more of the following additional elements of information to each subject:
 - A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently foreseeable.
 - Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent.

- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
- The approximate number of subjects involved in the study.

PIs shall be responsible for ensuring that informed consent is documented by the use of a written consent form approved by the Board within the past 12 months or less, and signed by the subject or the subject's legally authorized representative and the person obtaining the consent, unless the requirement for consent is specifically waived by the Board. The names of all signatories to an informed consent also shall be typed or printed and dated.

PIs shall ensure that each person signing the written consent form is offered a copy of that form. PIs may use a consent form that is either:

- A written consent document that embodies the elements of informed consent required by 45 CFR 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the research investigator or other person obtaining the consent shall document by signing that either the subject or the representative has been given adequate opportunity to read or to listen to a recording of the form before signing it.
- A "short form" written consent document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. When the "short form" is used, PIs shall ensure that:
 - ü The written summary of what is to be said to the subject or the representative receives the prior approval of the Board.
 - ü A witness is present at the oral presentation.
 - ü The short form is signed by the subject or the representative; the witness signs both the short form and a copy of the written summary of the oral presentation.
 - ü The person obtaining consent signs a copy of the summary.
 - ü The names of all signatories shall be printed or typed and dated.
 - ü A copy of both the short form and summary is offered to the subject or the representative.

PIs and their supervisors are responsible for ensuring that all protocols, consent form(s), and necessary supporting documents for all research involving human subjects are submitted to the Board for review. All such research must be approved by the Board prior to its implementation.

In accordance with 45 [CFR 46.117](#), the Board shall require documentation of informed consent by use of a written consent form currently approved for project-specific use for a period of up to 12 months, or may waive the requirement for the PI to obtain a signed consent form for some or all subjects if the Board finds either:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of

confidentiality. Each subject will be asked whether he/she wants documentation linking him/her with the research and his/her wishes will govern; or

- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

When the documentation requirement is waived, the Board may require the PI to provide subjects with a written statement regarding the research.

Waiver or Alteration of Informed Consent

Waiver of Informed Consent: An IRB may waive the requirement to obtain informed consent (45 CFR 46.116(d)) provided it finds and documents that:

- The proposed research presents no more than minimal risk to the subjects,
- A waiver or alteration of informed consent not adversely affect the rights and welfare of subjects,
- It is impracticable to carry out the research without a waiver or alteration of informed consent, and
- Whenever appropriate, the subjects will be provided with additional pertinent information about participation (i.e., Fact Sheet).

Waiver of Documentation of Informed Consent: An IRB may waive the requirement for the investigator to obtain a signed consent form (45 CFR 46.117(c)) for some or all subjects if it finds that either:

- the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a break of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern, or
- the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

A waiver of Informed Consent shall be requested in the case of records-based studies where the study participants will not be contacted and the primary risk from the study is loss of privacy. Procedures must be in place to protect the privacy of the data and to protect any Personal Identifiable Information (PII).

Managers

The PI's supervisor/manager/department head must approve the IRB Application Form

Institutional Review Board (IRB)

The IRB is responsible for reviewing all Oak Ridge Site-wide human subjects research and has the authority to approve, to require modifications in order to secure approval or to disapprove such research.

The IRB is further authorized to suspend or terminate previously approved research that is not being conducted in accordance with its requirements or that has been associated with unexpected serious harm to subjects. No individual or committee at the participating institutions may initiate

any research involving human subjects that has not been approved by the IRB. The Board also has the following responsibilities:

- Ensure that research is reviewed at intervals appropriate to the degree of risk, but not less than once a year.
- Notify investigators in writing and maintain records of its determinations of review status of research proposals involving human subjects, and of its decisions to approve or disapprove proposed research, to require modifications as a condition of approval, or to suspend or terminate previous approval.
- Provide human subjects education information, and training as required.

In addition, Board members must be familiar with:

- The ethical principles of human research (*Belmont Report*).
- The requirements of federal regulations, DOE directives, and applicable state laws. Board members must also have effective knowledge of:
 - Subject populations.
 - Institutional constraints.
 - Differing legal requirements (e.g., DHHS and FDA, federal and state).

CHAPTER 4: ORSIRB STRUCTURE

Authority

The Board shall have the responsibility to review all research activities involving human participants conducted at or by participating institutions or involving workers at DOE facilities under the purview of OR, and the authority to approve, require modification in or deny approval of all these activities or proposed changes to previously approved activities.

The Board shall approve research if the following requirements are satisfied:

- Risks to subjects are minimized by using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk; and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the Board shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
- Selection of subjects is equitable. In making this assessment the Board shall take into account the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited, being particularly cognizant of vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally-disadvantaged persons.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, including those who are members of vulnerable populations.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of their data, including those who are members of vulnerable populations.
- The Board shall have the authority and be responsible for promptly reporting information to the institution, the DHHS/OHRP and sponsoring agencies, or all, on a variety of issues. In conjunction
- with this requirement, the Board must be prepared to receive and act on information received from a variety of sources, such as human subjects, PIs, or other institutional staff. For reporting purposes, the Board will follow the procedures described below:
 - ❖ Any serious or continuing noncompliance by PIs with the requirements of the Board. This information shall be reported promptly to the appropriate department/program head.
 - ❖ Injuries to human subjects. Information received by the Board concerning injuries to subjects resulting from the performed research shall be reported promptly to the institutions, DOE, OHRP, and any other sponsoring agencies.
 - ❖ Unanticipated problems. Information received by the Board concerning unanticipated problems involving risks to subjects or others shall be reported promptly to OHRP and other sponsoring agencies.
 - ❖ Notification by the Board of its suspension or termination of its previous approval of research protocols shall be in writing and shall include a statement of the reasons for the Board's action. The Board shall report the action promptly to the research investigator (PI), his or her supervisor, OHRP, DOE, and any other sponsoring agencies.

Jurisdiction

The jurisdiction of the ORSIRB includes all research activities that involve human subjects if that research:

- Is sponsored by any of the participating institutions.
- Is conducted or directed by an employee or agent of these institutions in connection with his or her institutional responsibilities.
- Is conducted or directed by any employee or agent of these institutions using any property or facility of these institutions.
- Involves the use of information by these institutions to identify or contact human research subjects or prospective subjects.

- Involves the use of information compiled for present/former employees of DOE, its contractors and predecessors at facilities under OR purview, by non-affiliated institutions sponsored by DOE, NIOSH, or other government agency (federal, state, local), for which this IRB provides site-specific review.

Composition

45 CFR 46 provides that an IRB must have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institutions. The IRB members must be sufficiently qualified in expertise, experience, and diversity of background, including diversity in racial and cultural heritage and sensitivity to issues such as community attitudes, to promote respect for its advice and counseling in safeguarding the rights and welfare of human subjects. The IRB members must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are nonscientific. The IRB must also include at least one member who is not affiliated with the institutions and who is not an immediate family member of a person affiliated with the institution.

When reviewing research involving a vulnerable population such as children, prisoners, workers, pregnant women, handicapped or mentally disabled persons, the IRB may invite individuals with competence in the special areas applicable to the research to assist in the review of issues that may require expertise beyond or in addition to the expertise routinely available to the IRB. Such specialists shall not vote.

The Board includes both male and female members.

The Board includes at least one member who represents the interests of the community at large.

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Selection and Appointment of Members

Board members and representatives to the Board of participating institutions are responsible for nominating persons for membership to the Board. Board members serve renewable 3-year terms. . New members will be officially notified of their appointment to the Board by the IRB Chair. New members do not vote at their first Board meeting. A confidentiality statement and a statement promising to acknowledge [conflict of interest](#) as it occurs will be signed at least annually.

The Board shall nominate an active or former member to serve as its Chair for renewable 3-year terms;. The Board's nomination shall have the concurrence of a simple majority of members of the Board.

The Board shall nominate an active or former member to serve as the Vice-Chair for renewable 3-year terms... The Vice-Chair has the authority to act for the Chair in his/her absence.

The immediate past Chair is invited to attend meetings as a guest for a period of up to one year to provide expertise as needed to the new Chair.

The responsibilities of the Board Secretary shall be assigned by ORAU; the Secretary shall serve as the Secretary of Record of the IRB.

Resignation/Termination of Members

Members are free to resign from the IRB at any time, but fulfilling existing terms is encouraged. Termination of a member from the IRB prior to expiration of his or her term requires documented “just cause” to show that continuation or renewal of a member’s term would be detrimental to the Board. Just cause for removal may include, but is not limited to, lack of minimum attendance (defined as 3 consecutive scheduled board meetings), misconduct, unresolved conflict of interest, failure to complete required training or failure to complete work as assigned or requested by the Chair, Vice-Chair, or Administrator.

Member Training

New and current members of the Board must complete training as prescribed by the IRB Chair.

In addition, time is allocated on the agenda during each meeting to educate members and to address current issues and pending changes in regulations. The IRB Administrator and Chair also use this time to disseminate information obtained from national meetings and conferences attended throughout the year.

CHAPTER 5: REVIEW AND APPROVAL

The length of time required for review of all relevant documents (an application, informed consent, protocol, etc.) is necessarily dependent on the review category into which a given application falls. In general, based on an assessment of the risks and benefits, complexity of the protocol, and quality and completeness of the information provided IRB review may be accomplished in as little as a day for exempt protocols or from 4-8 weeks for expedited or full Board review.

Levels of Review

Federal regulations allow for three levels of review: exempt, expedited, and full Board. The level of potential risk to the subject determines the level of review required. The higher the risk, the higher the rigor of review.

Note: The IRB makes the **final determination** on which type of review a protocol warrants.

[Exempt Review](#)

Certain low-risk research activities are exempt from rigorous IRB review; however, the IRB still must conduct a preliminary review to determine whether the research meets the criteria for exemption. This determination can only be made by the IRB, and once determined, is in effect only as long as

there are no changes in the proposed research. The IRB Administrator will follow-up with the PI at least annually to determine if the study is still active and that no changes have been made to alter the exemption approval.

Categories of exemption include:

- ❖ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- ❖ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - ❖ information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- ❖ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section,
- ❖ if: the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- ❖ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- ❖ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- ❖ Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

[Expedited Review](#)

Expedited review may be conducted by the IRB Chair, a designated voting member, or a group of voting members. During an expedited review, the IRB may approval a proposal, ask for

modifications to achieve approval, or refer it to the full Board. However, proposed research cannot be disapproved under expedited review.

To be considered for expedited review, proposed research must meet two conditions:

- (1) It must present no more than **minimal risk** to subjects, and
- (2) It must fit into one of the identified research categories

Expedited review may also be used for minor changes to approved research.

The identified research categories are:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
 - a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

When the expedited review procedure is used, Board members are informed by including those projects on the agenda for discussion at the Board's next meeting. At a convened meeting, any member may request that an activity that has been approved under the expedited process be reviewed by the full Board in accordance with non-expedited procedures.

Full Board Review

All other human subjects research requires review at a convened meeting by a valid quorum of IRB members. This is the highest level of review and to be approved, proposed research must receive the approval of a majority of those voting members present.

Note: No IRB member may participate in the review of any project in which he or she has a conflicting interest, except to provide information requested by the IRB.

Research protocols scheduled for review shall be distributed to all members of the Board at least 10 working days prior to the meeting.

A Board member whose concerns are primarily in nonscientific areas must be present at the convened meeting before the Board can conduct its review of research.

A simple majority of the voting membership of the Board constitutes a quorum and is required in order to convene a meeting for the review of research protocols.

If the Board Chair determines that consultants or experts are required to advise the Board in its review of a protocol, such an expert or consultant will be recruited, and will receive copies of the research project. Their presence at the meeting as non-voting attendees or their written comments on the protocol will be invited, whichever is more appropriate. Their opinions will be considered by the Board in reaching its decision on the protocol.

If warranted, IRB meetings may be conducted via telephone conference call that may be recognized as a “convened” meeting provided that each participating IRB member has received all pertinent material prior to the meeting, and can actively and equally participate in the discussion of all protocols. Minutes of such meetings must clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements (e.g., attendance, initial and continued presence of a majority of members, including at least one nonscientist member; actions taken by the IRB; the vote on such actions; discussion and resolution of controverted issues).

For a research protocol to be approved it must receive the approval of the majority of the eligible voting members present at the convened meeting.

Board members who have active affiliations with the participating institutions shall not be eligible to vote on protocols/consent forms submitted by investigators (PIs or Co-PIs) at the institutions with which the members are affiliated, nor serve as Primary Reviewers of such protocols.

The Board shall notify the PI(s) by electronic submission and management system, e-mail, fax, or regular mail of the Board’s decisions, conditions, and requirements within five working days. If a protocol is disapproved by the Board, notification shall be provided to the PI(s) in writing within 5 working days describing the reasons for its decision to disapprove a research protocol. The PI(s) shall be given an opportunity to respond within a reasonable time as set forth by the Board. The Board also shall provide to the PIs in writing within 5 working days the reasons for its decision to disapprove a research protocol and an opportunity for the research investigator to respond within a reasonable time as set forth by the Board.

Special Classes of Subjects: Vulnerable Populations

Federal regulations require that IRBs give special consideration to protecting the welfare of vulnerable subjects such as children, prisoners, workers, pregnant women, mentally disabled

persons, or economically or educationally disadvantaged persons (45 CFR 46, Subparts B, C and D). Vulnerable persons are compromised in their ability to give informed consent. IRB's must be vigilant to prevent any perception of coercion and/or undue inducement.

The special vulnerability of children and minors makes consideration of involving them as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are in place for reviewing research involving children. When children or minors are involved in research, both the assent of the child or minor and permission of the parents are required in lieu of informed consent of the subject. Because children have not reached their full intellectual and emotional capacities and are legally unable to give valid consent, their involvement in research requires the permission of parents or legally authorized representatives. The IRB must determine whether the permission of both parents is necessary and, if not, the conditions under which one parent may be considered not reasonably available. The IRB must also determine that adequate provisions are made for soliciting the assent of the children when the IRB judges that the children are capable of providing assent.

When a protocol proposes to use prison inmates as a study population, the first question the IRB must ask is whether that population was chosen simply out of convenience to the investigator. A second issue is whether confidentiality of participation and of data can be adequately maintained in the prison. Yet another question is whether prisoner subjects can ethically be paid for participation and, if so, how much. When the IRB knows it will be reviewing protocols involving prisoners as subjects, IRB members will familiarize themselves with 45 CFR 46 Subpart D, and discuss these regulations before any actual protocol using prisoners is presented.

Workers may be a vulnerable group because they may experience management or union pressure to participate, not participate, or respond to a study in some way that the employer or union may perceive as advantageous. In addition, worker subjects also face risks in the areas of privacy and confidentiality.

Research involving women who are or may become pregnant requires special attention from IRBs because of women's additional health and psychological concerns during pregnancy.

Primary Reviewers

When the IRB uses the Primary Reviewer System, the primary reviewer(s) should do an in-depth review of all pertinent documentation (application, protocol, informed consent, advertisements, recruitment materials, questionnaires, survey instruments, and any other relevant material). All other IRB members should receive and review a protocol summary (of sufficient detail to make the determinations required under DHHS regulations at 45 CFR 46.111), the proposed informed consent document, and any advertising material.

Frequency of Review

The Board shall determine, in its review of research protocols, which projects will require Board review more often than annually. Such a determination will be made by the Board based primarily on the nature and magnitude of the risk(s) of the research to the subjects.

Collaborative Projects

45 CFR 46 permits cooperative research projects involving more than one institution and potentially more than one IRB. With the approval of DOE, an institution participating in a cooperative project may enter into a joint review arrangement, may rely upon the review of another institution's qualified IRB, or may make similar arrangements to avoid duplication of effort. In conducting cooperative research, each participating institution is responsible specifically for safeguarding the rights and welfare of the human subjects involved.

International Projects

When research takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in 45 CFR 46 and 10 CFR 745. In these circumstances, if a department or agency head determines that the procedures described by the institution afford protections that are at least equivalent to those provided in 10 CFR 745, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in 45 CFR 46. It is DOE's policy that, prior to initiation, such projects be approved by DOE Headquarters, the DOE or NNSA human subjects protection (HSP) program manager and if intelligence-related, also IN-10.

Initial Review and Approval

PIs shall prepare a protocol giving a complete description of the proposed research and make provisions for the adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed. This is required even in situations where the research is exempt under 45 CFR 46.101.

Investigators shall include with the protocol, a draft of the informed consent document that addresses all the required elements of informed consent as prescribed in 45 CFR 46, section 116, and other elements recommended by the IRB to be routinely included in a consent form.

Note: Mandatory training may be a requirement of the funding agency, or a condition of IRB approval. The IRB Administrator investigates whether any training is mandatory for the PI, his or her manager, or members of the research team. If so, this training must be completed before the IRB will approve a protocol review package. The Administrator also determines whether the IRB members who will review the protocol require mandatory training before conducting the review.

Upon receipt of the proposal package, the IRB Administrator verifies that the package contains all required components and all are complete, reviews the package for missing information and items that need clarification, and verifies that any required training has been completed. The IRB Administrator then schedules a review session (for Exempt and Expedited reviews) with the IRB Chair or adds the review to the agenda for the next meeting of the full board. When the IRB reviews a proposed protocol, it has four options:

- ❖ **Approve** as is (protocol is approved as submitted).
- ❖ **Approve with conditions** (review package requires modifications or PI must furnish additional information).
- ❖ **Defer** (protocol/review package needs major work before IRB can complete review).
- ❖ **Disapprove** (protocol does not meet the minimum criteria required for approval).

Approval

To approve a research study, the IRB must ensure that all the following requirements have been satisfied:

- ❖ Risks to subjects are minimized and reasonable in relation to anticipated benefits.
- ❖ Selection of subjects is equitable.
- ❖ Participation is voluntary, and informed consent will be sought and appropriately documented.
- ❖ Adequate provisions are made to protect subject privacy and confidentiality of data.
- ❖ When any subjects are likely to be vulnerable to coercion or undue influence, additional safeguards are included to protect the rights and welfare of those vulnerable subjects.

If the IRB requests changes to the proposal, such changes must be completed before the IRB Chair will certify final approval of the proposal. Alternatively, the IRB may approve, but impose certain restrictions or conditions on the researchers or on the conduct of the research (e.g., the IRB may require third-party observation of the consent process).

Approval Period

When the IRB approves a study, it must also determine how often it needs to be re-reviewed. The maximum approval period is one year and is used for studies that are determined to be no greater than minimal risk. Studies that have potential for greater than minimal risk shall be evaluated on a case-by-case basis, and review frequency shall be determined by considering factors such as the health and vulnerability of subjects involved, previously reported adverse events, and investigator/group experience with the proposed work.

Notice of Approval

Once all IRB conditions for approval have been satisfied, the IRB Administrator prepares an approval letter to be reviewed by the Chair that specifies the IRB approval date and the date that approval expires. This notice also includes the requirements the PI must meet while conducting the research.

Disapproval

If a study is disapproved, the IRB Administrator notifies the PI in writing and must specify the reason(s) for the disapproval so the investigator has an opportunity to respond (in person or in writing). Investigators have the right to request the IRB to reconsider research proposals that it did not approve.

Note: Research that has been approved by the IRB may be subject to further review and approval by other institutional officials; however, **no individual or committee member at the participating institutions may approve or conduct a research project that has been disapproved by the IRB.**

Modification Review

PIs are responsible for submitting an amendment to the original protocol to the Board when it is proposed to:

- ❖ Involve human subjects, and the activity previously had only indefinite plans for the involvement of human subjects.
- ❖ Involve human subjects, and the activity previously had no plans for the involvement of human subjects.
- ❖ Significantly change the involvement of human subjects (such as changes in procedures or the number of subjects) from what was initially approved by the IRB.

Continuing Review

The Board shall conduct continuing review of all active research protocols, consent forms, and supporting documents at intervals appropriate to the degree of risk posed by the research on the research subjects as determined by the Board on a protocol-by-protocol basis, but not less than once per 12-month period. Expedited continuing review shall be carried out by the Chair, a designated Board member, or group of Board members when the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. Continuing review of research previously approved by the convened IRB may be carried out by the expedited review process where:

- ❖ The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or
- ❖ No subjects have been enrolled and no additional risks have been identified; or the remaining research activities are limited to data analysis.; or Continuing review of research, not conducted under an investigational new drug application or investigational device exemption but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Note: If a PI fails to submit an Annual Review/Continuation Request to the IRB Administrator at least two weeks prior to the IRB Approval expiration date, the study may be suspended.

CHAPTER 6: AFTER APPROVAL

Documentation

After IRB approval and before beginning a research protocol, the PI must be able to show that the proposed research and consent documents have been reviewed and approved by the IRB and that all subjects are fully informed, and their consent has been documented in signed consent forms (unless the signature requirement or informed consent document was specifically waived by the IRB).

Research Conduct

During the course of the research, the PI must comply with all IRB decisions and conditions and the responsibilities described in these Guidelines.

Note: The IRB may contact subjects directly or monitor the research to evaluate the PI's conduct and compliance with requirements.

Unanticipated Problems and Adverse Events

When unanticipated problems or adverse events occur in the research process, they must be systematically evaluated, corrected, and possibly reported. The phrase *unanticipated problems* involving risks to subjects or others is found but not defined in 45 CFR 46. OHRP considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

- (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- (2) related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Likewise, the term *adverse event* is found but not defined in 45CFR 46. In OHRP guidance, the term *adverse event*, in general, is used very broadly and includes any event meeting the following definition: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subjects participation in the research, whether or not considered related to the subjects participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

The PI must immediately report to the IRB all unanticipated problems or adverse events, even if there is no obvious causal relationship between the study activities and the event. The IRB, in turn, reports all adverse events to the institution's management, to DOE/HQ, and to any other federal agency funding the research protocol.

The PI may not deviate from an approved protocol without written ORSIRB approval, except when such deviation is necessary to eliminate an immediate hazard to a study subject.

Any individual noting a deviation from an approved protocol should report the deviation or concern to the ORSIRB. The ORSIRB will then review the protocol and relevant documentation and assess the deviation according to two main criteria:

- ❖ Potential or actual harm to the subject.
- ❖ Potential or actual effect on the integrity of the study data.

The ORSIRB will determine whether the incident is a serious violation (a subject was harmed, the potential for harm was created, or the violation compromised the integrity of the study) or non-serious (violation did not harm or potentially harm a subject and does not compromise study integrity).

The ORSIRB will also determine whether further corrective action is warranted:

- ❖ If the protocol violation is deemed serious, the ORSIRB will suspend the study.
- ❖ If the protocol violation is deemed non-serious, correspondence will be sent from the Chair, ORSIRB, to the PI and the Designated Institutional Representative of the PI's parent institution, directing investigation of the incident (if not already accomplished) and corrective actions.

All findings and conclusions of the ORSIRB will be documented in the protocol file. All the actions outlined above will be conducted in conjunction with all engaged IRBs.

Serious Adverse Events

The PI must immediately report to his/her institution's IRB and the ORSIRB all adverse events and unanticipated problems within 48 hours, even if there is no obvious causal relationship between the study activities and the event. If there is any possibility of loss or compromise of personally identifiable information (PII), the PI must report to his/her institution's IRB and the ORSIRB immediately. In the case of the Former Worker Program (FWP), the PI must additionally report the incident immediately to the appropriate DOE Project Officer. In turn, the ORSIRB must report the incident to the DOE-Cyber Incident Response Capability (DOE-CIRC) at 866-941-2472 immediately, as well as to DOE SC (Human Subjects Program Manager). When required, the responsibility for reporting the serious adverse event to the Office of Human Research Protections (OHRP), devising a remediation plan, and for all related follow-up activities will be managed by the ORSIRB in conjunction with the institutional IRBs for each research project, as well as the Central Department of Energy IRB (CDOEIRB).

Suspension or Termination of IRB Approval

In accordance with federal regulations 45 CFR 46.113, the IRB has the authority to place administrative hold, suspend, or terminate approval of research that is not being conducted in accordance with the terms and conditions of the IRB approval (including the requirements for continuing review), or has been associated with unexpected or serious harm to subjects.

Suspension of IRB approval is "a temporary withdrawal of IRB approval for some or all research procedures or a permanent withdrawal of approval for some research procedures." Studies that have been suspended still require continuing review. A suspended study may be re-opened after the unanticipated problem triggering the suspension has been resolved.

Termination of IRB approval is defined as "a permanent withdrawal of IRB approval for all research procedures." Terminated protocols are considered closed and no longer require continuing review.

Any suspension or termination of IRB approval will be reported promptly to the PI and to his/her line management via a letter that will clearly describe the action and the reasons for the action taken

by the IRB. Issues not resolved within 30 working days will be reported to the DOE IO and the research sponsor.

If the IRB finds a pattern of protocol violations by a particular PI with no evidence of effective corrective action measures having been taken by that Investigator's Department the IRB will suspend all protocols for which he/she is the PI and request his/her Departmental Manager to investigate the root causes. The Department has the responsibility to ensure that individuals named as PIs are competent to perform their duties.

Completion

When a study is completed or the PI wishes to terminate it, the PI must notify the IRB and fill out a closure form, at which time the protocol will be placed on inactive status for a period of 5 years. During this time, a PI may request re-activation of the protocol without submitting a new protocol (unless there are significant changes in the protocol).

CHAPTER 7: MONITORING

Research Conduct

During the course of the research, the PI must comply with all ORSIRB decisions, directives, conditions, and the responsibilities described in these Guidelines. The ORSIRB may contact subjects directly or monitor the research to evaluate the PI's conduct and compliance with requirements.

Noncompliance/Violations/Complaints

All reports of non-compliance, alleged violations of human subjects' regulations, and complaints from research subjects will be investigated by the ORSIRB Administrator. Substantiated allegations will be forwarded to the ORSIRB Chair for appropriate action as outlined below.

The ORSIRB Chair must report the following to the appropriate institutional official and to the DOE SC Human Subjects Program Manager (and the NNSA Human Subjects Program Manager for NNSA sites):

- ❖ Any serious or continuing noncompliance with the regulations or requirements of the ORSIRB.
- ❖ Any suspension or termination of ORSIRB approval for research.

Self-Assessment

The IRB shall periodically conduct self-assessment, at a minimum of every 3 years, to ensure compliance with requirements and to evaluate the effectiveness/efficiency/suitability of procedures. Each participating institution is encouraged to conduct periodic self-assessments of their Human Subjects Protection Program. In addition, the IRB is subject to audit by DOE and DHHS/OHRP.

CHAPTER 8: MEETINGS

Scheduled Meetings

One or two convened meetings of the Board shall occur at least within a 12-month period. Meetings may be held more frequently as necessary to assure that the Board meets its responsibilities in accordance with 45 CFR 46. A PI may request, or be requested, to attend a meeting in person or by teleconference to discuss his/her protocol; however, no PI may be present during a vote on his/her proposal.

Agendas

The IRB Administrator prepares a preliminary agenda for each meeting. A tentative agenda and copies of each project assigned to the meeting will be available electronically at least one week prior to the meeting. Members will be required to review these documents prior to the meeting. Paper copies will be distributed on a case-by-case basis.

Minutes

The IRB Secretary records the minutes of each convened meeting of the IRB (see "Record Keeping" for required content of minutes). Minutes will be posted electronically for review as soon as possible following each meeting. Minutes are approved by the Board at the next full Board meeting.

The officers of the participating institutions shall be kept informed of Board activities with copies of decision letters.

Quorum and Voting

A quorum is defined as a majority of IRB voting members, including at least one non-scientist member. When a proposal will be reviewed at a meeting, the IRB Administrator assures a quorum is present. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a non-scientist member), the IRB may not take further actions or votes unless the quorum can be restored.

All voting is conducted in closed session, and voting privileges shall be limited to IRB members present at the meeting. Proxy votes are not accepted. Member votes are recorded by the IRB Administrator via a show of hands, and a majority vote is required for any IRB determination. Voting results will be recorded in the minutes of the meeting including the number of members voting for, against, and abstaining. The IRB Chair votes only in the case of a tie vote of the membership present at the meeting.

An IRB member may abstain from voting to approve a protocol as long as she/he can provide a reasonable explanation for abstaining. This abstention, and the explanation, shall be included in the minutes of the meeting.

Alternates

Alternates may be appointed for voting members. An alternate votes (and only counts toward satisfaction of a quorum) if that alternate has been seated to replace someone who is absent. If a voting member for whom the alternate is eligible to substitute, is absent, the alternate may be seated, counted in the quorum, and vote. If no member is missing for whom the alternate is an

eligible replacement, the alternate may contribute to the discussion, but may not vote or count toward a quorum.

CHAPTER 9: RECORD KEEPING

Records Retention and Access

All records related to the participating institutions' human subjects research shall be retained indefinitely electronically, and shall be accessible for inspection and copying by authorized representatives of the funding Department or Agency at reasonable times and in a reasonable manner.

IRB Records

All official IRB records are stored indefinitely in either paper or electronic format.

Protocol Records

The IRB Administrator assigns each protocol a unique, chronological number that indicates the fiscal year and order it was received in that year. Official IRB records for each protocol include the following:

- ❖ All documentation reviewed by the IRB.
- ❖ All correspondence related to the protocol.
- ❖ Copies of any press releases or media coverage of the protocol.
- ❖ Notes from protocol review sessions, including Reviewer's written comments.
- ❖ All other documents specifically approved by the IRB relating to the protocol (e.g., any subject recruitment material, questionnaires, etc.).

Meeting Minutes

Minutes of IRB meetings shall be taken in sufficient detail to show the following:

- ❖ Attendance, including members (and any guests) present, as well as late arrivals or early departures by members.
- ❖ Actions taken by the IRB (including listings of exempt and expedited reviews) and annual progress reports.
- ❖ The vote on these actions, including the number of members voting for, against, and abstaining.
- ❖ The basis for requiring changes in or disapproval of research.
- ❖ A written summary of the discussion of controverted issues and their resolution.
- ❖ Reports of unanticipated problems and adverse effects.

Training Records

The IRB Administrator retains a copy of all training material distributed to members as well as records of all relevant seminars and conferences attended by any IRB member. Members are

encouraged to send copies of any completion certificates from online tutorials or other training sessions to the IRB Administrator.

PI Records

The PI must retain all research-related records, including original, signed and witnessed consent forms that originate with the PI or the research team.

CHAPTER 10: REFERENCES

Regulatory

[45 CFR 46](#) *Protection of Human Subjects*

[10 CFR 745](#), Common Rule," DOE

[Department of Energy Order DOE O 443.1B, "Protection of Human Subjects,"](#)

Implementation

[DOE, *Protecting Human Research Subjects Handbook*](#)

CHAPTER 11: DEFINITIONS

Adverse event - An undesirable effect, whether expected or unexpected, that occurs from the time a subject consents until the subject's final study follow-up is completed. **All** adverse events must be reported even if there is no obvious causal relationship between the protocol procedures and the event.

Code of Federal Regulations (CFR) - the code of Federal Regulation (CFR) is published in the federal register, a publication of the federal Government that codifies the general and permanent rules for executive departments and agencies. There are 50 titles that represent broad areas subject to federal regulation. The CFR is updated once each calendar year and is issued on a quarterly basis.

Conditional Approval – A protocol the Chair, CDOEIRB will approve contingent upon the PI successfully addressing a set of specified concerns identified during any type of protocol review.

Conflict of Interest – Any affiliation, personal, professional, or financial connection with the institution or person submitting a protocol that might create the appearance of impropriety that could undermine the confidence in the conflicted individual.

De-identified Data - A data set that has no, or limited, identifiers and for which a person with current knowledge of generally accepted scientific principles determines that the risk that the information could be used, alone or in combination with other reasonably available information, by

an anticipated recipient, has been reduced to the extent practicable. A graded approach must be used in balancing the de-identification of the datasets and the usability of the dataset to accomplish the needed research.

DOE/HQ - The Human Subjects Research Program Manager in the Office of Science (SC-72), Department of Energy, Germantown, MD.

DOE Human Subjects Research Database - A compilation of summary information, which is available on the DOE website, updated annually, on every human subjects research project conducted by DOE personnel, with DOE funding, or at DOE institutions or facilities.

Engaged in Human Subjects Research – Awardee institutions are automatically considered to be “engaged” in human subject research whenever they receive a direct DOE or other federal agency award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. The awardee institution is also responsible for ensuring that all collaborating institutions engaged in the research hold an OHRP-approved Assurance prior to their initiation of the research.

Exculpatory Language – Wording in a consent document in which a volunteer research subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. Informed consent may not contain any exculpatory language. Subjects may not be asked to waive, or appear to waive, any of their legal rights, nor may they be asked to release the investigator, sponsor, or institution (or its agents) from liability for negligence.

Federalwide Assurance – A written commitment from ORAU, the Oak Ridge Site-wide Institutional Review Board that ensures institutional compliance with and implementation of DOE or DHHS regulations for the protection of human research subjects at the Oak Ridge sites.

HIPAA - Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, a foundation of Federal protections for the privacy of protected health information.

Human Subject - A living individual about whom an investigator 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 (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.

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 (e.g., 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 obtaining the information to constitute research involving human subjects.

Human Terrain Mapping - Research and data gathering activities primarily conducted for military or intelligence purposes to understand the - human terrain, the social, ethnographic, cultural, and political elements of the people among whom the U.S. Armed Forces are operating and/or in countries prone to political instability. This work includes observations, questionnaires, and interviews of groups of individuals, as well as modeling and analysis of collected data, and may become the basis for U.S. military actions in such locations. In addition to Human Terrain Mapping (HTM), such activities are often referred to as human social culture behavior (HSCB) and human terrain systems (HTS) studies. It is DOE policy that HTM activities will be managed as HSR.

Informed Consent – A person’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or undergo a diagnostic, therapeutic, or preventive procedure. It is obtained after providing to the subject the basic elements of informed consent as set forth in 45 CFR Part 46 and 10 CFR Part 745. Informed consent documents shall include disclosure of all potential risks and related consequences or adverse effects, as well as any benefits that may occur as a result of such participation. In giving informed consent, participants may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

Internet research - Any human subjects’ research conducted using the [Internet](#). On the internet are two types of information: *publicly available* and *for authorized use only*.

Publicly Available: Information is publicly available when it is lawfully made available to the general public from: (1) Federal, state, or local government records; (2) Widely distributed media, including information that has been published or broadcast for public consumption, is accessible online to the public, or is available to the public by subscription or purchase; or (3) Disclosures to the general public that are required to be made by federal, state, or local law. Publicly available does not mean “without restriction” (see note below).

For Authorized Use Only: Information that is restricted to authorized users and governed by specific data protection rules.-

Legally authorized representative - An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Office for Human Subjects in Research Protection (OHRP) - the Office of Human Research Protection (OHRP) is the Department of Health and Human Services oversight body that provides guidance to IRBs.

ORSIRB – Oak Ridge Site-wide Institutional Review Board (IRB) established in accordance with and for the purposes expressed in 10 CFR 745.

Personally Identifiable Information (PII) – Any information collected or maintained about an individual, including but not limited to, education, financial transactions, medical history and criminal or employment history, and information that can be used to distinguish or trace an individual’s

identity, such as his/her name, Social Security number, date and place of birth, mother's maiden name, biometric data, and any other personal information that is linked or linkable to a specific individual. Information regarding Federal and DOE requirements for the protection of PII of human research subjects and DOE employees is included in Attachment B.

Principal Investigator (PI) - The scientist or other individual designated by the Oak Ridge sites who is responsible for the scientific or technical direction of the project.

Private information - This 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Such 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 obtaining the information to constitute research involving human subjects.

Proposal review package – The minimal information required by the IRB of the PI in order to conduct a review of proposed research. This package includes the following:

- ❖ A completed Review Request form signed by the PI and his or her Director
- ❖ A 1-2 page abstract of the proposed research, (including a description of risks and benefits)
- ❖ A complete research proposal, including provisions for the protection of human subjects in accordance with all applicable laws and regulations, and any related paperwork (e.g., an activity- specific Standard Operating Procedure, manufacturer's specification sheets, safety reports, etc.)
- ❖ A proposed Informed Consent form that includes all required elements (see Attachment E,
- ❖ "Elements of Informed Consent")
- ❖ Any proposed advertisement or recruitment material for human volunteers.
- ❖ Copies of approvals by the PI and any collaborating institutions' IRBs.

Protected Health Information – HIPAA regulations define health information as "any information, whether oral or recorded in any form or medium" that

- "[i]s created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse"; and
- "[r]elates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."

Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable* knowledge. Activities that meet this definition constitute research for purposes of this document, whether or not they are conducted or supported under a program that is considered research for other purposes.

Serious Adverse Event - Any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

- results in death;
- is life-threatening (places the subject at immediate risk of death from the event as it occurred);

- requires inpatient hospitalization or prolongation of existing hospitalization; (4) results in a persistent or significant disability/incapacity;
- results in a congenital anomaly/birth defect; or
- any other adverse event that, based upon appropriate medical judgment, may jeopardize
 - the subject's health and may require medical or surgical intervention to prevent one of
 - the other outcomes listed in this definition (examples of such events include allergic
 - bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Unanticipated Problem - Unanticipated problems involving risks to participants or others mean any problem that is:

- (1) Unanticipated; **and**
- (2) Indicates that participants or others are at increased risk of harm.

Adverse Event - Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:

- (1) the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
- (2) the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

Attachment A

Oak Ridge Sitewide Institutional Review Board Template for Reviewing Human Subjects' Research Protocols that Utilize Personally Identifiable Information

The following items must be addressed in all protocols:

1. Keeping PII confidential;
 2. Releasing PII, where required, only under a procedure approved by the responsible IRB(s) and DOE;
 3. Using PII only for purposes of this program;
 4. Handling and marking documents containing PII as "containing PII or PHI;"
 5. Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII;
 6. Making no further use or disclosure of the PII except when approved by the responsible IRB(s) and DOE, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research project under these same conditions and with DOE written authorization; (c) for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project; (d) when required by law; or (e) with the consent of the participant.
 7. Protecting PII data stored on removable media (CD, DVD, USB Flash Drives, etc.) using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified;
 8. Using passwords to protect PII used in conjunction with FIPS 140-2 certified encryption that meet the current DOE password requirements cited in DOE Guide 205.3-1;
 9. Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped;
 10. Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products;
 11. Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e. separate e-mail, telephone call, separate letter;
 12. Using FIPS 140-2 certified encryption methods for websites established for the submission of information that includes PII;
 13. Using two-factor authentication for logon access control for remote access to systems and databases that contain PII. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2 found at: <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf>.)
 14. Reporting the loss or suspected loss of PII immediately upon discovery to: 1) the DOE funding office Program Manager or, if funded by a DOE laboratory, the DOE laboratory Program Manager; and 2) the applicable IRBs (as designated by the DOE/DOE laboratory Program Manager). If the DOE or DOE laboratory Program Manager is unreachable, immediately notify the DOE-CIRC (1-866-941-2472, by FAX: at 702-932-0189, or by e-mail at: circ@jc3.doe.gov). For additional information, see: <http://energy.gov/cio/office-chief-information-officer/services/incident-management/jc3-incident-reporting>.
 15. Classified projects that use PII must also comply with all requirements for conducting
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Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

September 24, 2004

