



## Pacific Northwest National Laboratory Decision Quadrant and Consent Check List

(Note: See Page 3 for Additional Considerations Related to Continuing Review and Review of Modifications and New Findings)

### 1. This protocol meets the basic criteria for approval [45 CFR 46.111].

(a) 1) Risks are minimized 2) Risks are reasonable in relation to anticipated benefits, if any to subjects and the importance of knowledge that may reasonably be expected to result, 3) Selection of subjects is equitable 4) informed consent will be sought, 5) Informed consent will be appropriately documented, 6) when appropriate, the research plan makes adequate provisions for monitoring the data to ensure the safety of subjects, 7) When appropriate, the research plan makes adequate provisions to protect the privacy of subjects and maintain the confidentiality of data and (b) When vulnerable subjects are involved, additional safeguards have been included to protect their rights and welfare.

Yes  No If No, please explain.

### 2. The research meets the regulatory criteria for expedited review found under 45 CFR 46.110 which includes:

For initial or continuing review:

- The research (or remaining research procedures) presents no more than minimal risk to participants (*Does not apply to category (8)(b)*)
- The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. (*Does not apply to category (8)(b)*)
- The research is not classified.
- The research falls into one or more “Categories of Research that May be Reviewed by the IRB through an Expedited Review Procedure”

For modifications to previously approved research modifications all modifications are minor changes defined as “those which do not involve an increase in risk that is more than minimal, do not change the risk potential benefit relationship of the study, and in which all added procedures fall into categories (1)(7) of research that can be reviewed using expedited procedures”.

### 3. The requirements for informed consent [45 CFR 46.116 (a) and (b)] are met. Yes No If no, explain:

- The criteria for alteration or waiver of consent have been met.  NA  Yes  No If no, explain:
- The criteria for waiver of documentation of consent have been met.  NA  Yes  No If no, explain:

### 4. The use of Battelle staff as subjects has been justified in accordance with Corporate Policy 1.1.1.6.

NA  Yes  No If no, explain:

### I recommend this protocol be:

- Approved as presented
- Approved with the following contingencies:
- Tabled or  Denied approval for the following reasons:

### I suggest the following for consideration by the IRB:

- a. The IRB Administrative Team may expedite final approval when contingencies for approval are satisfied.  Yes  No  NA

b. The IRB Administrative Team should expedite minor changes to the protocol/consent.

Yes  No  NA

c. The IRB should monitor the consent process and/or perform compliance reviews.

Yes  No  NA If yes, please explain.

d. Continuing Review should be conducted every:

12 Months  6 Months or \_\_\_Months. If more often than annually, please explain:

## Additional Considerations Related to Continuing Review and Review of Modifications and New Findings

### Continuing Review Checklist

Is the enrollment rate as planned and reasonable to meet the goals of the study?
If enrollment is notably slow, is adequate justification/explanation provided to continue with the study?
Is there a notable rate of subject withdrawals?
Were all unanticipated problems, changes to the protocol or supporting documents that occurred since the last report period reported and approved by the IRB? Is a protocol modification or change being requested during this review? Is it a minor change? Were any subject complaints documented for this study? Are any significant new findings or interim reports provided? <ul style="list-style-type: none"> <li>• Do the problems/changes alter the risk/benefit ratio?</li> <li>• Should subjects be informed of the problems/changes?</li> <li>• Should the consent or protocol be amended to include new information resulting from these events?</li> </ul>
If there is a Data Safety Management Plan, is the study adequately following the approved plan?
If this is a multi-site study and PNNL is the coordinating site, is there evidence of communication among the sites?
<input type="checkbox"/> For review using the expedited procedure: <ul style="list-style-type: none"> <li><input type="checkbox"/> The research (or remaining research procedures) presents no more than minimal risk to participants (<i>Does not apply to category (8)(b)</i>)</li> <li><input type="checkbox"/> The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. (<i>Does not apply to category (8)(b)</i>)</li> <li><input type="checkbox"/> The research is not classified.</li> <li><input type="checkbox"/> The research falls into one or more “Categories of Research that May be Reviewed by the IRB through an Expedited Review Procedure”</li> </ul>
Comments:

### Protocol Modifications and New Findings Checklist

Does the modification or new finding alter the risk/benefit ratio to the subjects?
Is the modification or change considered “minor”?
Does the change in risk alter the required level of IRB review or oversight?
Are the supporting documents revised in accordance with the change in risks or benefits?
If there is a change in management, has the new PI, signed the application? Completed educational requirements?
Are all changes updated in the study materials and included for review?
If revised, does the consent reflect all changes and clearly indicate any increase in risk?
Is re-consent or notification to subjects required?
If revised, does the new consent meet the basic federal requirements?
Has the source of funding changed?
Are there any new conflicts of interest?
<input type="checkbox"/> All modifications are minor changes defined as “those which do not involve an increase in risk that is more than minimal, do not change the risk potential benefit relationship of the study, and in which all added procedures fall into categories (1)(7) of research that can be reviewed using expedited procedures”  <input type="checkbox"/> Yes <input type="checkbox"/> No <b>If no, please explain:</b>
Comments:

## Pacific Northwest National Laboratory Informed Consent Check List

### The Consent Process [45 CFR 46.116]

1. Consent is sought under circumstances that provide prospective subjects or their legally authorized representative sufficient opportunity to consider whether or not to participate and which minimize the possibility of coercion or undue influence.  Yes  No
2. The information given to subjects or their legally authorized representative is in language understandable to the subject or to their representative.  Yes  No
3. The information or informed consent (oral or written) does 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 investigator, the sponsor, the institution or its agents from liability for negligence.  
 Yes  No
4. If compensation is provided, are the type of compensation, the amount, and the schedule for payment clearly described in the consent?  
 NA  Yes  No
5. The consent process meets the general requirements for informed consent below including additional elements where appropriate.  Yes  No

### The Basic and Additional Elements of Consent as Provided in 45 CFR 46.116 (a) and (b)

- (1) 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, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

- (1) 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 unforeseeable;

- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) 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; and
- (6) The approximate number of subjects involved in the study.

### **Alteration or Waiver of Consent [46.116 (c) and (d)]**

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirement to obtain consent provided the IRB finds and documents that:

The research or demonstration project is conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or other 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; and

The research could not practicably be carried out without the waiver or alteration.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information following their participation.

### **Documentation of Informed Consent [46.117]**

Informed consent will be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy will be given to the person signing the form. The consent form may be either of the following:

A written consent document that embodies the required elements of informed consent required in 45 CFR 46.116. This document may be read to the subject or the subject's legally authorized representative; but in any event, the investigator will give either the subject or the representative adequate opportunity to read it before it is signed; or

A "short form" written consent document stating that the elements of consent have been presented orally to the subject or the subject's legally authorized representative. The short form consent is generally used for participants who do not speak English. For participants who do not speak English, the witness must be conversant in both English and the language of the participant. When using the short form consent, the IRB must confirm that the following requirements are met:

\_\_\_ A written summary embodying the basic and appropriate additional elements of disclosure will be provided to the participant and/or to the participant's legally authorized representative.

\_\_\_ There will be a witness to the oral presentation

\_\_\_ The witness will sign both the short form and a copy of the summary.

\_\_\_ The person actually obtaining consent will sign a copy of the summary.

\_\_\_ A copy of the short form will be given to the participant or the participant's legally authorized representative.

\_\_\_ A copy of the summary will be given to the participant or the participant's legally authorized representative.

## **Waiver of Documentation of Informed Consent [46.117(c)]**

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

That 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 the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

That 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. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

## **Notes/Items for Discussion**

## IRB Decision Quadrant – Items for Consideration

### Collaborative Research Involving other Institutions

- All activities involving human subjects are conducted by the collaborating institution.
- This review is based on documentation provided by the collaborating institution.
- An IRB Authorization Agreement has been established between PNNL and the collaborating institution.

### Scientific Design and Purpose

- Scientific peer review has been conducted and documented.
- The hypothesis (purpose and overall objective) is clearly stated.
- The study design is scientifically sound and appropriate to prove the hypothesis.
- The study is designed to minimize risk and maximize benefits to subjects.
- The research will contribute to generalizable knowledge.
- The anticipated results justify exposure of subjects to (any) risk, discomfort, or inconvenience.
- The proposal provides results from previous animal, human, or other supporting research.
- The participation of human subjects is necessary to meet research objectives.
- Subjects' rights and welfare are considered as an integral part of study design.
- The investigator has access to a population that allows recruitment of adequate numbers of participants.
- The Investigator has sufficient time to conduct and complete the research.
- The Investigator has adequate numbers of qualified staff and adequate facilities.
- The research team is adequately informed about the protocol and their research-related duties and functions.
- Adequate medical or psychological resources subjects might require as a consequence of the research are available.

### Subjects

#### Subject Population

- ✓ Are the inclusion/exclusion criteria (sex, age, health status, ethnicity, and number of subjects) clearly stated?
- ✓ Is the proposed subject population appropriate for the goals of the study?
- ✓ Are the subjects, or the society they participate in likely to benefit from participation in the study?
- ✓ Is the selection of subjects equitable, given restrictions imposed by justifiable inclusion/exclusion criteria?
- ✓ Will physiological, psychological, sociological, or cultural characteristics of the subject population pose special medical, ethical, or legal problems? Are appropriate steps taken to minimize potential problems?
- ✓ Could “second or third party subjects,” (family or social groups) be impacted (genetics/social exposure)?

#### The Informed Consent Process - Subject Selection, Recruitment, and Consent

- ✓ What is the purpose of the research?
- ✓ What is the setting in which the research will be conducted?
- ✓ Are the inclusion and exclusion criteria appropriate for the study?
- ✓ Is the method used to identify the subject population ethically and legally acceptable?
- ✓ Are the selection criteria for subjects equitable?
  - Are the recruitment and enrollment procedures appropriate for the subjects and for the study?
  - Is the procedure used to recruit subjects free of coercion and undue influence?
  - Could the payment have an affect on the equitable selection of subjects?
- ✓ Could the subjects be vulnerable to coercion or undue influence?
- ✓ Do the advertisements or solicitations used to recruit subjects contain sufficient information?

- ✓ Does the information being communicated to the participant or the representative during the consent process include exculpatory language through which the participant or the legally authorized representative was made to waive or appear to waive any of the participant's legal rights?"
- ✓ Does the advertisement do any of the following, ***all of which are prohibited?***
  - State or imply a certain favorable outcome or other benefits beyond what was outlined in the consent document and the protocol?
  - Include exculpatory language?
  - Emphasize the payment or the amount to be paid, by such means as larger or bold type?
- ✓ Note: If draft versions of the following are submitted for initial review, the IRB must approve the final version before these documents may be used in the conduct of the research.
  - Any type of materials used for solicitation or advertising for subjects.
  - Audio or video taped advertisements
  - Interview scripts

**Vulnerable Subjects**  NA.

- ✓ Additional safeguards are required for subjects likely to be vulnerable to coercion or undue influence. The IRB should confirm that the inclusion of any vulnerable subject population is justified and in compliance with guidance found in Federal Regulation 45 CFR 46 Subparts, B, C, and D and must provide adequate representation for those subjects during its review. Supporting documentation may be found in the PNNL Human Subject web site under Special Classes of Subjects - Vulnerable Subjects.

**Risks/Benefits**

**Risk**

A risk is a potential harm or injury associated with the research that a reasonable person in the subject's position would likely be considered injurious. Risks can be categorized as physical, psychological, sociological, economic, and legal. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects and to the importance of knowledge that may reasonably be expected to result from the research.

“Minimal Risk means that 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 activities or during the performance of routine physical or psychological examinations or tests.”

- ✓ What are the potential risks/discomforts/inconveniences associated with the research?
- ✓ Has full consideration been made of the risk to vulnerable subjects and/or other special populations?
- ✓ What is the overall risk classification: minimal, minor increase over minimal, more than minor increase over minimal, or is it unacceptable?
- ✓ What are the estimated probability, severity, average duration, and reversibility of any given harm?
- ✓ Have adequate safeguards been taken to minimize the magnitude or possibility of an adverse event?
- ✓ What steps will be taken to treat subjects who suffer an injury?

**Benefits**

A research benefit is generally considered to be a health-related, psychosocial, or other value that is realized by the individual research subject, or that will contribute to the acquisition of generalizable knowledge. Compensation for participation is not considered a benefit.

- ✓ What are the potential benefits to the subject? To society?

## Risk/Benefit Analysis

- ✓ Is the potential risk to subjects outweighed or balanced by the potential benefit to them or to the society in which they participate?
- ✓ Is the risk/benefit relationship acceptable according to the requirements of 45 CFR 46 Subparts B, C, and D?
- ✓ Is the research designed to maximize benefits and minimize risks to subjects?
- ✓ What is the magnitude and importance of the risk and benefit to the subject?
- ✓ How does the Principal Investigator assess risk/benefit?
- ✓ Is a Data Safety Management Plan required to ensure the safety of subjects?

## Compensation NA.

- ✓ Is compensation reasonable in relation to the requirements for subject participation?
- ✓ Could compensation unduly influence the subjects' willingness to participate?
- ✓ The entire payment is not contingent upon completion of the entire study.
- ✓ Is the schedule and amount of payment clearly stated in the consent?
- ✓ Note: The following practices are prohibited in general, and more specifically, may not be used in advertisements or consent forms:
  - Payment to professionals in exchange for referrals of prospective participants (finder's fees).
  - Payment designed to accelerate recruitment that is tied to the rate or timing of enrollment ("bonus payments") - unless they are judged by the IRB not to interfere with providing prospective participants with sufficient opportunity to consider whether to participate and do not increase the possibility of coercion or undue influence on investigators or participants.

## Privacy and Confidentiality

Joan Sieber, California State University, describes privacy and confidentiality as follows. You might want to keep her definitions in mind as you review the sections on data collection and biological materials.

Privacy in research typically refers to whether the subject considers it the researcher's business to delve into the subject's life concerning whatever matter is the topic of the research. Privacy is about persons and their sense of being in control of the access of others to themselves.

Confidentiality is an extension of the concept of privacy; it refers to (a) identifiable data and (b) agreement about the handling of the data in keeping with the subject's interest in controlling the access of others to information about themselves.

## Data Collection

- ✓ How will research data be collected and recorded?
- ✓ How sensitive are the data?
- ✓ Who will have access to the data?
- ✓ Will personal identifiers or codes be associated with the data?
- ✓ Is there potential for medical and research data to be mixed?
- ✓ What provisions exist to protect subjects' privacy?
- ✓ Do HIPAA regulations apply?
- ✓ How will the data be stored and maintained during the study?
- ✓ How will data be handled if more than one site is involved?
- ✓ Is a Data Management Plan needed? Should it be read and signed by all project staff?

- ✓ Is personal privacy adequately protected and confidentiality of records maintained?
- ✓ How will the data be stored or destroyed at conclusion of the study?

**Biological Materials Derived from Humans**  NA.

- ✓ How will samples or tissues be collected, recorded, stored, and disposed of?
- ✓ If embryonic stem cells, do they meet current Federal requirements?
- ✓ Are personal identifiers associated with the samples?
- ✓ Will private information be coded/linked to subjects?
- ✓ Are there genetic or DNA issues?
- ✓ Will samples, tissues, cell lines, etc., be used for any purpose other than this research?
- ✓ Are samples obtained from FDA-licensed or -registered suppliers, not on a warning list?
- ✓ Will the sponsor provide data involving specimens gathered as a result of this research to the FDA?
- ✓ Will subjects or their families receive results of the study? Should they?

**Conflict of Interest**

- ✓ Does the potential for conflict of interest exist for investigators, IRB members, or the sponsor? Conflict of interest might include an ownership interest or other financial interest in the results of this research, such as equity ownership, stock options, paid consultant fees, membership in management or Board of Directors, or a proprietary interest related to the research including, but not limited to a patent, trademark, copyright or licensing agreement. For related policies and procedures, refer to “Items for Consideration – Conflict of Interest” in the HRPP web site.

**Other Considerations**

- ✓ Is the research controversial? Could it generate public concern or require special recommendations/protections?
- ✓ Does the research involve the use of ionizing or non-ionizing radiation? Chemical, biological or physical risk?
- ✓ Is this collaborative research? Is other IRB review required?
- ✓ Will human subject involvement take place at PNNL or another location?
- ✓ Will the research be conducted in another country?
- ✓ Is this FDA-regulated research? Is an Investigational New Device (IND) or an Investigational Device Exemption (IDE) involved?
- ✓ Does this project require more than annual continuing review? If so, how often and at what level?
- ✓ Does this research require compliance review? IRB observance of the consent process?
- ✓ Are multiple sites or collaborations with other institutions involved? If so, are provisions for monitoring data provided to ensure the safety of subjects for more than minimal risk studies?
- ✓ Does this research require review by the Cleared IRB?
- ✓ For Continuing Review: Does the protocol need verification from sources other than the investigators that no material changes have occurred since previous IRB review?
- ✓ For Continuing and Modification Review: Could significant new findings influence the subjects’ willingness to continue participation and if so, has that information been provided to the participants?