Informed Consent Requirements

Instructions:

- *If you answer "Yes", the required element is satisfied.*
- *If you answer "No", the required element is not satisfied. You may request modifications in the "Specific Concerns" section.*
- *According to the guidelines provided, if you mark "not applicable (N/A)", the element is not required. However, based upon the IRB's discretion, the information may be required. You may request the information or modifications in the "Specific Concerns" section.*
- *The IRB may require additional information be given to the participants to protect their rights and welfare. You may request the information in the "Specific Concerns" section.*

Circumstances of Consent

Refer to the Consent Process portion of the application to view the investigator's explanation.

Does the proposal (e.g. application) clearly outline who can provide consent (e.g. participant, legally authorized representative, parents) and is it appropriate?

- *If applicable, is it clear who can serve as a legally authorized representative?*
- *Will the participants or representatives understand the facts?*
- *Will the participants or representatives appreciate the implications of decision?*
- *Will the participants or representatives be able to communicate a decision?*

Yes
No
Clear

Does the proposal provide the prospective participant or representative sufficient opportunity to consider whether to participate in the consent process?

Yes
No
Clear

Does the proposal minimize the possibility of coercion or undue influence in the consent process?

Yes
No
Clear

Is the information communicated in a language understandable to the participant or the representative?

- *Technical and scientific terms must be adequately explained using common or lay language.*

Yes
No
Clear

Is the information that will be provided to the participant or the representative free of language that waives or appears to waive any of the participant's legal rights, or that releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence?

Yes
No
Clear

Based on the information provided, may the study be approved without observation of the consent process?

- *There may be situations when the observation of the consent process might provide additional protections, such as but not limited to:*
  - *Research involving adults with diminished decision-making capacity*
  - *Research involving participants who are vulnerable to coercion*
  - *Complex projects*
- *If the IRB requires the observations of the consent process, the IRB must also determine who will perform the observation of the consent process.*
- *Please see the Board Member Guidance Series: IRB Authority-Observation of Consent and Conduct of Research.*

Elements of Informed Consent

Yes
No

Is there a statement that the study involves research?

Clear

Yes
No
Clear

Is there an explanation of the purposes of the research?

Yes
No
Clear

Is the expected duration of the individual's participation included?

Yes
No
Clear

Is there a description of the procedures to be followed?

Yes
No
N/A
Clear

Are the participants informed of any procedures which are experimental?
N/A if there are no experimental procedures.

- *Participants should be informed of any procedures that are experimental versus standard of care.*

Yes
No
N/A
Clear

Is there a description of reasonably foreseeable risks or discomforts to the participant?
N/A if the study is minimal risk AND there are no risks.

Yes
No
N/A
Clear

Is there a description of any benefits to the participant or to others (society) which may reasonably be expected from the research?
N/A if the study is minimal risk AND there are no benefits.

- *If the study is moderate risk and there are no benefits, a statement should be included that there are no benefits to the participant.*
- *Compensation should not be presented as a "benefit".*

Yes
No
N/A
Clear

Are alternative procedures or courses of treatment disclosed?
N/A if there are no alternative procedures OR if the research is minimal risk.

Yes
No
Clear

Is there a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained?

- *A statement concerning confidentiality is required. However, a promise to maintain confidentiality is not required by regulation.*
- *For VA studies, this should include a statement of where the data will be stored and analyzed if this is outside of the VA facility.*

Yes
No
N/A
Clear

If the research is subject to FDA regulation, is there a statement that notes the possibility that FDA may inspect the records?
N/A if not FDA regulated.

Yes
No
Clear

Is there contact information (including a name, phone number and the hours of availability) for the research team for:

1. For answers to pertinent questions about the research
2. A research-related injury or harm
3. Concerns or complaints

- *For studies involving serious risks, the researcher must list a number with 24-hour availability. The Hospital Operator is not always an acceptable contact person. If the operator is used for after-hours calls, it should be clear as to whom the participant can ask for when calling.*

Yes
No
Clear

Is the IRB statement (contact information for the IRB) included verbatim?

- *The template statement provides the IRB contact number for questions regarding research participant rights, questions, concerns or complaints when the participant wants to talk to someone other than the research team.*

Yes
No
N/A
Clear

Is there a statement regarding research-related injury including:

1. An explanation as to whether any compensation is available if injury occurs.
2. If compensation is available if injury occurs, what it consists of, or where further information may be obtained.
3. An explanation as to whether any medical treatment is available if injury occurs.
4. If medical treatment is available if injury occurs, what it consists of, or where further information may be obtained.

N/A for research involving minimal risk unless it is a VA study.

- *Language provided on the templates includes all elements.*
- *Use appropriate language for each participating site (i.e., VA, PCH, Shriners, U of Utah)*

Yes
No
N/A
Clear

If there is language from the sponsor or funding agency regarding research-related injury, does it provide information for participants without being exculpatory or contradictory to the University's statement?
N/A if no additional provisions provided for research related injury.

Yes
No
Clear

Is there a statement that 1) participation is voluntary; 2) refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled; and 3) the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled?

Yes
No
N/A
Clear

Is there a statement about the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation?
N/A if the study is minimal risk

OR

N/A if there are no adverse consequences to withdrawal.

Yes
No
N/A
Clear

Is there a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable?
N/A if the study is minimal risk

OR

N/A if there are no investigational drugs/devices AND the risks of all the research procedures are well known (e.g. blood draw).

Yes
No
N/A
Clear

If the participant is or may become pregnant or father a child, are the risks (foreseeable and unforeseeable) to the embryo or fetus described?
N/A if the study is minimal risk

OR

N/A if the study excludes pregnant women or women of child bearing potential.

Yes
No
N/A
Clear

Are any circumstances anticipated under which the individual's participation may be terminated by the investigator without regard to the participant's consent?
N/A if the study is minimal risk

OR

N/A if there are no anticipated circumstances under which the individual's participation may be terminated (e.g. one time intervention).

Yes
No
Clear

Is there a disclosure of any additional costs to the participant that may result from participation in the research or is there a statement included that there are no additional costs?

- *For VA studies, a statement must be included that a veteran-participant will not be required to pay for care received as a participant in a VA research project (except for veterans required to pay co-payments).*

Yes
No
N/A
Clear

Is there a statement that the participant will be notified of any new findings that may influence the participant's willingness to continue to participate in the study?
N/A if the study is minimal risk

OR

N/A if new information could not reasonably alter participation (e.g. a one time intervention).

Yes
No
N/A
Clear

Is the approximate number of participants involved in the study stated?
N/A if the research is minimal risk.

Additional Considerations for Informed Consent

Yes
No
N/A
Clear

Is the HIPAA Authorization language included?
N/A if the study is conducted outside the Covered Entity.

Yes
No

Have the University of Utah Genetic Guidelines been met?
N/A if the genetic testing is not involved in the research.

○ N/A *See Genetic Research Guidelines*

Clear

○ Yes
○ No
○ N/A

Have the University of Utah Tissue Banking Guidelines been met?
N/A if no specimens will be banked.

- *See Tissue Banking Check Boxes*
- *If the University of Utah Tissue Banking Guidelines are met, VA requirements are also met.*

Clear

○ Yes
○ No
○ N/A

Is appropriate language included for diseases reportable to the Utah Department of Health?
N/A if no testing for reportable diseases is required for study participation.
See list of Utah's Reportable Diseases

Clear

○ Yes
○ No
○ N/A

Is appropriate language included for mandatory reporting of confidential information (e.g. researcher is legally obligated to reveal instances of child abuse, elder abuse or abuse of the disabled)?
N/A if it is unlikely that the disclosure or abusive situations will occur in the study.

Clear

○ Yes
○ No
○ N/A

Is the proposed use of a legally authorized representative appropriate for this study?
N/A if a legally authorized representative will not be used.

Clear

Specific Concerns:
If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolutions to Concerns:
Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

DETERMINATION: Are the informed consent requirements met?

○ Yes.
○ Yes, if the above stipulation is met.
○ No.

Clear