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### INFORMED CONSENT REQUIREMENTS

**Instructions:**

Mark the appropriate box.

- 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.

<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Clear	Does the proposal (e.g. application, protocol summary) clearly outline who can provide consent (e.g. participant, legally authorized representative, parents) and is it appropriate?  <ul style="list-style-type: none"> <li>• If applicable, is it clear who can serve as a legally authorized representative?</li> <li>• Will the participants or representatives understand the facts?</li> <li>• Will the participants or representatives appreciate the implications of decision?</li> <li>• Will the participants or representatives be able to communicate a decision?</li> </ul>
<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Clear	Does the proposal provide the prospective participant or representative sufficient opportunity to consider whether to participate in the consent process?
<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Clear	Does the proposal minimize the possibility of coercion or undue influence in the consent process?
<input type="radio"/> Yes <input type="radio"/> No	Is the information communicated in a language understandable to the participant or the representative?  <ul style="list-style-type: none"> <li>• Technical and scientific terms must be adequately explained using common or lay</li> </ul>

Clear	language.
<input type="radio"/> Yes <input type="radio"/> 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?

**Elements of Informed Consent**

<input type="radio"/> Yes <input type="radio"/> No Clear	Is there a statement that the study involves research?
<input type="radio"/> Yes <input type="radio"/> No Clear	Is there an explanation of the purposes of the research?
<input type="radio"/> Yes <input type="radio"/> No Clear	Is the expected duration of the individual's participation included?
<input type="radio"/> Yes <input type="radio"/> No Clear	Is there a description of the procedures to be followed?
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A Clear	Are the participants informed of any procedures which are experimental? N/A if there are no experimental procedures. <ul style="list-style-type: none"> <li>• Participants should be informed of any procedures that are experimental versus standard of care.</li> </ul>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> 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.
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> 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. <ul style="list-style-type: none"> <li>• If the study is moderate risk and there are no benefits, a statement should be included that there are no benefits to the participant.</li> <li>• Compensation should not be presented as a "benefit".</li> </ul>
	Are alternative procedures or courses of treatment disclosed? N/A if there are no alternative procedures OR if the research is minimal risk.

<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	
<input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a>	<p>Is there a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained?</p> <ul style="list-style-type: none"> <li>• <a href="#">A statement concerning confidentiality is required. However, a promise to maintain confidentiality is not required by regulation.</a></li> </ul>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	<p>If the research is subject to FDA regulation, is there a statement that notes the possibility that FDA may inspect the records?  <a href="#">N/A if not FDA regulated.</a></p>
<input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a>	<p>Is there contact information (including a name, phone number and the hours of availability) for the research team for:</p> <ol style="list-style-type: none"> <li>1. For answers to pertinent questions about the research</li> <li>2. A research-related injury or harm</li> <li>3. Concerns or complaints</li> </ol> <ul style="list-style-type: none"> <li>• <a href="#">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.</a></li> </ul>
<input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a>	<p>Is the IRB statement (contact information for the IRB) included verbatim?</p> <ul style="list-style-type: none"> <li>• <a href="#">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.</a></li> </ul>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	<p>Is there a statement regarding research-related injury including:</p> <ol style="list-style-type: none"> <li>1. An explanation as to whether any compensation is available if injury occurs.</li> <li>2. If compensation is available if injury occurs, what it consists of, or where further information may be obtained.</li> <li>3. An explanation as to whether any medical treatment is available if injury occurs.</li> <li>4. If medical treatment is available if injury occurs, what it consists of, or where further information may be obtained.</li> </ol> <p><a href="#">N/A for research involving minimal risk unless it is a VA study.</a></p> <ul style="list-style-type: none"> <li>• <a href="#">Language provided on the templates includes all elements.</a></li> </ul>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	<p>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?  <a href="#">N/A if no additional provisions provided for research related injury.</a></p>
	<p>Is there a statement that 1) participation is voluntary; 2) refusal to participate will</p>

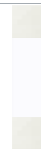
<input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a>	involve no penalty or loss of benefits to which the participant is otherwise entitled; and 3) the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled?
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	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.
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	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).
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	If the participant is or may become pregnant, 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
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	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).
<input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a>	Are any additional costs to the participant that may result from participation in the research disclosed or a statement included that there are no additional costs?
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	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).
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	Is the approximate number of participants involved in the study stated? N/A if the research is minimal risk.

**Additional Considerations for Informed Consent**

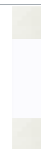
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	Is the HIPAA Authorization language included? <a href="#">N/A if the study is conducted outside the Covered Entity.</a>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	Have the University of Utah Genetic Guidelines been met? <a href="#">N/A if the genetic testing is not involved in the research.</a>  <ul style="list-style-type: none"> <li>• <a href="#">See Genetic Research Guidelines</a></li> </ul>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	Have the University of Utah Tissue Banking Guidelines been met? <a href="#">N/A if no specimens will be banked.</a>  <ul style="list-style-type: none"> <li>• <a href="#">See Tissue Banking Check Boxes</a></li> </ul>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	Is appropriate language included for diseases reportable to the Utah Department of Health? <a href="#">N/A if no testing for reportable diseases is required for study participation.</a>  <ul style="list-style-type: none"> <li>• <a href="#">See list of Utah's Reportable Diseases</a></li> </ul>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</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)? <a href="#">N/A if it is unlikely that the disclosure or abusive situations will occur in the study.</a>
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A <a href="#">Clear</a>	Is the proposed use of a legally authorized representative appropriate for this study? <a href="#">N/A if a legally authorized representative will not be used.</a>
<input type="radio"/> Yes <input type="radio"/> No <a href="#">Clear</a>	Is the study a VA study? <a href="#">If yes, continue the checklist for the additional VA informed consent requirements.</a>  <b><a href="#">If no, the following questions do not apply and do not need to be answered.</a></b>
<input type="radio"/> Yes <input type="radio"/> No	Is the VA research-related injury statement included?  <ul style="list-style-type: none"> <li>• <a href="#">The template language includes statements that 1) in the event of a research-related injury the VA must provide necessary medical treatment; 2) that in the event of a research-related injury the necessary care had to be provided in VA</a></li> </ul>

Clear	medical facilities; and 3) the VA's authority to provide medical treatment to participants injured by participation in a VA study.
<input type="radio"/> Yes <input type="radio"/> No Clear	Is the VA costs statement included?  <ul style="list-style-type: none"> <li>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).</li> </ul>

**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

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**Written Documentation of Informed Consent**

**At least one option must be used to meet the requirement for documentation of informed consent. Select the method the investigator will use to document informed consent.**

Informed Consent will be documented in writing with a consent document.

- If subject to FDA regulation, the participant or participant's legally authorized representative should date the document when signed.

Informed Consent will be documented in writing with a short form.

- The short form must be signed by the participant or participant's legally authorized representative and the witness.
- The written summary (of the information presented orally) must be signed by the witness and the person obtaining consent.
- The participant or the participant's legally authorized representative must be provided both a copy of the short form and a copy of the written summary.
- If subject to FDA regulation, the participant or participant's legally authorized representative should date the document when signed.

<input type="radio"/> Yes <input type="radio"/> No Clear	Is consent documented in writing with a consent document and a VA study?  If yes, continue the checklist for the additional VA documentation requirements.  If no, the following questions do not apply and do not need to be answered.
<input type="radio"/> Yes <input type="radio"/> No Clear	Is the consent in VA Format (10-1086) including PI name and title of study in the header?
<input type="radio"/> Yes <input type="radio"/> No Clear	Is there a line for the witness signature and date?
<input type="radio"/> Yes <input type="radio"/> No Clear	Is there a line for the PI signature and date?

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**WAIVER OF DOCUMENTATION OF INFORMED CONSENT**

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the IRB (or reviewer) finds and documents either 1 OR 2 as outlined below:

**1**

(1) The research involves no more than minimal risk to the participants and (2) the research involves no procedures for which written consent is normally required outside of the research context. State the study specific procedure:

- Example: "(1) The research involves no more than minimal risk because the procedure is a single urine sample and (2) written consent is not normally required outside of the research context."
- Example: "(1) The research involves no more than minimal risk because the interviews do not collect sensitive information which could place participants at risk of harm and (2) outside of the research context written consent is not normally required for interviews."

**2**

**All of the following apply:**

A. Is the research subject to FDA regulation? *If the study is subject to FDA regulation, a waiver of documentation of consent cannot be granted.*

- Yes
- No

Clear

B. The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality because:

- Example: "because the information collected is sensitive and a link to the information may potentially cause harm such as embarrassment or social stigma."
- Example: "because no identifying information is being kept with the tumor specimen that would otherwise be discarded by pathology."

C. The Investigator has indicated that each participant will be asked whether he or she wants documentation linking the participant with the research and the participant's wishes will govern. If no, this waiver cannot be granted.

- Yes
- No

Clear

- Please see the Consent Process page of the application to verify the investigator's plan.

**Does the investigator have to provide subjects with a written statement regarding the**

**research?** If yes and not described in the protocol, include as a stipulation for approval.

Yes

No

[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:** Is the requirement for obtaining written documentation of informed consent waived?

Yes.

Yes, if the above stipulation is met.

No.

[Clear](#)

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**WAIVER OR ALTERATION OF INFORMED CONSENT (HIPAA, when applicable):**

The IRB may waive or alter of informed consent provided that the IRB (or reviewer) finds and documents all of the following:

1. Is the research subject to FDA regulation? If the study is subject to FDA regulation, a waiver or alteration of informed consent cannot be granted.

 Yes No[Clear](#)

2. The research involves no more than minimal risk to the participants because:

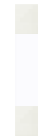
- Example: "because the main risk is a breach of confidentiality and procedures are in place to make such breaches very unlikely."
- Example: "because the review of subjects' medical records is for limited information and is not sensitive in nature."
- Example: "because the questionnaire responses could not reasonably damage the participants' reputation or employability."

3. The waiver or alteration will not adversely affect the rights and welfare of the participants because:

- Example: "because the information was collected for clinical care and the research will not change the care the individual received."
- Example: "because the information collected is not sensitive and a reasonable person who is in the participant's position would not consider the waiver as adversely affecting his/her rights."
- Example: "because participants will be given a questionnaire cover outlining the purpose of the research and that they may refuse to participate."

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

- Refer to the application for the investigator's explanation of why the research could not be conducted without the waiver.
- Explain why the research could not be conducted.
- Example: "If consent were a requirement, the investigator would be unable to obtain consent for about 30% of participants because they have moved and lost to follow-up and the contact information in our database is incorrect. With a loss of 30% of participants, the investigator would be unable to answer the research question."
- Example: "If consent were a requirement, the investigator would have to obtain consent on about 100,000 individuals which would require about 10 years of time for the two person staff to accomplish assuming that the staff spend 50% of their time on obtaining consent. The degree of effort would make it not practicable to conduct the research. "



**5. Providing participants additional pertinent information after participation is or is not appropriate because (specify whether or not information should be provided):**

- Example: "Providing participants pertinent information after participation is not appropriate as the results would have no effect on the individuals."
- Example: "Providing participants pertinent information after participation is appropriate because deception was used and the participants should be debriefed according to the investigator's protocol."



**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:** Is the requirement for obtaining informed consent waived or altered?

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

Clear

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