**Informed Consent Checklist**

## General Requirements of Informed Consent

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| --- | --- |
|  | **Yes** |
| Is legally effective informed consent or permission obtained before enrolling a participant in research? |  |
| Is the possibility of coercion minimized? |  |
| Is the language used in the consent process understandable to the participants? |  |
| Is information necessary to make an informed decision provided in the consent process? |  |
| Does the consent process begin with a concise and focused presentation of key information?   1. *The fact that consent is being sought for research, and participation is voluntary.* 2. *Purpose of the research, expected duration, and procedures.* 3. *Reasonably foreseeable risks.* 4. *Benefits that may be reasonably expected.* 5. *Appropriate alternative procedures or courses of treatment, if any.*   **(Final Rule)** |  |
| Is sufficient detail provided in the consent process?  **(Final Rule)** |  |
| Is the consent process free from exculpatory language? |  |

## Basic Elements of Informed Consent

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|  | **Yes** | **N/A** |
| Is there a statement that the study involves research and an explanation of the purposes of the research? |  |  |
| Is the expected duration of participation stated? |  |  |
| Is there a description of the procedures to be followed including the identification of any procedures that are experimental? |  |  |
| Is there a description of any foreseeable risks or discomforts to the participant? |  |  |
| Is there a description of any benefits to the participants or others? |  |  |
| Is there a disclosure of any alternative procedures or courses of treatment?  *N/A if there are no alternative procedures.* |  |  |
| Is there a statement describing the confidentiality of records? |  |  |
| For research involving more than minimal risk, is there a statement about what options are available if injury to the participant occurs?  *Specific language should be used. See Examples.*  *N/A if the study is minimal risk.* |  |  |
| Is the necessary contact information provided?  *Some specific language should be used. See Examples.* |  |  |
| Is there a statement that participation is voluntary? |  |  |
| Is there a statement that individuals may refuse to participate or discontinue participation without penalty or loss of benefits? |  |  |
| Is there a statement about the collection of identifiable private information or identifiable biospecimens?  *N/A if identifiable private information or biospecimens*  **(Final Rule)** |  |  |

## Additional Elements of Informed Consent

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| *Generally, the University of Utah does not require that the additional elements of informed consent as described below be provided for studies that are no more than minimal risk. However, the IRB may determine that any of the additional elements of informed consent be required. If a study is greater than minimal risk (as determined by the IRB), the additional elements of informed consent are generally required. However, the IRB may determine if any of the additional elements of informed consent may be omitted.* | **Yes** | **N/A** |
| Is there a statement that the treatment or procedure may involve risks to the participant that are currently unforeseeable? |  |  |
| Isthere a description of anticipated circumstances under which the investigator may terminate participation? |  |  |
| Is there a description of any additional costs to the participant? |  |  |
| Is there a description of any compensation given to the participant including the anticipated prorated payment, if any? |  |  |
| Is there a description of the consequences of a participant’s decision to withdraw and procedures for withdrawal? |  |  |
| Is there a statement regarding significant new findings? |  |  |
| Is there a statement with the approximate number of participants involved in the study? |  |  |
| Is there a statement about whether the participant’s biospecimens may be used for commercial profit?  **(Final Rule)** |  |  |
| Is there a statement about whether clinically relevant research results will be disclosed to participants?  **(Final Rule)** |  |  |
| For research involving biospecimens, is there a statement about whether the research may include whole genome sequencing?  **(Final Rule)** |  |  |

## Supplemental Elements of Informed Consent

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| *Investigators should provide participants with information that a reasonable person would want to have in order to make an informed decision. Use this checklist to help ensure that, if necessary, important information is shared with participants.* | **Yes** | **N/A** |
| Does your study involve the possible disclosure of confidential information (e.g. reportable diseases, disclosure of abuse, or self-harm)? |  |  |
| Is there a possibility of the disclosure of incidental genetic findings? |  |  |
| Does your study involve placebo or withheld treatment? |  |  |

## HIPAA Authorization

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| *Use this checklist if your study will require HIPAA authorization for the use of protected health information (PHI).* | **Yes** |
| Does the authorization include a description of the information to be used or disclosed? |  |
| Does the authorization include the name or identification of the recipient of the information and describe the purpose of the requested use or disclosure? |  |
| Does the authorization include a description of expiration? |  |
| Is there a statement about the revocation of authorization? |  |
| Is there a statement describing authorization and the ability or inability to condition enrollment on the authorization? |  |
| Is there a statement about the potential of PHI being re-disclosed? |  |
| Does the authorization include the name of the person authorized to make the requested disclosure and obtain a signature? |  |

## Additional Elements Required by the VA

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| *Use this checklist if your study involves the VA.* | **Yes** | **N/A** |
| Is there a statement about the investigators’ conflict of interest? |  |  |
| Is there a statement that the VA will provide treatment for research related injury? |  |  |
| When appropriate, is there a statement that informs VA subjects that insurance will not be charged for costs related to the research? |  |  |
| Is there a description of the use of photographs, video, and/or audio recordings to be taken for research purposes? |  |  |

## Future Use of Private Information or Biospecimens

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| *Use this checklist for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens .* | **Yes** |
| Is there a description of what is collected, the purpose(s), and the type(s) of future research? |  |
| Is the option to participate in banking biospecimens or the data repository thoroughly explained? |  |
| Is there a description of whether personally identifiable information will be collected with the biospecimens? |  |
| Is there a description of the procedures that participants should follow if they want to withdraw samples or information? |  |
| Is there a statement about whether the future use of the participant’s biospecimens may be used for commercial profit? |  |
| Is there a description of whether future results or findings will be given to the participants? |  |