**Institutional Review Board**

**Informed Consent Process Worksheet**

This worksheet is to help Reviewers determine whether criteria for consent procedures are met in the study. Informed Consent must be sought and properly documented through the use of an IRB-approved consent form.

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| Broad Consent | Prospective consent for unspecified future research using identifiable private information or identifiable biospecimens |
| Key Information | Concise and focused information presented at the beginning of a consent discussion that is most likely to assist an individual in understanding the reasons why or why not to participate in the study |
| Legally Authorized Representative (LAR) | An individual or judicial or other body authorized under applicable law or recognized by institutional policy (if no law applies) to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. |
| Vulnerable | Subjects in research studies vulnerable to the possibility of coercion or undue influence |

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| **Informed Consent Process and Documentation** |
|[ ]  Type of Consent Form (fill in the subsequent section) |
|  |[ ]  Written Informed Consent Process (Sections A-C)  |[ ]  Waiver or of documentation (See the Waiver or Alteration of Consent worksheet) |
|  |[ ]  Short Form Consent Process  |[ ]  Broad Consent (Sections A and D) |
|  |[ ]  Waiver or alteration of consent (Sections A-C and the Waiver or Alteration of Consent worksheet) |[ ]  Enrollment is closed to the study (CR) |
|  | Comments: Click or tap here to enter text. |
|[ ]  The subject or the subject’s legally authorized representative will sign and date the consent form |
|[ ]  The PI/Researcher will sign and date the consent form |
|[ ]  The PI/Researcher will provide a copy of the signed and dated consent form to the subject or the subject’s legally authorized representative |

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| **Section A: General Requirements for Informed Consent (all must be checked)** |
|[ ]  The PI/Researcher will obtain the legally effective informed consent of the subject or the subject's LAR |
|[ ]  The circumstances of consent allow the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate  |
|[ ]  The circumstances of consent minimize the possibility of coercion or undue influence |
|[ ]  The information given to the subject or the LAR is in language understandable to the subject or the LAR |
|[ ]  The subject or the LAR will be provided information that a reasonable person would want to have in order to make an informed decision about whether or not to participate and will be provided an opportunity to discuss that information  |
|[ ]  Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate [ ]  N/A if using broad consent |
|[ ]  Informed consent must begin with a concise and focused presentation of the key information that is organized and presented in a way that facilitates comprehension [ ]  N/A if using broad consent |
|[ ]  Informed consent as a whole presents information in sufficient detail relating to the research [ ]  N/A if using broad consent |
|[ ]  Informed consent as a whole presents information that is organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or LAR’s understanding of the reasons why one might or might not want to participate [ ]  N/A if using broad consent |
|[ ]  The consent process does NOT include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any legal rights |
|[ ]  The consent process does NOT include any exculpatory language through the subject or the LAR is made to release or appear to release the PI/Researcher, sponsor, institution, or its agents from liability for negligence |

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| **Section B: The Basic Elements of Informed Consent (all must be checked)** |
|[ ]  A statement that the study involves research |
|[ ]  Explanation of the purposes of the research |
|[ ]  The expected duration of the subject’s participation |
|[ ]  A description of the procedures to be followed |
|[ ]  Identification of experimental procedures |
|[ ]  Any foreseeable risks or discomforts to the subject |
|[ ]  Any benefits to the subject or others that may reasonably be expected from the research |
|[ ]  Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |
|[ ]  The extent, if any, to which confidentiality of records identifying the subject will be maintained |
|[ ]  Whom to contact for answers to pertinent questions about the research and research subjects’ rights |
|[ ]  Whom to contact in the event of a research-related injury to the subject |
|[ ]  That participation is voluntary, refusal to participate involves no penalty or loss of benefits, and the subject may discontinue participation at any time without penalty or loss of benefits |
|[ ]  For research involving more than minimal risk: [ ]  **N/A** |
|  |[ ]  An explanation as to whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained |
|  |[ ]  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 |
|[ ]  For research involving the collection of identifiable private information or identifiable biospecimens: [ ]  **N/A** |
|  |[ ]  That identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject of the legally authorized representative, if this might be a possibility, OR |
|  |[ ]  That the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies |

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| **Section C: Additional Elements of Informed Consent (check all that apply)** [ ]  **N/A** |
|[ ]  That the treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable |
|[ ]  Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s or the LAR’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 or participation by the subject |
|[ ]  A statement that significant new findings developed during the course of the research that may related to the subject’s willingness to continue participation |
|[ ]  The approximate number of subjects involved in the study |
|[ ]  A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit  |
|[ ]  A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions |
|[ ]  For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing  |

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| **Section D: Elements of Broad Consent (for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens)** [ ]  **N/A** |
|[ ]  Any foreseeable risks or discomforts to the subject |
|[ ]  Any benefits to the subject or others that may reasonably be expected from the research |
|[ ]  The extent, if any, to which confidentiality of records identifying the subject will be maintained |
|[ ]  Participation is voluntary, refusal to participate involves no penalty or loss of benefits, and the subject may discontinue participation at any time without penalty or loss of benefits |
|[ ]  A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit [ ]  **N/A** |
|[ ]  For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing [ ]  **N/A** |
|[ ]  A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. |
|[ ]  A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur |
|[ ]  The types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens |
|[ ]  A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite) |
|[ ]  A description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite) |
|[ ]  Unless the subject or LAR will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies |
|[ ]  Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject |
|[ ]  An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm |

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| **Requirements for Short Form Informed Consent** |
|[ ]  The requirements of Section A, B, and, when applicable, Section C have been presented orally to the subject or the subject’s LAR |
|[ ]  The key information required by 46.116(a)(5)(i) was provided before any other information (in Section A) |
|[ ]  A written summary of what is to be said to the subject or the LAR has been provided to the IRB for approval |
|[ ]  A witness will be present for the oral presentation |
|[ ]  The witness will sign both the short form and a copy of the summary |
|[ ]  The person obtaining consent will sign a copy of the summary |
|[ ]  A copy of the summary shall be given to the subject or the subject’s legally authorized representative |

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| **Posting of Clinical Trials Consent Form** [ ]  **N/A** |
|[ ]  For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trail on a publicly available Federal Web site that will be established as a repository for such informed consent forms |
|[ ]  If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted |
|[ ]  The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol |
|[ ]  When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: “A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”  |