**VA Informed Consent Checklist – UCSF/Local Studies**

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| **IRB Number** |  |
| **Title of Project** |  |
| **VA Principal Investigator** |  |

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| 1. **Required Elements** | **YES** | **NO** | **N/A** |
| 1. Is there a statement indicating that the project involves research? |  |  |  |
| 1. Is there an explanation of the purposes of the research? |  |  |  |
| 1. Is the duration of the participant’s expected participation stated to include long-term follow-up? |  |  |  |
| 1. Is there a detailed chronological description of the procedures to be followed? |  |  |  |
| 1. Are procedures that are being done solely for the purposes of the research identified as such and clearly distinguished from the usual care provided to the participant? |  |  |  |
| 1. Are procedures which are experimental identified as such? |  |  |  |
| 1. Is the participant advised of any reasonably foreseeable risks or discomfort that may occur as a result of their participation? |  |  |  |
| a. Are these risks only pertaining to the research interventions and not to any usual care provided? |  |  |  |
| b. Is the participant advised to consult his/her health care provided for information on the risks of usual care? |  |  |  |
| 1. Is there a description of any potential benefits to the participant or to others that may reasonably be expected from the research? |  |  |  |
| 1. If there is no direct benefit to the participant, is this clearly stated? |  |  |  |
| 1. Are appropriate alternative treatments or procedures that may be advantageous to the participant disclosed or if there are none, is this section omitted? |  |  |  |
| 1. Is there a statement describing the extent to which the confidentiality of records identifying the participants will be maintained? |  |  |  |
| 1. If the study is regulated by the FDA, is the FDA included in the list of other agencies who may have access to the participant’s data? |  |  |  |
| 1. If the study is regulated by the FDA and is a clinical trial is the required statement informing the participant that the study will be published on   the government clinical trials website in the consent? |  |  |  |
| 1. Is there a detailed description of the procedures that will be followed to ensure adequate privacy and security? |  |  |  |
| 1. For research involving more than minimal risk, is there a description of what compensation may be available if an injury occurs as a result of the research to include where further information may be obtained? |  |  |  |
| 1. Are points of contact provided for the participant to contact for answers to questions about the research, research participant’s rights, and in the event of a research-related injury to the participant? |  |  |  |
| 1. Is there a statement that VA will provide treatment for research-related injury in accordance with VA regulations?   **For all UCSF-VA or VA only studies, the following language regarding VA treatment and compensation for research-related injury must be included either verbatim or in VA approved UCSF language in the consent form:**  If you are experiencing a medical emergency, please call 9-1-1. If you incur an injury or illness as a result of being in this study, the Department of Veterans Affairs (VA) will ensure that treatment is made available at a VA medical facility or non-VA facility, as appropriate. If you were following study instructions, the costs of such treatment will be covered by the VA or the study sponsor (if applicable). If you were NOT following study instructions, the costs of such treatment may be covered by the VA or the study sponsor (if applicable) or may be billed to you or your insurer just like any other medical costs, depending on a number of factors. The VA and a study sponsor do not normally provide any other form of compensation for injury or illness. For further information about this, call the study team at the number(s) provided. |  |  | ☐ |
| 1. Is at least one of the points of contact someone other than the investigator or project team members whom the potential participant can contact to verify the validity of the project? |  |  |  |
| 1. Is there a statement that participation is voluntary and that refusal to participate or a decision to terminate their participation will involve no penalty or loss of benefits to which the participant is otherwise entitled? |  |  |  |
| 1. Does the study involve the collection of identifiable private information or identifiable biospecimens? If yes, are one of the following statements provided to prospective subjects?   **For VA studies, include one of the following two statements verbatim:**   1. 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 or the legally authorized representative, OR 2. 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. |  |  |  |
| 1. If appropriate, is there a statement that a veteran participant will not be required to pay for care in a VA research project except for any applicable co-payments unrelated to the research project? |  |  |  |
| 1. Does the informed consent document accurately convey the project procedures described in the project documents? |  |  |  |

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| 1. **Additional Elements** | **YES** | **NO** | **N/A** |
| 1. If applicable, is there a statement that the research treatment or procedure may involve risks to the participant (or to the embryo, fetus, or nursing infant if the participant is or becomes pregnant during the course of the project) which are unforeseeable? |  |  |  |
| 1. Are the responsibilities of the participant regarding his/her participation spelled out? |  |  |  |
| 1. Are any anticipated circumstances under which a participant’s participation may be terminated by the investigator without the participant’s consent explained? |  |  |  |
| 1. Are there any additional costs to the participant that may result from his/her participation in the research and are these spelled out? |  |  |  |
| 1. Are participants being offered payment for their participation?   If **No**, skip to item 6.  If **Yes**, answer the following questions. |  |  |  |
| a. Is the payment reasonable and non-coercive? |  |  |  |
| b. Is there a description of how payment is to be made and by whom? |  |  |  |
| c. If subjects are reimbursed from VA, are only traceable (non-cash) payment methods listed? This may include EFT, debit card, or check. |  |  |  |
| d. Are there provisions included for pro-rating the payment if a  subject’s participation is terminated prior to completion of the project? |  |  |  |
| e. If Austin Financial Services Center is disbursing the payment (i.e., if payments are disbursed using EFT), is the participant advised that an IRS 1099 form will be generated if total research payments equal $600 or greater in the calendar year? |  |  |  |
| 1. Are the consequences of a participant’s decision to withdraw from the project adequately explained? |  |  |  |
| 1. Is there a description for the orderly termination of the participant’s participation? |  |  |  |
| 1. Is there a statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant in a timely manner? |  |  |  |
| 1. Is the approximate total number of participants involved in the project specified? If a different, is the approximate number of participants to be enrolled at the VA specified? |  |  |  |
| 1. Is there a statement regarding whether clinically relevant research results (to include individual research results) will be disclosed to participants, and if so, under what conditions? |  |  |  |
| 1. If the study involves biospecimens, are participants informed whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimens with the intent to generate the genome or exome sequence of that specimen)? |  |  |  |
| 1. If any of the participant’s data are going to be retained after the study for future research, is where the data are to be stored and who will have access to the data included? |  |  |  |
| 1. If the subject is going to be contacted in the future about participating in future research, are the circumstances under which the contact occurs explained? If **Yes,** be sure to also complete Page 5 of the VA HIPAA form. |  |  |  |
| 1. For projects involving biospecimens, is there a statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not profit from any products or tests that might result from use of their sample? |  |  |  |
| 1. Does the research project involve tissue banking?   If **No**, skip to item 16.  If **Yes**, ensure the following requirements are described in the consent. |  |  |  |
| a. Is the location of the bank or repository indicated? |  |  |  |
| b. Is who has access to the specimens detailed? |  |  |  |
| c. Is how long the specimens are going to be retained indicated? |  |  |  |
| d. Is there a clear statement as to whether the participant will be re-contacted after the project is completed? |  |  |  |
| d. Is there a provision for the participant to request that all his/her  specimens and all links to the clinical data be destroyed if desired? |  |  |  |
| e. If research results are going to be conveyed to the subject, the  subject’s provider, or the subject’s family are the circumstances under which this would occur explained? |  |  |  |
| 1. If the investigator is receiving payment to conduct the research and/or has been mandated by the IRB or the Conflict of Interest Committee to disclose any conflicts of interest, is this stated? |  |  |  |
| 1. If applicable, are appropriate HIPAA elements included in the HIPAA Authorization form and are they consistent with the informed consent document and the protocol? |  |  |  |
| 1. If the participants are minors or have impaired decision-making capacity is the signature block for the participant’s legally authorized representative included? |  |  |  |
| 1. Is the form written in language understandable to the participants or the participant’s legally authorized representative? |  |  |  |
| 1. Has a readability score been provided that is between the 6th and 8th grade level or, in your opinion, is the readability level of the informed consent document acceptable for the population to be targeted? |  |  |  |
| 1. Is the informed consent document free of exculpatory language? |  |  |  |
| 1. If the participant does not read or write English, is an appropriate translation of the consent form provided or going to be provided? |  |  |  |

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| 1. **Administrative Requirements** | **YES** | **NO** | **N/A** |
| 1. Is the consent form properly formatted in accordance with the approved template, to include all required headers? Is there a current version date in the footer? |  |  |  |
| 1. Is there at least a 1.25” top margin and no text in the upper right-hand corner (to allow for the IRB approval stamp)? |  |  |  |
| 1. Is medical jargon avoided and are any and all technical terms explained? |  |  |  |
| 1. Does the consent form use the second person (you, your, etc.)? |  |  |  |
| 1. Is the potential participant clearly invited to participate and informed why he or she has been invited to participate? |  |  |  |
| 1. For research involving questionnaires, surveys, or interviews, does the consent form provide an adequate description of the types of questions that will be asked or topics that will be covered? |  |  |  |
| 1. If a Certificate of Confidentiality is required for the project, does the consent form state this, as well as providing a description of the extra protection (and limitations to such protection) that is afforded? |  |  |  |
| 1. Is the potential subject given a chance to discuss the project with the investigator or other project team members and does it state that the participant will be given a copy of the consent form after signature? |  |  |  |
| 1. For amendments and continuing review applications, has the consent form been adequately modified to reflect current procedures or is it still reflective of current procedures? |  |  |  |
| 1. Is there a statement describing the extent to which the confidentiality of records identifying the participants will be maintained and a detailed description of the procedures that will be followed to ensure adequate security? |  |  |  |
| 1. For clinical trials regulated by the FDA, is the appropriate language from the template included concerning the Clinical Trials.Gov website. |  |  |  |
| 1. For genetic studies, is the applicable GINA language included? |  |  |  |
| 1. Based on the study design and procedures, is there a requirement for a witness statement? |  |  |  |