* **Informed consent information should be consistent with procedures, etc. as described in eProtocol application**
* **VA research:** Refer to CHK-7 [VA Research](https://stanfordmedicine.box.com/shared/static/y0iewqaeeq7lcgk19t28krxspqu0qk4v.docx) and AID-27m [Reviewing VA Research](https://stanfordmedicine.box.com/shared/static/20xhu8go436rp3dxe5rwc051w8qrioie.pdf) for additional requirements
* **Comment Code:** explanation; ****Denotes text that must appear verbatim

|  |  |  |
| --- | --- | --- |
| ***Protocol reviewed:*** | ***Review completed by:*** | |
| Protocol #: | Name: | Date: |
|  | | |

| **Yes** | | **No** | | **N/A** | **General Requirements for Informed Consent and Other Elements**  Ref: [GUI-C41](https://stanfordmedicine.box.com/shared/static/abnw9zaduffrrj48okqf0bdsue8m83iz.pdf) | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Header** | | | | | | | | | | | |
|  |  | |  | | Appropriate headers (Title of study, Protocol Director, Approval and Expiration dates, Stanford vs. VA) | | | | | | |
|  |  | |  | | Combined ICF for adult & parental consent | | | | | | |
| **Description** | | | | | | | | | | | |
|  | |  | |  | States study involves research | | | | | | |
|  | |  | |  | Explains the purpose(s) of the research | | | | | | |
|  | |  | |  | **Procedures 1, Procedures 2:** Describes procedures, consistent with procedures as described in eProtocol application | | | | | | |
|  | |  | |  | For Joint SU/VA Studies: *Purpose* must include: “*This study is being done by researchers at VA Palo Alto and Stanford University.*” | | | | | | |
|  | |  | |  | **Future Use – Specimens and Data/Future Use – Data Only:** Describes whether identifiable private information or specimens will be saved for future use | | | | | | |
|  | | | | | Yes | No | | N/A | | |  |
| Tissues (i.e., tissues, cells, blood, or body fluids) and Genetics  N/A | | | | |  |  | |  | | | ****Includes Tissue Sampling for Research if samples will be taken or banked for use in research.  See VA template for banking/storing language. |
|  |  | |  | | | **Tissues - Disposition**: States final disposition of tissues |
|  |  | |  | | | **Tissues-Sent Out:** States that specimens may be sent outside of Stanford |
|  |  | |  | | | **Tissues Commercial Development:** States if the specimens could be used in the development of a new diagnosis or treatment product |
|  |  | |  | | | **Tissues-Genetic testing**: Includes Tissue Sampling for Genetic Testing language |
|  |  | |  | | | **Tissues –Genome:** States if the research will/might/will not include whole genome sequencing |
|  |  | |  | | | ****States if research results will be shared with the participant |
|  |  | |  | | | **Genomic Data Sharing ICF, Genomic Data Sharing Policy:** Included if there is a possibility for genetic data sharing in NIH repository now or in the future |
|  |  | |  | | | **Future Stem Cell –** If specimens banked under this protocol may be used for future stem cell research (meaning under another protocol) – consent form includes restrictions language |
|  |  | |  | | | **Creating Cell Lines-** If future cell lines may be created from specimens banked under this protocol (stem cell research) – consent form explains what it means to create cell lines |
| Video, Audio, and Photo  N/A | | | | |  |  | |  | | | **Video/Audio2:** Includes statement as to what will become of tapes after use, e.g., shown at scientific meetings, erased. See VA template for photo, video and audio language. |
|  |  | |  | | | **Video/Photo:** If taping/photo optional, place for participant to consent to be taped/photographed |
|  |  | |  | | | **Audio:** If recording optional, place for participant to consent for recordings to be used, for identity to be made known from the audio/video tapes |
| Reporting  N/A | | | | |  |  | |  | | | **Harm – Referral:** Included if information may be obtained relating to serious concerns (severe depression, physical abuse, etc.) in which case participants may be referred for additional care |
|  |  | |  | | | **Harm – Mandated Reporting**: Included if information may be obtained about possible child abuse |
|  |  | |  | | | **Assent – Tell Minors:** Included if information may be obtained relating to suicide or abuse |
| HIV or other communicable diseases  N/A | | | | |  |  | |  | | | **HIV:** If DHHS/PHS funded and includes HIV testing, states identifiable participants will be informed if the result is positive and provided with the opportunity for counseling |
|  |  | |  | | | **Communicable Diseases:** If screening or study procedures include testing for communicable disease (e.g. HIV, HCV, TB, Covid), includes statement that positive test results will need to be reported to the local health agency |
| Other  N/A | | | | |  |  | |  | | | Includes question asking participant if they are participating in other research studies |
|  |  | |  | | | Includes number of subjects involved in the study at SU/VA and at all sites |
|  |  | |  | | | **Random:**States the probability for random assignmentto each treatment |
| **Possible Risks, Discomforts, and Inconveniences** | | | | | | | | | | | |
|  | |  | |  | Describes any reasonably foreseeable risks or discomforts to the participant | | | | | | |
|  | |  | |  | ****States that the decision whether or not to participate in this study will not affect employment/medical care | | | | | | |
| **Potential Benefits** | | | | | | | | | | | |
|  | |  | |  | **Benefits:** Describes any benefits to participant or,if no intended clinical benefit, the consent states so | | | | | | |
|  | |  | |  | **We***:* Includes *“*We cannot and do not guarantee or promise that you will receive any benefits from this study." | | | | | | |
| **Duration of Study Involvement** | | | | | | | | | | | |
|  | |  | |  | Explains the duration of active participation | | | | | | |
| **Payments/Reimbursements/Financial Considerations** | | | | | | | | | | | |
|  | |  | |  | **Pay 1, Pay Prorated**: Describes payment and is consistent with protocol application and consent form. For VA, include statement that SSN is required for payment or participants will not be paid. | | | | | | |
|  | |  | |  | **Pay Legal:** If payments will be $200 or more | | | | | | |
|  | |  | |  | **Financial:** Sponsor/funding source is identified | | | | | | |
|  | |  | |  | If consultative/financial relationship exists**:**  COIC/IRB-approved disclosure language included | | | | | | |
| **Participants Rights/Confidentiality** | | | | | | | | | | | |
|  | |  | |  | Describes records will be confidential and results may be presented at scientific meetings (Stanford template 1st paragraph. See VA template for required verbatim language.) | | | | | | |
|  | |  | |  | ****States participation is voluntary and the participant may refuse to participate or discontinue participation at any time with no penalty or loss of benefits | | | | | | |
|  | |  | |  | **Questions:** Includes statement that the participant has right to refuse answering individual questions | | | | | | |
|  | |  | |  | Discloses the alternative procedures, if any, that might be advantageous to the subject and their potential benefits | | | | | | |
|  | |  | |  | States that results may be presented at scientific meetings or published**,** but identity will not be disclosed | | | | | | |
|  |  | |  | | **CoC:** Included if NIH funded study (or funded by one of the NIH institutes) and collecting identifiable or coded information or generating individual‐level genetic Information | | | | | | |
|  |  | |  | | **CT.gov- consent:** States trial listed on ClinicalTrials.gov for applicable clinical trials | | | | | | |
| **HIPAA Authorization** | | | | | | | | | | | |
|  | | | | | Yes | No | N/A | | |  | |
| N/A | | | | |  |  |  | | | **HIPAA–11(b):** Describes PHI Obtained, Used or Disclosed and is consistent with eProtocol section 11b | |
|  |  |  | | | Lists the sponsor, collaborators, FDA, etc., under “who may receive…?” | |
|  |  |  | | | **HIPAA Date Suggestion:** HIPAA expiration date appropriate for study duration? | |
|  |  |  | | | **HIPAA CA:** Appropriate HIPAA elements are included (e.g. 14 point font, separate page and signature) | |
|  |  |  | | | For Joint SU/VA Studies:HIPAA Authorization includes Stanford and VA in the appropriate “Who may use or share your health information?”/ “Who may receive and use your health information” section? | |
| **Withdrawal from Study** | | | | | | | | | | | |
|  | | | | | Yes | No | N/A | |  | | |
| N/A | | | | |  |  |  | | States the consequences of a subject’s decision to withdraw and procedures for orderly termination of participation by the subject | | |
|  |  |  | | States investigator may terminate the participant’s participation and for unanticipated circumstances | | |
| **Contact Information** | | | | | | | | | | | |
|  |  | |  | | ****Includes Research Team Contact. For VA consents, confirm the VA address is used. | | | | | | |
|  |  | |  | | **** Includeswho to contact if hurt by being a part of this study | | | | | | |
|  |  | |  | | **IRB Address:** Includes IRB Independent Contact | | | | | | |
| **Signatures** | | | | | | | | | | | |
|  | | | | | Yes | No | N/A | |  | | |
| N/A | | | | |  |  |  | | **Bill** of Rights**:** Required for all medical experimentation studies | | |
|  |  |  | | ****Includes statement that a copy of the signed and dated consent form has been provided | | |
|  |  |  | | Includes signatures lines for the adult participant and/or two parental signature lines | | |
|  |  |  | | **LAR 2:** If consent may be obtained from the LAR or **LAR 3:** if consent will not be obtained from a LAR | | |
|  |  |  | | **POC:** Includes signature and date lines for the Person Obtaining Consent if Bill of Rights or short form. | | |
|  |  |  | | **Short Form – Witness:** Included if the short form consent process is requested | | |
|  |  |  | | **46.404/50.51:** Includes one parent signature statement | | |
| **Overall Content of ICF** | | | | | | | | | | | |
|  |  | |  | | No exculpatory language through which the participant is made to waive or appear to waive any of the participant’s legal rights or releases or appears to release the investigator, the sponsor, or the institution from liability for negligence. <https://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm#exculpatory> | | | | | | |
|  |  | |  | | **Lay terms:** The information is given to a participant or their representative in language understandable to them | | | | | | |
| **notes** | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | |