* **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

|  |  |  |
| --- | --- | --- |
| ***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, VA 10-1086) | | | | | | | |
|  |  | |  | | Combined ICF for adult & parental consent | | | | | | | |
|  |  | |  | | ****Includes question asking participant if they are participating in other research studies | | | | | | | |
| **Purpose of research** | | | | | | | | | | | | |
|  | |  | |  | **Common Rule- Key Information:** For VA and federally supported studies, describe a concise summary of the key information | | | | | | | |
|  | |  | |  | States study involves research | | | | | | | |
|  | |  | |  | Explains the purpose(s) of the research | | | | | | | |
|  | |  | |  | **Consent FDA Status:** Indicate whether the study drug/device is FDA approved drug | | | | | | | |
|  | |  | |  | **Number Participants:** Includes number of subjects involved in the study at SU/VA and at all sites. | | | | | | | |
|  | |  | |  | For Joint SU/VA Studies: *Purpose* must include: “*This study is being done by researchers at VA Palo Alto and Stanford University.*” | | | | | | | |
| **Voluntary Participation** | | | | | | | | | | | | |
|  | |  | |  | ****States participant may refuse to participate or discontinue participation at any time with no penalty or loss of benefits | | | | | | | |
| **Duration of Study Involvement** | | | | | | | | | | | | |
|  | |  | |  | Explains the duration of active participation | | | | | | | |
| **Procedures** | | | | | | | | | | | | |
|  | |  | |  | **Table of Procedures:** If study includes complex procedures and timelines | | | | | | | |
|  | |  | |  | **Procedures 1, Procedures 2:** Describes experimental procedures, and trial treatment(s) | | | | | | | |
|  | |  | |  | **Random:**States the probability for random assignmentto each treatment | | | | | | | |
|  | |  | |  | **Future Use – Specimens and Data/Future Use – Data Only:** Describes whether identifiable private information or specimens will be saved for future use. | | | | | | | |
| If applicable, check if complete: | | | | | | | | | | | | |  |  | **Creating Cell Lines-** If creating cell lines (stem cell research) has language explaining what creating a cell lines means |
|  | | | | | Yes | No | | N/A | |  | | |
| MRI  N/A | | | | |  |  | |  | | States MRI (Magnetic Resonance Imaging) risk language for Lucas Center MRI | | |
|  |  | |  | | **MRI Diagnostic Scan**: States MRI research scans and are not optimized to find medical abnormalities paragraph (e.g., Lucas Center MRI, CNI MRI, other non-diagnostic MRIs) | | |
|  |  | |  | | If using contrast, includes language pertaining to use of Contrast (Gadolinium) | | |
| Childbearing  N/A | | | | |  |  | |  | | Includes applicable Women of Childbearing Potential language | | |
|  |  | |  | | Includes risks related to men fathering a child | | |
|  |  | |  | | **Pregnancy Minor- Testing:** if study involves pregnancy testing for those under 18 | | |
| 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-Commercial Development**: A statement that specimens could be used in the development of a commercially valuable product | | |
|  |  | |  | | **Tissues - Disposition**: Describes final disposition of tissues | | |
|  |  | |  | | **Tissues-Sent Out:** A statement that specimens may be sent outside of Stanford | | |
|  |  | |  | | **Tissues-Genetic testing:** A statement that specimens may be used for genetic testing now or in future research (ensure it states whether they will receive results) | | |
|  |  | |  | | **Tissues –Genome:** Describes whether specimens will, might or will not undergo whole genome sequencing (required if study involves any specimen collection) | | |
|  |  | |  | | **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. | | |
|  |  | |  | | **Gene Transfer-long term follow-up and autopsy/pre-existing conditions/retroviral vectors:** Statement needed for all gene transfer protocols | | |
|  |  | |  | | **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 a cell line. | | |
| HIV or other communicable diseases  N/A | | | | |  |  | |  | | **HIV:** 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 | | |
| Drugs and Reporting  N/A | | | | |  |  | |  | | **Addicting:** Included if any drugs in the study are known to have a significant potential for addiction | | |
|  |  | |  | | **Drug:** Included if responses to questions about illegal drug use could be self-incriminating | | |
|  |  | |  | | **Drug screen:** Included if research includes a drug screening | | |
|  |  | |  | | **Assent- Tell Parents:** Included if information may be obtained/volunteered relating to suicide, physical or sexual abuse | | |
|  |  | |  | | **Harm – Referral:** Included if information may be obtained/volunteered 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/volunteered about possible child abuse | | |
| Video and Audio  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/Audio/Photo:** If taping/recording/photo optional, place for participant to consent to be taped/audio recorded/photographed | | |
|  | |  | |  | **Questions:** Includes statement participant has right to refuse answering individual questions if study primarily includes questionnaires/surveys. | | | | | | | |
| **Participants Responsibilities Language** | | | | | | | | | | | | |
|  | |  | |  | States participants responsibilities | | | | | | | |
| **Withdrawal from Study** | | | | | | | | | | | | |
|  | |  | |  | 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 | | | | | | | |
| **Possible Risks, Discomforts, and Inconveniences** | | | | | | | | | | | | |
|  | |  | |  | Risks of all commercial drugs listed in section 9(a)(iii) of the protocol application are included | | | | | | | |
|  | |  | |  | States the particular treatment or procedure may involve risks to the subject (or embryo, or fetus, or nursing infant if subject is or may become pregnant) which are currently unforeseeable | | | | | | | |
| **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." | | | | | | | |
|  | |  | |  | Discloses the alternative procedures, if any, that might be advantageous to the subject and their potential benefits | | | | | | | |
| **Participant’s Rights and ClinicalTrials.gov** | | | | | | | | | | | | |
|  | |  | |  | **** States significant new findings that affect participation in the study will be provided to participants | | | | | | | |
|  | |  | |  | **CT.gov- consent:** States trial listed on ClinicalTrials.gov for applicable clinical trials | | | | | | | |
| **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 recordsidentifying the subject will be kept confidential and will not be made publicly available. | | | | | | | |
|  |  | |  | | ****Describes the possibility that the FDA may inspect the records | | | | | | | |
|  |  | |  | | **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. | | | | | | | |
| **HIPAA Authorization** | | | | | | | | | | | | |
|  |  | | |  | **HIPAA – 11(b):** Describes PHI “Obtained, Used or Disclosed” and is consistent with eProtocol Confidentiality section | | | | | | | |
|  |  | | |  | 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 not included (e.g. 14 point font, embedded) (specify what is missing). | | | | | | | |
|  |  | | |  | For Joint SU/VA Studies:HIPAA Authorization includes Stanford and VA in the appropriate “Who may use or share your health information?” or “Who may receive and use your health information” section? | | | | | | | |
| **Financial Considerations: Payment and Costs** | | | | | | | | | | | | |
|  | | | | | Yes | | No | | N/A | |  | |
| Payment  N/A | | | | |  | |  | |  | | **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, includes “Payment may be made to U.S. citizen…” | |
|  | |  | |  | | **SSN Justification:** if SSN is required for payment | |
|  | |  | |  | **Cost**: States any costs to the participant that may result from participation. See VA template for Costs language. | | | | | | | |
|  | |  | |  | **Medicare Preauthorization:** Included if the study has an IDE | | | | | | | |
|  | |  | |  | **Financial:** Sponsor/funding source is identified | | | | | | | |
|  | |  | |  | If consultative/financial relationship exists**:**  COIC/IRB-approved disclosure language included | | | | | | | |
| **Compensation for Research-Related Injury** | | | | | | | | | | | | |
|  |  | |  | | **Compensation 1, Compensation 2:** Correct option depending on funding for research that is more than minimal risk. See VA template for VA liability language(Note: Option 2 usually applies to SIR studies). If needed, add COVID-19 Declaration language. See VA template for COVID PREP Act language. | | | | | | | |
| **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** | | | | | | | | | | | | |
|  |  | |  | | **Bill** of Rights**:** Required for all medical experimentation studies | | | | | | | |
|  |  | |  | | **** Includes statement that a copy of the signed and dated consent form has been provided | | | | | | | |
|  | | | | | Yes | | No | | N/A | | |  |
| LAR  N/A | | | | |  | |  | |  | | | **LAR 1:** If protocol indicates consent may be obtained from the LAR |
|  | |  | |  | | | **LAR 2:** If protocol indicates consent may be obtained from the LAR |
|  | |  | |  | | | **LAR 3:** If protocol indicates participants who are not competent to consent will not be |
|  |  | |  | | Includes signature and date lines for the Person Obtaining Consent if Bill of Rights included. | | | | | | | |
|  |  | |  | | **Short Form – Witness:** Included if the short form consent process is requested in the protocol application | | | | | | | |
|  |  | |  | | If enrolling minors, includes the required signature lines for (both parents) and checkboxes | | | | | | | |
| **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 that is given to a participant or their representative in language understandable to them. | | | | | | | |
| **Notes** | | | | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | | | | |