**Protocol ID:**

 **Protocol Director:**       Reference: [GUI-C41](https://stanfordmedicine.box.com/shared/static/abnw9zaduffrrj48okqf0bdsue8m83iz.pdf)

|  |  |  |  |
| --- | --- | --- | --- |
| **Met** | **Not Met** | **N/A** | **Element** |
| [ ]  | [ ]  | [ ]  | Study Title |
| [ ]  | [ ]  | [ ]  | Protocol Director |
| [ ]  | [ ]  | [ ]  | A statement that the study involves **research**, |
| [ ]  | [ ]  | [ ]  | An explanation of the **purposes** of the research, |
| [ ]  | [ ]  | [ ]  | A description of the **procedures** to be followed, |
| [ ]  | [ ]  | [ ]  | A description of any reasonably foreseeable **risks** or discomforts to the subject; |
| [ ]  | [ ]  | [ ]  | A description of any **benefits** to the participant or to others which may reasonably be expected from the research; |
| [ ]  | [ ]  | [ ]  | A statement that “**We cannot and do not guarantee or promise that you will receive any benefits from this study**.” - verbatim |
| [ ]  | [ ]  | [ ]  | An explanation of the expected **duration** of subject’s participation, |
| [ ]  | [ ]  | [ ]  | A statement that participant will be **paid** (or not paid) for participation |
| [ ]  | [ ]  | [ ]  | When applicable, a statement that “Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa.” |
| [ ]  | [ ]  | [ ]  | A statement that participation is **voluntary**. |
| [ ]  | [ ]  | [ ]  | A statement that the participant **may withdraw or discontinue participation** at any time without penalty or loss of benefits to which the subject is otherwise entitled. |
| [ ]  | [ ]  | [ ]  |  A disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject. |
| [ ]  | [ ]  | [ ]  | The consequences of a subject’s decision to withdraw from the research (if applicable). |
| [ ]  | [ ]  | [ ]  | A statement that the participant has the right to refuse to answer **particular questions**. |
| [ ]  | [ ]  | [ ]  | A statement describing the extent, if any, to which **confidentiality** of records identifying the participant will be maintained;  |
| [ ]  | [ ]  | [ ]  | Language stating either that **identifiers will be removed and data may be used for future research** without additional consent OR that the data will not be used in the future even if identifiers are removed  |
| [ ]  | [ ]  | [ ]  | An explanation of **whom to contact** for answers to pertinent questions about the research, including concerns or complaints. |
| [ ]  | [ ]  | [ ]  | **Injury Notification** (if applicable): If you feel you have been hurt by being a part of this study…who to contact  |
| [ ]  | [ ]  | [ ]  | A statement describing **how to contact someone independent of the research team** for concerns, complaints, or general questions about the research, as well as when participants wish to talk to someone other than the research staff. |
| [ ]  | [ ]  | [ ]  | A **copy** shall be given to the person signing the form. |
|  |  |  |  |
|  |  |  |  |
| **Met** | **Not Met** | **N/A** | **Documentation of Informed Consent** |
| [ ]  | [ ]  | [ ]  | Informed consent documented by written consent form approved by the IRB and **signed by subject**, or subject’s legally authorized representative.  |
| [ ]  | [ ]  | [ ]  | Parental permission signature lines / Authority to sign for participant |
| [ ]  | [ ]  | [ ]  | Include protocol approval and expiration dates. |
| [ ]  | [ ]  | [ ]  | Protocol includes a **Waiver of Documentation** of Informed Consent (Online consent or Information sheet) – not required outside research |
| [ ]  | [ ]  | [ ]  | Protocol includes a **Waiver of Documentation** of Informed Consent (Online consent or Information sheet) –only link |
| [ ]  | [ ]  | [ ]  | Protocol includes a **Waiver of Documentation** of Informed Consent (Online consent or Information sheet) –signing not the norm among distinct cultural group |
| [ ]  | [ ]  | [ ]  | Protocol includes a **Waiver of Informed Consent.** |
| [ ]  | [ ]  | [ ]  | Protocol includes an **Alteration of Informed Consent** (e.g. Research uses Deception) |

| **Met** | **Not Met** | **N/A** | **Additional Items** |
| --- | --- | --- | --- |
| [ ]  | [ ]  | [ ]  | For research involving more than minimal risk, an explanation as to whether any **compensation** and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information can be obtained. |
| [ ]  | [ ]  | [ ]  | A statement that the particular treatment or procedure may involve risks to the subject which are currently **unforeseeable.** |
| [ ]  | [ ]  | [ ]  | Anticipated circumstances under which the subject’s participation may be **terminated by the investigator** without regard to the subject’s consent. |
| [ ]  | [ ]  | [ ]  | Any **additional costs** to the subject that may result from participation in the research. |
| [ ]  | [ ]  | [ ]  | A statement that **significant new findings** developed during the research which may relate to the subject’s willingness to continue participation will be provided to the subject. |
| [ ]  | [ ]  | [ ]  | The approximate **number of subjects** involved in the study. |
| [ ]  | [ ]  | [ ]  | If the study involves video or audio taping, does the consent include a statement as to **what will become of tapes after use**, e.g., shown at scientific meetings, erased. |
| [ ]  | [ ]  | [ ]  | Place for subject to indicate/initial explicit **consent to be taped**. |
| [ ]  | [ ]  | [ ]  | Place for subject to indicate/initial explicit **consent for tapes to be used**. |
| [ ]  | [ ]  | [ ]  | Place for subject to indicate/initial explicit **consent for identity to be made known** from the audio or video tapes. |
| [ ]  | [ ]  | [ ]  | If applicable, is an **assent** document included? |
| [ ]  | [ ]  | [ ]  | If **interpreter** will be used, description of how confidentiality of interpreter will be maintained, who interpreter works for, and how interpreter will be recruited for the study |
| [ ]  | [ ]  | [ ]  | **Translated consent** for non-English speakers required |
| [ ]  | [ ]  | [ ]  | **CoC**: NIH funded study (or funded by one of the NIH institutes) and collecting identifiable or coded information or generating individual‐level genetic Information, CoC statement in the consent form. |
| **Notes** | Click or tap here to enter text. |