|  |  |  |  |
| --- | --- | --- | --- |
| **REQUIRED ELEMENTS** | | | |
| **YES** | **NO** | **ITEMS** | |
|  |  | Participating, supporting, or organizing institutions and those who may benefit from the project’s results listed? | |
|  |  | A statement that the study involves research. | |
|  |  | An explanation of the purposes of the research. | |
|  |  | The expected duration of the participant’s participation. | |
|  |  | A description of the procedures to be followed. | |
|  |  | Identification of any procedures which are experimental (vs. standard care). | |
|  |  | A description of any reasonably foreseeable risks or discomforts to the participant. | |
|  |  | A description of any benefits to the participant or to others which may reasonably be expected from the research. | |
|  |  | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. | |
|  |  | A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained | |
|  |  | If the research is subject to SFDA regulation, a statement that notes the possibility that SFDA may inspect the records. | |
|  |  | For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs. | |
|  |  | An explanation as to whether any medical treatments are available if injury occurs. | |
|  |  | If so, what they consist of, or where further information may be obtained. | |
|  |  | An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights. | |
|  |  | Who to contact in the event of a research-related injury to the participant. | |
|  |  | A statement that participation is voluntary. | |
|  |  | A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. | |
|  |  | A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. | |
|  |  | A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable. | |
|  |  | The subject’s responsibilities. | |
|  |  | Any additional costs to the participant that may result from participation in the research. | |
|  |  | The anticipated prorated payment, if any, to the subject for participating in the trial. | |
|  |  | 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. | |
|  |  | Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent. | |
|  |  | The approximate number of participants involved in the study (at this site and all sites). | |
|  |  |  | |
|  |  |  | |
| **Are the appropriate following additional elements of information included in the consent form, if applicable?** | | | |
| **ADDITIONAL ELEMENTS** | | | |
| **YES** | **NO** | **NA** | **ITEMS** |
|  |  |  | If the participant is or may become pregnant, a statement that the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable. |
|  |  |  | The consequences of a participant’s decision to withdraw from the research. |
|  |  |  | Procedures for orderly termination of participation by the participant. |
|  |  |  | Possible consequences of discontinuing current medication(s). |