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| **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). |
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| **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). |