

| Yes | No | ITEMS |
|--------------------------|----|--|
| REQUIRED ELEMENTS | | |
| | | 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 that are experimental |
| | | 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 Food and Drug Administration (FDA) regulation, a statement that notes the possibility that FDA may inspect the records |
| | | an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights |
| | | 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 |
| | | <p>one of the following statements about research that involves the collection of identifiable private information or identifiable biospecimens:</p> <ul style="list-style-type: none"> i. A statement that identifiers might be removed from the information or biospecimens and that, after such removal, the information or specimens could be used for future research studies or distributed to another investigator for future studies without additional informed consent being obtained. ii. A statement that the information or biospecimens, even if identifiers are removed, will not be used or distributed for future research studies. |