**Informed Consent Checklist**

(Please refer to DHS HHS OHRP 45 CFR 46 [§46.116](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116) for details)

| **Basic Elements** | **Indicate** | |
| --- | --- | --- |
| **Yes** | **No** |
| A statement that the study involves research |  |  |
| An explanation of the purposes of the research |  |  |
| The expected duration of the individual’s participation |  |  |
| A description of the procedures to be followed |  |  |
| Identification of any procedures which 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 |  |  |
| 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 may be obtained |  |  |
| An explanation of whom to contact for answers to pertinent questions about the research and participant’s rights, and whom to contact in the event of a research-related injury to the participant |  |  |
| A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits, to which he/she is otherwise entitled |  |  |
| A statement that must contain the following language: “A description of the clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time/” |  |  |

| **Additional Elements, as appropriate** | **Indicate** | |
| --- | --- | --- |
| **Yes** | **No** |
| A statement that the intervention may involve risks to the individual (or to the embryo or fetus, if the individual is or may become pregnant), which are currently unforeseeable |  |  |
| Anticipated circumstances under which the individual’s participation may be terminated by the investigator without regard to the subject's consent |  |  |
| Any additional costs to the individual that may result from participation in the research |  |  |
| The consequences of an individual’s decision to withdraw from the research and procedures for orderly termination of participation by the individual |  |  |
| A statement that significant new findings developed during the course of the research, which may relate to the individual’s willingness to continue participation, will be provided to the individual |  |  |
| The approximate number of study participants |  |  |