# Informed Consent Checklist

(Please refer to DHS HHS OHRP 45 CFR 46 §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](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