

CHECK LIST FOR VA CONSENT 10-1086

PURPOSE OF RESEARCH STUDY

- Must state this is a research study
- Must explain the purpose of the study

DESCRIPTION

- Must describe all research procedures in the study; must identify which procedures are experimental
- Must describe expected duration of subject's participation
- Must state the approximate total number of subjects to be involved in the study.

RISKS

- Must include statement about unforeseeable risks
- May include a statement that a particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant, which are currently unforeseeable.

BENEFITS

- Must describe the benefits to the subject and benefits to society, not payments to subjects

ALTERNATE COURSES OF ACTION

- Must include a statement that participation in the study is voluntary.
- Must include a statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- Must include a statement about the consequences of not participating in the study
- Must have a statement about any alternative accepted courses of therapy or diagnostic procedures, as well as the potential harms and benefits (if applicable)

STATEMENT OF RESEARCH RESULTS

- Must describe how subject confidentiality will be protected with specific details of privacy & security
- Must state subjects will not be identified in publications.
- Must state that significant new findings developed during the course of the research that may affect the subject's willingness to continue participation will be provided to the subject.

SPECIAL CIRCUMSTANCES

- Must have a statement about any additional costs to the subject (or none)
- Must include a statement that the subject may discontinue participation at any time, the consequences (if any); and the procedures for orderly termination of participation (if any)
- May have a statement about the circumstances under which the investigators may terminate the participation of the subject without regard to the subject's consent (if any).
- There should not be any exculpatory language through which the subject or the subject's legally authorized representative is made to waive or to appear to waive any of the subject's legal rights, or release or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

PAYMENTS

- Must have a statement about payments to subjects (or none)
- Must have a schedule of payments
- Should state how payments will be made (cash, vouchers, check)

CONFIDENTIALITY

- Must state that the Government Accounting Office (GAO) or the Office of Human Protection (OHRP) may have access to records.
- If the study is FDA regulated, must state that the FDA may inspect the records

SUBJECTS RIGHT'S PAGE

- The contact persons and phone numbers must be accurate and up to date
- Must include the Compensation or Treatment for Injury statement.