

Worksheet 305 – Primary Reviewer Supplement Worksheet
Vulnerable Populations

A. Vulnerable Populations in General.

- Pregnant women, fetuses, neonates, minors, prisoners, or other vulnerable populations [e.g., cognitively impaired or institutionalized] are included in the study population and additional safeguards are provided for participants vulnerable to coercion or undue influence to protect their rights and welfare.

B. Pregnant Women, Fetuses, or Neonates. *Note: If the research involves pregnant women, fetuses, or neonates, follow subpart B of the Department of Health and Human Services (HHS) regulations, 45 C.F.R. part 46, when reviewing the consent process.

- The research involves pregnant women or fetuses, and the consent of the pregnant woman will be obtained if the research offers:
 - the prospect of direct benefit to the pregnant woman;
 - the prospect of direct benefit to both the pregnant woman and the fetus; or
 - no prospect of benefit to the woman or the fetus when risk to the fetus is not greater than minimal and the purpose of the research is to develop important biomedical knowledge that cannot be obtained by any other means.

- The research involves pregnant women or fetuses, and the consent of the pregnant woman and the father will be obtained if the research holds out the prospect of direct benefit solely to the fetus. *Note: The consent of the father is not required if the father is not able to consent because of unavailability, incompetence, or temporary incapacity, or the pregnancy resulted from rape or incest.

- The research involves neonates of uncertain viability, and legally effective consent is required. *Note: Legally effective consent is required if
 - The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
 - The purpose of the research is to develop important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research.

- And consent will be obtained from either parent of the neonate, or the legally authorized representative (LAR) of either parent if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity. *Note: the consent of the father or his LAR is not required if the pregnancy resulted from rape or incest.

- The research involves nonviable neonates, and the following conditions are met:
 - Vital functions of the neonate will not be artificially maintained;
 - The research will not terminate the heartbeat or respiration of the neonate;
 - There will be no added risk to the neonate resulting from the research;
 - The purpose of the research is to develop important biomedical knowledge that cannot be obtained by other means;
 - Consent will be obtained from
 - both parents,
 - either parent if either parent is unable to consent because of unavailability, incompetence, or temporarily incapacity, or
 - the pregnant woman if the pregnancy resulted from rape or incest; and
 - Consent will not be obtained from the LARs of the parents.

C. Prisoners

*Note: If the research involves prisoners, follow subpart C of the HHS regulations, 45 C.F.R. part 46, when reviewing the consent process.

- Each prisoner will be informed in advance that participation in the research will have no effect on the prisoner's parole.
- The research meet the following seven requirements:
 1. The research under review represents one of the categories of research permissible under § [46.306\(a\)\(2\)](#); (Category #:)
 2. When compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, any possible advantages accruing to the prisoner through his or her participation in the research are not of such a magnitude that his or her ability is impaired in weighing the risks of the research against the value of such advantages in the limited choice environment of the prison;
 3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
 4. Procedures for selecting participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator justifies some other procedures in writing to the IRB, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
 5. The information is presented in language understandable to the participant population;
 6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in the boards' parole decisions, and each prisoner is clearly informed in advance that participation in the research will not have an effect on his or her parole; and
 7. When the IRB finds that participants need follow -up examination or care after the end of their participation, the investigator has adequately addressed such examination or care, taking into account the varying lengths of individual prisoners' sentences, and informing participants of this fact.

D. Children

*Note: If the research involves children, follow subpart D of the HHS regulations, 45 C.F.R. part 46, when reviewing the consent process, unless the study is also regulated by the FDA.

- The investigator included provisions and forms for parental permission and child assent.
- The provisions and forms for parental permission are appropriate.

*Note:

- The permission of one parent will suffice if the research involves no more than minimal risk, or involves more than minimal risk but presents the prospect of direct benefit to the individual children.
- The permission of both parents is required if the research involves more than minimal risk without the prospect of direct benefit to the individual children unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child.
- Parental permission can be waived or altered if
 - the study meets the requirements under 45 C.F.R. § 116(c) or (d) for waiver or alteration of consent process; or
 - it is not reasonable to require parental permission for the purpose of protecting the participants (e.g., neglected or abused children).

- The provisions and forms for child assent are appropriate.
- Is assent a requirement for
 - all children;
 - some children; describe which children are not required to assent:
 - none of the children?
- If assent is waived for some or all children, is it because
 - the children are not capable of providing assent based on the age, maturity, or psychological state;
 - the capability of some or all of the children is so limited that they cannot reasonably be consulted;
 - the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, or
 - assent may be waived on the ground that the research meets the criteria for waiver or alteration of consent process.
- If assent is required, assent will be documented;
 - ♦ and the process of documenting assent is appropriate.

E. Adults with Diminished Capacity.

- The research involves participants who have diminished decision - making capacity, and
 - There are additional safeguards to ensure appropriate consent processes.
 - The proposed plan is adequate to assess the participants' capacity to consent.
 - If the participants lack capacity to consent, the investigator will seek the consent from the legally authorized representatives of the participants.
 - The investigator should obtain assent from the participants;
 - and the plan for assent is adequate.

F. Additional Safeguards for Vulnerable Population (required)

Describe the protocol-specific safeguards added to the research design to protect the rights and welfare of this study population: