Quick Reference Guide
Vulnerable Populations Overview

This guide is a supplement to CHECKLISTS HRP 305: Pregnant Women, HRP-306: Neonates of Uncertain Viability, HRP-307: Nonviable Neonates, HRP-308: Prisoners, HRP-309: Unexpected Incarceration, HRP-310: Children, and HRP-311: Wards, and WORKSHEET HRP-414: Adults Lacking Capacity. Help Sheets and Quick Guides that provide additional detail are noted within.

1. Vulnerable populations that trigger specific regulatory requirements

- **Children** – may mean subjects under age 18, under age 15, or other ages, depending on the intent of the study and the procedures involved. Additional restrictions apply for wards of the state in certain types of research. See Vulnerable Populations – Children (Quick Guide).
- **Pregnant Women** – pregnancy is defined from implantation to delivery. This category includes research on fetuses.
- **Neonates** – up to 28 days post birth. Viable neonates are considered Children for regulatory purposes. Research on nonviable neonates or neonates of uncertain viability triggers a separate set of regulatory requirements.
- **Prisoners** – Any individual involuntarily confined or detained in a penal institution, including individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution. See Vulnerable Populations – Prisoners (Help Sheet).
- **Adults Unable to Consent (Decisionally Impaired)** – includes permanent, temporary, fluctuating, and progressive decisional impairment. See Vulnerable Populations – Decisionally Impaired Adults (Help Sheet).

Other populations may be vulnerable to coercion or undue influence depending on the circumstances of the study. The protocol should address additional protections for those subjects as appropriate. Common examples include OHSU students or employees, persons with drug or alcohol addictions, and persons with limited English proficiency.

2. What does it mean to “include” vulnerable populations?

A vulnerable population is included if:

- Subjects will belong to the vulnerable population at any time during the intervention, interaction, or collection of identifiable private information for the study; and
- You will obtain knowledge that identifies a subject as a certain member of the vulnerable population.

You need to consider the involvement of vulnerable populations even if you are not specifically targeting a vulnerable population for enrollment.

In general, you do not have an affirmative duty to determine a person’s status as a member of a vulnerable population unless determining that status is necessary to minimize risks to subjects or to ensure an appropriate informed consent process. In other words, you are not including a vulnerable population if you will have no way of identifying subjects as a certain member of a vulnerable population and no reason to do so.

- **Example:** You may need to determine whether a subject is pregnant in order to exclude pregnant women from a study of a particular investigational drug due to potential risks to the fetus.
- **Example:** You do not need to ask each subject if she is pregnant in order to administer a survey on an unrelated topic.

You are not including a vulnerable population if you are accessing records from a time when a subject was a member of a vulnerable population, but is no longer a member of that population at the time the information is accessed (or you would have no way of knowing whether the subject is a current member of that population).

- **Example:** A chart review of pregnancy and delivery outcomes does not involve pregnant women as a vulnerable population because, having delivered, subjects are no longer pregnant when the data is collected for research.
• **Example:** A chart review of data collected five years ago concerning children who were ages 14 and older at the time does not involve children as a vulnerable population.

3. **How to describe involvement of vulnerable populations in your protocol**

**If your study will not identify whether subjects are members of a vulnerable population:** State the following, modifying as appropriate to fit your study.

**Example Protocol Language:** This study will not include any vulnerable populations. We will not collect any information about subjects’ status as [prisoners, pregnant women, children, neonates, and/or adults lacking capacity].

**If your study will deliberately exclude members of vulnerable populations:** State the population[s] to be excluded and, if not described elsewhere, how you will identify these individuals as members of the vulnerable population. If applicable, justify how excluding that population is consistent with principles of equitable recruitment.

**Example Protocol Language:** This observational study will include neonates, but will exclude neonates of uncertain viability and non-viable neonates based on [state criteria for determining exclusion].

**If your study will include known members of vulnerable populations:** State which populations will be included, why their inclusion is appropriate and does not pose unreasonable additional risks, and any additional measures to ensure protection of these populations. Refer to checklists for applicable regulatory requirements.

**Example Protocol Language:** Adults lacking capacity to consent will be included. This study does not pose additional physical risks for adults lacking capacity than for the general population. Informed consent will be sought from the subject’s Legally Authorized Representative (LAR) in accordance with HRP-021 POLICY: Legally Authorized Representatives, Children, and Guardians. If a subject regains capacity during the course of the study, he or she will be asked to consent to further participation.

**Example Protocol Language:** Pregnant women may be included in this retrospective chart review. The study is minimal risk and does not pose any additional risks for pregnant women than for the general population. We are requesting a waiver of informed consent for this study.

**Example Protocol Language:** This study will include children. The inclusion of children is important to the research because the disease being studied affects children, and little is known about the available treatment options in the pediatric population. Parent or guardian permission will be sought before a child may be enrolled. In addition, written assent will be obtained from children who, in the assessment of the investigator, have capacity to assent. If a child subject reaches the age of majority during the study, he or she will be asked to consent to further participation.

**Subsequent Incarceration – If you are excluding prisoners at the time of enrollment, but your population has a high likelihood of arrest and some subjects may become prisoners later in the study:** Be specific about how you will handle this situation and whether prisoners will continue in the study. If they will be removed from the study upon incarceration, explain why that is scientifically and ethically appropriate and why it does not expose subjects to unreasonable risk. If you will continue to include subsequently incarcerated participants, provide justification and describe additional protections (see Vulnerable Populations – Prisoners [Help Sheet] for more details).

**Example Protocol Language:** Persons who are known or suspected to be prisoners at the time of enrollment are excluded. However, it is possible that they may not be recognized as a prisoner at the time of enrollment, or be arrested during or after their hospitalization. These participants will remain in the study if the subject or LAR consents to continued participation. To exclude these subjects would significantly bias the study by eliminating important safety and outcome data. Study participation will have no effect on their later parole. All data collected are coded with a unique identifier, and officers present during study procedures are required by law to maintain confidentiality.