

Guidance Document 6:
Observational Studies Involving Vulnerable Populations

involving specific vulnerable populations, in particular as it relates to the level of risk of a study. The more general issues regarding research ethics can be found in Guidance Document 2 on Principles Guiding Research. For more information on the Guidance Document section of the [Resources page of the IRB](#).

2.0 Observation of Children

Observational research involving children (under the age of 18) does not, in and of itself, involve more than minimal risk. However, special considerations may be involved, e.g., regarding children's security, their capacity to understand the implications of their actions, and/or their status as legal minors. Thus, potential risks to children may require greater ethical scrutiny than those in similar observational studies involving adults, and the study might be deemed to involve more than minimal risk. If this is the case, the researcher should explain the circumstances fully in the project description, taking particular care to address any special ethical considerations that might apply, as well as how the potential risks and benefits of the study will be balanced.

3.0 Observation of Captive or Dependent Populations

Observation involving captive or dependent populations (e.g., in prisons, schools, hospitals, psychiatric facilities, treatment programs, etc.) may or may not involve more than minimal risk. If the researcher is unable to obtain informed consent (due to lack of maturity to self-consent in matters related to the subject of the research), the proposal will be considered to involve moderate or higher risk. In the project proposal, the researcher should explain the circumstances fully, as well as describe the safeguards that will be used to protect the participants if informed consent cannot be obtained. The researcher should also explain how potential risks will be balanced against potential benefits of the study. Extra review time may be required to resolve ethical issues.

4.0 Observation of Vulnerable Persons

Observation of vulnerable persons (those who are legally or otherwise not competent to give