

WOU Institutional Review Board  
Level of Research Review Categories

## Full Board Research

C. **Full Board** Research:

Research requiring Full Board approval includes special populations of participants including:

- fetuses,
- pregnant women
- human in vitro fertilization
- incarcerated individuals
- children (except in situations noted in Exempt categories 1 – 4)

Information to consider when determining research project category:

- All research proposals that are not **Exempt** or **Expedited** must receive full board review
- Risk or potential for harming participants or violating their rights appears more than minimal. May require special protections for participants.
- Researcher must provide assurance of precautions to minimize the risk and significance of injury.
- Cannot be approved unless in the IRB's judgment the sum of direct benefits to the subject and the importance of the knowledge to be gained outweigh the risks to the subject.
- If a determination is made by the IRB that participants will be placed at risk of injury, the IRB must determine, before approving a research project:
  - a. that the risks of injury to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;
  - b. that the rights and welfare of the subject will be adequately protected; and
  - c. that informed consent will be obtained that includes discussion of risks involved in the project.

Examples of risk

- a. Psychological risk: *May be experienced during the research situation and/or later, as a result of participation in the research. Including but not limited to: depression, loss of self-esteem, feelings of stress, guilt, anxiety, confusion, embarrassment, invasion of privacy.*
- b. Social risk: *Including but not limited to: negative effects on standing in group or community, overt hostile reaction by others, reduced opportunity for communication, diminished access to otherwise available roles, lost or endangered membership in groups.*
- c. Physical risk: *Including but not limited to: illness, injury, minor discomfort such as temporary dizziness, headaches or pain associated with venipuncture.*

- d. Economic risk: *Including but not limited to: loss of present or future employment, loss of opportunity for career advancement, loss of eligibility for insurance, cost relating to participation in research (including cost for research-related injuries).*
- e. Legal risk: *Including but not limited to: criminal prosecution, civil lawsuit.*