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### **Vulnerable Populations**

1. Vulnerable populations are based on federal regulations. In addition, decision impaired should be considered a vulnerable population. The Reviewing IRB will apply the criteria and measures of protections when reviewing vulnerable populations based on their policies.
2. Additional populations may be considered vulnerable based on study specific procedures and the Relying Institution's requirements:
  - Physically Handicapped
  - Mentally Disabled
  - Economically Disadvantaged
  - Educationally Disadvantaged
  - Racial Minorities
  - Terminally Ill
  - Elderly/Aged
  - Institutionalized
  - Employees/Students/Normal Volunteers
  - International Research Subjects
  - Individuals of Domestic
  - Violence/Sexual Assault
3. The Reviewing IRB must receive any additional info regarding a Relying Institution's policies and local laws during the approval process.
4. Target return time for review of other IRB documents
  - 14-17 days
5. Significant Modifications:
  - a. Addition or removal of a vulnerable population can occur based on the changes to the protocol driven by the main PI request
  - b. **Pre-approval**  
Relying Institutions assess and confirm that all site-specific requirements and policies regarding vulnerable populations are met. Any site-specific measures related to protection of vulnerable population or additional vulnerable populations – the Relying Institution provides a Reviewing IRB with a site-specific protocol addendum to outline additional info to ensure state law and Institutional policy are complied with.
  - c. **Post-approval**  
For addition or removal of a vulnerable population, a Relying Institution's impact assessment should be provided to the Reviewing IRB prior to approval.