**Are Studies Involving Vulnerable Populations Eligible for Exemption?**

The involvement of a vulnerable population does not automatically disqualify studies from an exemption. The Common Rule allows for the involvement of most vulnerable populations covered by subparts B, C, and D (see table below) assuming the study activities meet the requirements of an exemption. The AU IRB will consider the nature or characteristics of the vulnerability to determine eligibility.

|  |  |  |  |
| --- | --- | --- | --- |
| **Application of Exemption Categories to Subpart Populations** | | | |
| **Exemption Category** | **Subpart B Fetuses, Pregnant Women, and Human In Vitro Fertilization**  **45 CFR 46.104 (b)(1)** | **Subpart C Prisoners 45 CFR 46.104 (b)(2)** | **Subpart D Children**  **45 CFR 46.104 (b)(3)\*** |
| **1** Normal Educational   Practices and Settings | Each of the exemptions may be applied | None of the exemptions may be applied “except for research aimed at involving a broader subject population that only incidentally includes prisoners” | May be applied |
| **2i**  Educational Test, Surveys   Interviews, or Observations:   Anonymous  **2ii** Educational Tests, Surveys,   Interviews, or Observations:   not sensitive | May only be applied to “educational tests and observation of public behavior when the investigator(s) do not participate in the activities being observed” |
| **2iii** Educational Tests, Surveys,  Interviews, or Observations:   not anonymous but has   limited IRB review | May not be applied |
| **3** Benign Behavioral   Interventions with Adults | May not be applied |
| **4** Secondary Research for   which Consent Is Not   Required | May be applied |
| **5** Public Benefit or Service   Programs | May be applied |
| **6** Taste and Food Quality   Evaluation and Consumer   Acceptance Studies | May be applied |
| **7** Storage or Maintenance for  Secondary Research for   Which Broad Consent is   Required | Exempt categories 7 and 8 require broad consent. The AU IRB has determined the regulatory requirements for legally effect broad consent are not feasible within the current institutional infrastructure. Exempt categories 7 and 8 will not be implemented at this time. | | |
| **8** Secondary Research for   Which Broad Consent Is   Required |

Table from Institutional Review Board Management and Function Third Edition, chapter 5-3 (Bankert, etal.)

**\*Research which occurs out of the United States and targets minors/children as participants is not eligible for exempt review.**