**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.**