



Understanding the common rule

Exempt and Vulnerable Populations

See Introduction to Exempt and Exempt Categories 1-6 for Additional Details

**Exempt Revisions
(to be effective January
21, 2019)**

The New Rule makes a lot of changes to the exempt categories. This document discusses the applicability of exempt categories to vulnerable populations.

- **Children (Subpart B)**

Under exempt category 2, the research may involve children ONLY if the research involves only educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

If the research requires limited review under category 2, it may not involve children. This is because protections, including IRB review and parental permission, are appropriate for research involving children and educational tests, surveys or interview procedures, or observation of public behavior when the information collected may be individually identified and sensitive in nature.

The new exempt Category 3 - benign behavioral interventions- does not allow children.

The other exemptions (1, 4, 5, 6, 7 and 8) do allow the inclusion of children.

- **Pregnant women, fetuses and neonates (Subpart B)**

All of the exemptions may be applied to research conducted under subpart B if the conditions of the exemption are met.

- **Prisoners (Subpart C)**

None of the exemptions may be applied to research conducted under subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

**Implications for
Researchers:**

Be sure to consider your intended population when considering whether your study may meet exempt criteria. If you request exempt review for a study that involves a population not allowed under that exemption, your xform will have to be sent back to you for revisions. This will likely cause delays in your review process.