Exempt Human Subjects Research

Meets the definition of human subjects research.
Exempt studies involve human subjects research: research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generate

Meets the criteria of one of the following exemptions:

1. **Exemption 1**: conducted in an educational setting using normal educational practices*
   *Cannot include any other procedures, such as collection of clinical data or biospecimens

2. **Exemption 2**: uses educational tests, surveys, interviews, or observations of public behavior unless identifiable and pose risks

3. **Exemption 3**: uses benign behavioral interventions

4. **Exemption 4**: involves the collection or study of data or specimens if publicly available or information recorded such that subjects cannot be identified

5. **Exemption 5**: public service program or demonstration project

6. **Exemption 6**: taste and food quality

7. **Exemption 7**: storage of identifiable information or biospecimens for secondary research use. Broad consent is and limited IRB review are required.

8. **Exemption 8**: secondary research use of identifiable information or biospecimens. Broad consent and limited IRB review are required.

Consider

**Requirements:**
- HS education
- Inclusion tracking for all except 4
- Limited IRB review for 7 & 8; and some study designs under 2 and 3.
- Broad consent for 7 & 8

- FWA and IRB not required for 1, 4, 5, 6

**Cannot involve prisoners**, unless includes a broader population that happens to include prisoners.

**Cannot involve children in:**
- Exemption 2 if investigators participate in the activity being observed or includes identifiable info. OR
- Exemption 3

For more information see the [OER website for Research Involving Human Subjects](https://example.com). Send questions/comments to OEP-HS@mail.nih.gov.
<table>
<thead>
<tr>
<th>Exemption 1 (X1)</th>
<th>Exemption 2 (X2)</th>
<th>Exemption 3 (X3)</th>
<th>Exemption 4 (X4)</th>
</tr>
</thead>
</table>
| **Effectiveness of on-line training as supplement to regular instructional approach.**
  - Effectiveness of activities to increase awareness of oral health delivered at a community science museum. | **Focus group of adult community members to discuss access to dental care.**
  - Observation of food chosen from public vending machines. | **Study evaluating preferred snack foods following television program.**
  - Study investigating text vs. voice message appointment reminders on self-reported annual physical appointment attendance. | **Patient data extracted from medical records without name or ID number every 6 months as follow up visits occur.**
  - A collaborator removes an aliquot of blood from coded samples. Aliquots are re-labeled to a random, non-linked code. |
| **Testing a manual for parents to identify severe asthma symptoms.**
  - Evaluation of health education that includes collection and analysis of heart rate and body measurements from students. | **Survey of subjects engaged in illegal drug use.**
  - Focus group of pre-teens to discuss bullying. | **Diet and physical activity intervention for people with diabetes.**
  - Smoking cessation intervention. | **De-identified blood drawn from subjects for the study by a blood bank.**
  - Use of collaborator’s coded samples and the collaborator retains the code key. |

<table>
<thead>
<tr>
<th>Exemption 5 (X5)</th>
<th>Exemption 6 (X6)</th>
<th>Exemption 7 (X7)</th>
<th>Exemption 8 (X8)</th>
</tr>
</thead>
</table>
| **Study of barriers to obtaining new Medicare benefits.**
  - Outcomes assessment from government-sponsored mental health services. | **Evaluation of wholesome food preferences.**
  - Study looking at approved levels of an agricultural chemical on taste of vegetables. | **Creating a dataset containing identifiers from a previous study to conduct future research.**
  - Saving blood samples from collaborator’s study for a future research question. (Broad consent obtained and limited IRB review conducted.) | **Using dataset from prior study containing identifiers to answer subsequent research question.**
  - Using blood samples from collaborator’s study for an additional research question. (Broad consent obtained and limited IRB review conducted.) |
| **Evaluation of investigator-sponsored diabetes intervention.** | **Study evaluating novel food additives.**
  - Testing high doses of environmental contaminant on food taste. | **Dataset containing identifiers from prior study stored for future research, with informed consent for disease-specific research.** | **Using blood drawn from subjects with study specific consent for future research questions.** |

**Please note:** these are possible examples only. Final determination of exemptions should be made in accordance with 45 CFR 46.