NIH 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/generated.

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*
   *Limited IRB review may be required.

3. **Exemption 3**: benign behavioral interventions in adults*
   *Limited IRB review may be required.

4. **Exemption 4**: involves the collection/study of data or specimens if publicly available, or recorded such that subjects cannot be identified*
   *May be identifiable in limited cases. See §46.104(d)(4)(iii) and (iv)

5. **Exemption 5**: research or demonstration projects designed to study, evaluate, improve, or examine an NIH public benefit or service program*
   *Applies to projects that NIH itself administers

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

7. **Exemption 7**: storage of identifiable information or biospecimens for secondary research use. Broad consent 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

For more information see the [NIH OER Human Subjects Research website](https://oer.nih.gov).
Send questions/comments to [OER-HS@nih.gov](mailto:OER-HS@nih.gov).

Consider

**NIH Requirements:**
- HS education
- Inclusion tracking for all except 4.

**45 CFR 46 Requirements:**
- Limited IRB review for 7 & 8, and some study designs under 2 & 3.
- Broad consent for 7 & 8.

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.
<table>
<thead>
<tr>
<th>Exemption 1 (X1)</th>
<th>Exemption 2 (X2)</th>
<th>Exemption 3 (X3)</th>
<th>Exemption 4 (X4)</th>
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</thead>
<tbody>
<tr>
<td><strong>Exemption 1 (X1)</strong></td>
<td><strong>Exemption 2 (X2)</strong></td>
<td><strong>Exemption 3 (X3)</strong></td>
<td><strong>Exemption 4 (X4)</strong></td>
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<tr>
<td>Effectiveness of on-line training as supplement to regular instructional approach.</td>
<td>• Focus group of adult community members to discuss access to dental care</td>
<td>• Study among young adults evaluating preferred snack foods following a television program</td>
<td>• Patient data extracted from medical records without name or ID number every 6 months as follow up visits occur</td>
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<td>• Effectiveness of activities to increase awareness of oral health delivered at a community science museum</td>
<td>• Questionnaire about outdoor exercise, including collection of participants’ age and zip code (limited IRB review conducted)</td>
<td>• Study investigating text vs. voice message appointment reminders on self-reported annual physical appointment attendance</td>
<td>• A collaborator removes an aliquot of blood from coded samples. Aliquots are re-labeled to a random, non-linked code</td>
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<td>Testing a manual for parents to identify severe asthma symptoms</td>
<td>• Substance abuse training for individuals engaged in illegal drug use, followed by a survey about the training</td>
<td>• Diet and physical activity intervention for people with diabetes</td>
<td>• De-identified blood drawn from subjects for the study by a blood bank</td>
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<td>• Evaluation of health education that includes collection and analysis of heart rate and body measurements from students</td>
<td>• Investigator-led focus group of pre-teens to discuss bullying</td>
<td>• Examining reactions of participants during brief exposure to painful stimuli</td>
<td>• Use of collaborator’s coded tissue samples and the collaborator retains the code key</td>
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### Exemption 5 (X5)

**Exemption 5 (X5)**

- Outcomes evaluation of NIH conducted mental health service program
  *NOTE: NIH anticipates use of this exemption will be rare*

### Exemption 6 (X6)

**Exemption 6 (X6)**

- Evaluation of wholesome food preferences
- Study looking at approved levels of an agricultural chemical on taste of vegetables

### Exemption 7 (X7)

**Exemption 7 (X7)**

- 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.)*

### Exemption 8 (X8)

**Exemption 8 (X8)**

- 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.)*

### Exemption 9 (X9)

**Exemption 9 (X9)**

- Using blood drawn from subjects with study specific consent for future research question

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*Please note: these are possible examples of exempt research accepted by NIH. Final determination of exemptions should be made in accordance with 45 CFR 46.*