Exempt Human Subjects Research

1. 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.

2. Meets the criteria of one of the following exemptions:

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

- **Exemption 2**: uses educational tests, surveys, interviews, or observations of public behavior*
  *Limited IRB review may be required.

- **Exemption 3**: uses benign behavioral interventions*
  *Limited IRB review may be required.

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

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

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

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

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

For more information see the OER website for Research Involving Human Subjects. Send questions/comments to 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
- FWA and IRB approval 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.
<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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| **Effectiveness of on-line training as supplement to regular instructional approach.**<br>• 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.**<br>• Questionnaire about outdoor exercise, including collection of participants’ age and zip code (limited IRB review conducted) | **Study evaluating preferred snack foods following a television program.**<br>• 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. | **Substance abuse training for individuals engaged in illegal drug use, followed by a survey about the training.**  
• Focus group of pre-teens to discuss bullying. | | **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. |
| Exemption 5  (X5) | Exemption 6  (X6) | Exemption 7  (X7) | Exemption 8  (X8) |
| • 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. | | **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.