**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.

**8 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**: public service program research or demonstration projects

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.

**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.

For more information see the [NIH OER Human Subjects Research website](https://www.nih.gov). Send questions/comments to OER-HS@nih.gov.
<table>
<thead>
<tr>
<th>Exemption 1 (X1)</th>
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<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.  
  • Effectiveness of activities to increase awareness of oral health delivered at a community science museum.  
  • 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. | • Focus group of adult community members to discuss access to dental care.  
  • Questionnaire about outdoor exercise, including collection of participants’ age and zip code (limited IRB review conducted)  
  • Substance abuse training for individuals engaged in illegal drug use, followed by a survey about the training.  
  • Investigator-led focus group of pre-teens to discuss bullying. | • Study among young adults evaluating preferred snack foods following a television program.  
  • Study investigating text vs. voice message appointment reminders on self-reported annual physical appointment attendance.  
  • Diet and physical activity intervention for people with diabetes.  
  • Examining reactions of participants during brief exposure to painful stimuli. | • 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.  
  • De-identified blood drawn from subjects for the study by a blood bank.  
  • Use of collaborator’s coded tissue samples and the collaborator retains the code key. |
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<tr>
<th>Exemption 5 (X5)</th>
<th>Exemption 6 (X6)</th>
<th>Exemption 7 (X7)</th>
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| • Study of barriers to obtaining new Medicare benefits.  
  • Outcomes assessment from government-sponsored mental health services.  
  • Evaluation of investigator-sponsored diabetes intervention. | • Evaluation of wholesome food preferences.  
  • Study looking at approved levels of an agricultural chemical on taste of vegetables.  
  • Study evaluating novel food additives.  
  • Testing high doses of environmental contaminant on food taste. | • 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.*  
  • Using dataset from prior study containing identifiers to answer subsequent research question.*  
  • Using blood samples from collaborator’s study for an additional research question.* | • Using dataset from prior study containing identifiers to answer subsequent research question.*  
  • Using blood samples from collaborator’s study for an additional research question.*  
  • 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.