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.

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.

For more information see the NIH OER Human Subjects Research website. Send questions/comments to OER-HS@nih.gov.
| Exemption 1 (X1) | 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. |
|---|---|
| Exemption 2 (X2) | 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. |
| Exemption 3 (X3) | 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. |
| Exemption 4 (X4) | 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. |
| Exemption 5 (X5) | Study of barriers to obtaining new Medicare benefits.  
- Outcomes assessment from government-sponsored mental health services.  
- Evaluation of investigator-sponsored diabetes intervention. |
| Exemption 6 (X6) | 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. |
| 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.*  
- Dataset containing identifiers from prior study stored for future research, with informed consent for study-specific research (no broad consent). |
| 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.*  
- 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.