

# Exempt Human Subjects Research

## 8 Exemptions

## Consider

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### 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

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### 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:** benign behavioral interventions in adults\*

\*Limited IRB review may be required.

**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)

**Exemption 5:** public service program research or demonstration projects

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

**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.

### 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](#).  
Send questions/comments to [OER-HS@nih.gov](mailto: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.\*
- \*(Broad consent obtained and limited IRB review conducted.)

- ✗ 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.\*
- \*(Broad consent obtained and limited IRB review conducted.)

- ✗ Using blood drawn from subjects with study specific consent for future research questions.

✓ = exempt      ✗ = non-exempt

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