

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 or more 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: *secondary* research using identifiable information or biospecimens if publicly available, or recorded such that subjects cannot be re-identified*

*See §46.104(d)(4)(ii), (iii), and (iv) for all criteria

Exemption 5: public service program research or demonstration projects

Exemption 6: taste and food quality evaluations

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

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

NIH Requirements:

- Human Subjects education.
- Inclusion tracking for all except exemption 4.

45 CFR 46

Requirements:

- Limited IRB review for exemptions 7 & 8, and some study designs under 2 & 3.
- Broad consent for exemptions 7 & 8.

Cannot involve **prisoners**, unless research includes a broader population that happens to include prisoners.

Cannot involve **children** in:

- Exemption 2 research if data is recorded with identifiers, for survey or interview procedures, or for observations of public behavior if investigators participate in the activity being observed.
- Exemption 3 research.



Exemption 1 (X1)

- ✓ Effectiveness of on-line training as supplement to regular instructional approach.
 - Testing the effect of biweekly science-focused field trips on middle school student learning.
- ✗ 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 for adults 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; the survey includes participants names.
 - 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 among adults 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)

- ✓ Collecting random samples of patient data every 6 months from medical records. Names and other identifiers are not recorded.
 - A collaborator removes an aliquot of blood from coded samples. Aliquots are re-labeled to a random, non-linked code.
- ✗ Use of deidentified blood samples purchased from a blood bank.
 - Use of co-investigator's coded tissue samples and the co-investigator 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 or waiver of consent documentation).

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.)
- ✗ Research with identifiable blood samples and data from subjects in a prior study; subjects previously signed consent for future research with data/specimens (no broad consent or waiver of consent documentation).

✓ = exempt ✗ = non-exempt or not HS research

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