Exempt Human Subjects Research

8 Exemptions

Consider

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 participants cannot be re-identified*

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

Exemption 5: research or demonstration projects designed to study, evaluate, improve, or examine an *NIH* public benefit or service program*

*Applies to projects that NIH itself administers

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

For more information see the NIH OER Human Subjects Research website.
Send questions/comments to OER-HS@nih.gov.

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 for survey or interview procedures, for educational tests or observations of public behavior when data is recorded with identifiers, or for observations of public behavior if investigator participates 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

•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

•Collaborator removes aliquots of blood from coded samples in a repository. Aliquots are re-labeled to a random, non-linked code

X •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)

✓ •Outcomes evaluation of NIH conducted mental health service program

*NOTE: NIH anticipates use of this exemption will be rare

⊘ •Evaluation of investigator-sponsored diabetes intervention

•Evaluation of U.S. state administered service program

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)

⊘ Research with identifiable blood samples and data from participants in a prior study; participants previously signed consent for future research with data/specimens (no broad consent)

✓ = exempt, ⊘ = non-exempt, X = not HS research

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