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 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.

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.