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: uses benign behavioral interventions*

*Limited IRB review may be required.

Exemption 4: involves the collection or study of data or specimens if publicly available or recorded such that subjects cannot be identified

Exemption 5: public service program or demonstration project

Exemption 6: taste and food quality

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
- FWA and IRB approval not required for 1, 4, 5, 6

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 OER website for Research Involving Human Subjects.
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.

X •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)

X •Substance abuse training for individuals engaged in illegal drug use, followed by a survey about the training.

•Focus group of pre-teens to discuss bullying.

Exemption 3 (X3)

✓ Study evaluating preferred snack foods following a television program.

•Study investigating text vs. voice message appointment reminders on self-reported annual physical appointment attendance.

X •Diet and physical activity intervention for people with diabetes.

•Smoking cessation intervention.

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.

X •De-identified blood drawn from subjects for the study by a blood bank.

•Use of collaborator's coded 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.

X •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.

X •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.)

X •Dataset containing identifiers from prior study stored for future research, with informed consent for disease-specific research.

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.)

X • Using blood drawn from subjects with study specific consent for future research questions.

✓ = exempt X = non-exempt

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