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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 unless identifiable and pose risks

Exemption 3: uses benign behavioral interventions

Exemption 4: involves the collection or study of data or specimens if publicly available or information 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 is and limited IRB review are required.

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

Requirements:

- HS education
- Inclusion tracking for all except 4
- Limited IRB review for 7 & 8; and some study designs under 2 and 3.
- Broad consent for 7 & 8
- FWA and IRB 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.



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.
 - Observation of food chosen from public vending machines.

- ✗ Survey of subjects engaged in illegal drug use.
 - Focus group of pre-teens to discuss bullying.

Exemption 3 (X3)

- ✓ Study evaluating preferred snack foods following 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.
 - 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.

- ✗ 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.

- ✗ 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 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.)

- ✗ 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 101.