

**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 3**: benign behavioral interventions in adults\*

\*Limited IRB review may be required.

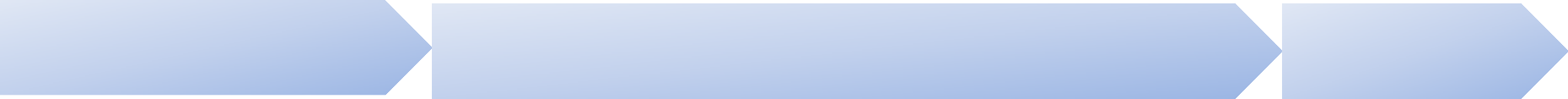
**Exemption 2**: uses educational tests, surveys, interviews, or observations of public behavior\*

\*Limited IRB review may be required.

**Exemption 1**: conducted in an educational setting using normal educational

practices\*

\*Cannot include any other procedures, such as collection of clinical data or biospecimens



**NIH Exempt Human**

**Subjects Research**

**8 Exemptions**

**Consider**

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](https://grants.nih.gov/policy/humansubjects.htm).

Send questions/comments to [OER-HS@nih.gov](mailto:OER-HS@nih.gov).

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

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

**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.

These studies may meet the criteria for this exemption.

Exemption 5 (X5)

Exemption 6 (X6)

Exemption 7 (X7)

Exemption 8 (X8)



* 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
* 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)



* 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

* 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



* Outcomes evaluation of NIH

conducted mental health service program\*

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



* Evaluation of wholesome food

preferences

* Study looking at approved levels of an agricultural chemical on

taste of vegetables



* 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.)



* 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

question



* 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
* 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

Exemption 1

(X1)

Exemption 2 (X2)

|  |
| --- |
| 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)



**= exempt**

**= non-exempt**

**Please note:** these are possible examples of exempt research accepted by NIH. Final determination of exemptions should be

made in accordance with 45 CFR 46.

* Dataset containing identifiers from prior study stored for

future research, with informed consent for study-specific research (no broad consent)

* Study evaluating novel food additives
* Testing high doses of environmental

contaminant on food taste

* Evaluation of U.S. state administered service program
* Evaluation of investigator-

sponsored diabetes intervention