**Exempt Human Subjects Research**

**8 Exemptions**

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 subjects cannot be re-identified*
   
   *See §46.104(d)(4)(ii), (iii), and (iv) for all criteria

   **Exemption 5:** public service program research or demonstration projects

   **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.

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**Consider**

**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 research if data is recorded with identifiers, for survey or interview procedures, or for observations of public behavior if investigators participate in the activity being observed.
- Exemption 3 research.

For more information see the [NIH OER Human Subjects Research website](https://oer.nih.gov). Send questions/comments to OER-HS@nih.gov.
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.

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).

Exemption 3 (X3)
- Substance abuse training for individuals engaged in illegal drug use, followed by a survey about the training; the survey includes participants names.
- Investigator-led focus group of pre-teens to discuss bullying.

Exemption 4 (X4)
- Collecting random samples of patient data every 6 months from medical records. Names and other identifiers are not recorded.
- A collaborator removes an aliquot of blood from coded samples. Aliquots are re-labeled to a random, non-linked code.
- 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)
- 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 or waiver of consent documentation).

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 subjects in a prior study; subjects previously signed consent for future research with data/specimens (no broad consent or waiver of consent documentation).

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

= exempt  = non-exempt or not HS research