

1 Meets the definition of human subjects research.

Exempt studies involve human subjects research: research involving a living individual about whom data is obtained through interaction/intervention or identifiable, private information

Cannot involve prisoners

Does not need:

- FWA
- IRB

Does need:

- HS education
- Inclusion tracking for E1 and E2

For Exemption 2:

Children can be included in studies involving educational tests or observation of public behavior if investigators do not participate in the activities being observed.

Exemption 1 (E1)

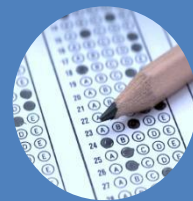


research conducted in an educational setting involving normal education practices.

- ✓ 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.

- ✗ Test a manual for parents to identify severe asthma symptoms.
- ✗ Cannot include any other procedures, such as collection of clinical or anthropometric data or biospecimens.

Exemption 2 (E2)



research using educational tests, surveys, interviews, or observations of public behavior unless identifiable and pose risks. (not collecting sensitive information)

- ✓ Focus group of adult community members to discuss access to dental care.
- ✓ Questionnaire to patients regarding willingness to use a tool to test for colon cancer.
- ✓ Observation of food chosen from public vending machines.

- ✗ Survey of subjects engaged in illegal drug use.
- ✗ Focus group of pre-teens to discuss bullying.
- ✗ Use of the mini-mental cognitive impairment test.

Exemption 4 (E4)



research involving the collection or study of existing data or specimens if publicly available or information recorded such that subjects cannot be identified.

- ✓ Patient data extracted from medical records without name or ID number.
- ✓ A collaborator removes an aliquot of blood from stored, 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.



2 meets the criteria of one of the following exempt study designs:

Questions/comments to OEP-HS@mail.nih.gov.