Exempt Human Subjects Research

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.

1. 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.

2. 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. Cannot include any other procedures, such as collection of clinical or anthropometric data or biospecimens.

3. 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.

Consider

Cannot involve prisoners

Does not need:
- FWA
- IRB

Does need:
- HS education
- Inclusion tracking for E1 and E2

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

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.