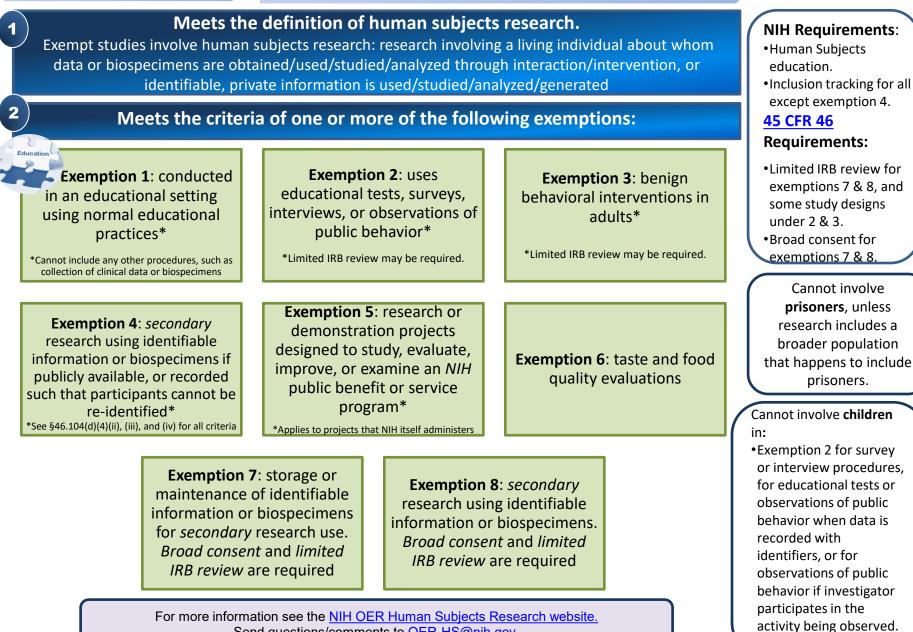
Exempt Human Subjects Research

8 Exemptions

Consider



Send questions/comments to OER-HS@nih.gov.

•Exemption 3 research.

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

•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 5 (X5)

•Outcomes evaluation of NIH conducted mental health service program

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

•Evaluation of investigatorsponsored diabetes intervention •Evaluation of U.S. state administered service program 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)

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

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 3 (X3)

 Study among young adults evaluating preferred snack foods following a television program
Study among adults investigating text vs. voice message appointment reminders on selfreported annual physical appointment attendance

•Diet and physical activity intervention for people with diabetes

•Examining reactions of participants during brief exposure to painful stimuli

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)

Exemption 4 (X4)

•Collecting random samples of patient data every 6 months from medical records. Names and other identifiers are not recorded

•Collaborator removes aliquots of blood from coded samples in a repository. 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 coinvestigator retains the code key

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 participants in a prior study; participants previously signed consent for future research with data/specimens (no broad consent)

= exempt, 🚫 = non-exempt, X = not HS research

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