### **Exempt Human Subjects Research**

research use. Broad consent

and *limited IRB review* are

required

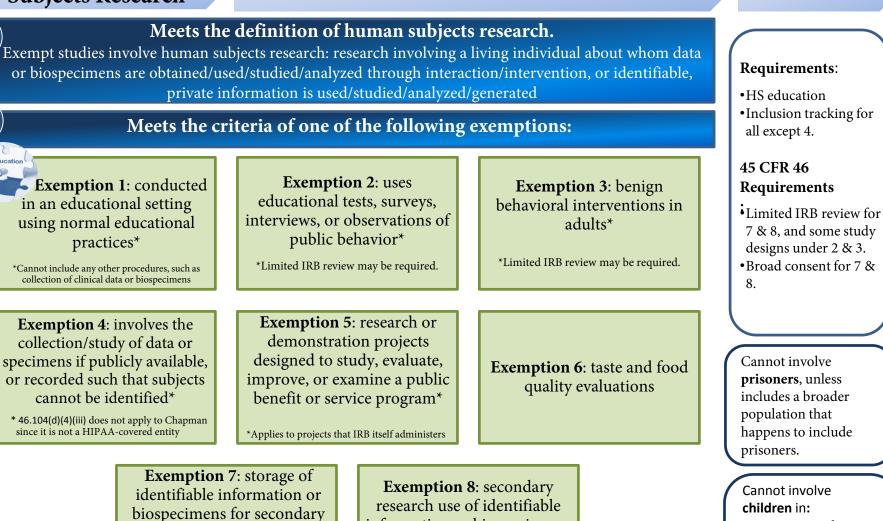
\*NOTE: Chapman does not use this exemption

2

Education

### 8 Exemptions

#### Consider



information or biospecimens.

Broad consent and limited

IRB review are required

\*NOTE: Chapman does not use this exemption

children in: •Exemption 2 if investigators participate in the activity being observed or includes identifiable info, OR •Exemption 3.

## Exemption 1 (X1)

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

YTesting 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: Use of this exemption is rare

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

= non-exempt

exempt

# Exemption 2 (X2)

 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)

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 investigating text vs. voice message appointment reminders on self-reported annual physical appointment attendance

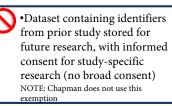
•Diet and physical activity intervention for people with diabetes

•Examining reactions of participants during brief exposure to painful stimuli

### Exemption 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.)



## Exemption 4 (X4)

•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

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

> 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.)

• Using blood drawn from subjects with study specific consent for future research question

NOTE: Chapman does not use this exemption

**Please note:** these are possible examples of exempt research accepted by IRB. Final determination of exemptions should be made in accordance with 45 CFR 46.