

3. Change Categories of Exempt Research

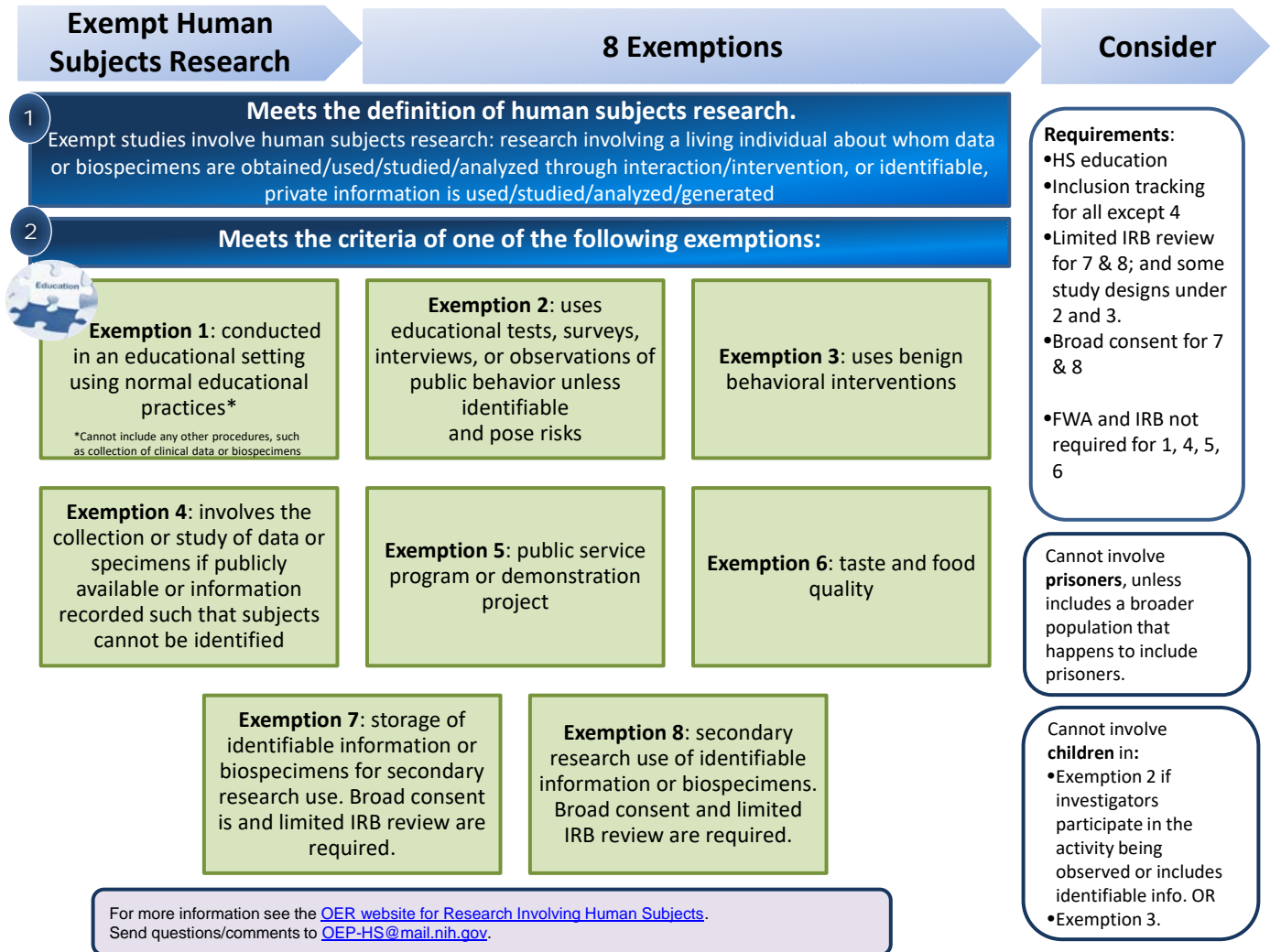
- It is recommended that all investigators who believe their research is exempt watch this video about the changes to exemption in the revised Common Rule:

<https://tinyurl.com/OHRP-exempt>

- What is not new:
 - The IRB (usually the chair) makes the determination of Exempt status. Researchers complete the standard IRB application and makes a case for exempt status.
 - Exempt means
 - no collection of signatures
 - only the chair (or a representative) reviews the application



Overview of Revised Exemption Categories



Exemption #1 (see guidelines)

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices **that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.** This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.



Exemption #2

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or



Exemption #2

- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review** to make the determination required by §46.111(a)(7).



Limited Review (expedited review mechanism)

- A committee member (other than the chair) reviews the Exempt application
- The review is "limited to a determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."
- No need for continuing review.



Exemption #3

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;



Exemption #3(i)

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).



Exemption #3

3(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.



Exemption #3

3(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

