START
Meets the definition of research

Are prisoners the targeted population?

Is research in an established educational setting?

Only normal educational practices?

Likely adverse impact on students or teachers?

Qualifies for Exempt Cat 1

Does not meet requirements for Exempt Category 1
Check other exempt categories

An established educational setting may vary based on the type of institution. Your institutional HRPP should be consulted.

This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, or classroom management methods.

Not likely to impact the student’s opportunity to learn required educational content or the assessment of educators who provide instruction.
2018 Exempt Category 2: Educational Tests, Surveys, Observations of Public Behavior Use after 21 Jan 2019

START
Meets the definition of research

Are prisoners the targeted population?

Yes

Does not meet requirements for Exemption

No

Children involved?

Yes

Any reasonable risk of criminal or civil liability?

No

Qualifies for Exempt Cat 2 (ii)

Yes

Investigators participating?

No

Subject identifiers readily ascertainable?

Yes

Qualifies for Exempt Cat 2 (i)

No

Subject identifiers readily ascertainable?

May qualify as Exempt Category 2 (iii) if a limited IRB review approves the plan for the privacy and confidentially of the data.

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)

Identifiers: 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.

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

The exempt category does not apply if the investigator participates in the activities involved in the educational test or the public behavior being observed

A protocol need only meet ONE of the requirements to meet the exemption.
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.

Identifiers: 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,

104.(d)(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

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
2018 Exempt Category 4: Secondary Use of Identifiable Data or Specimens
After 21 Jan 2019

What is new is that the private information and/or biospecimens can be identifiable and can be prospectively collected. HIPAA authorization or waiver is still required.

START

YES

Study meets the definition of research?

NO

STOP

HIPAA Rules apply and study must meet the requirements for HIPAA waiver.

The data/specimens are publicly available?

YES 4(i)

All study data and use is covered by HIPAA*?

YES 4(iii)

NO

YES 4(ii)

Deidentified: The information is recorded in a way that there is no possible way to link the data to the subjects’ identities, the researcher does not have any contact with the subjects, and will not re-identify the data;

Identified data or specimens to be deidentified?

NO

YES 4(iv)

Data is from a federal department or agency collected for non research purposes?

Does not meet exempt Cat 4

Qualifies as exempt under Category 4.

The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.