Exemption 1 [45 CFR 46.104(d)(1)]
Educational Strategies, Curricula or Classroom Management Methods
Modified

"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."

> Most educational research on regular and special educational instructional strategies, and research on the effectiveness of, or comparison among, instructional techniques, curricula, or classroom management methods may be exempt under this category.
>
> Changes to this exempt category include the caveat that there must not be any impact of subject's opportunity to learn or any negative impact if the research involves an evaluation of the instructors. If the research involves significant time and attention away from the delivery of regular curriculum or withholding of standard educational content, this exemption would not apply. Also, there must be protection against negative impact on employment if instructors are being evaluated. Research involving randomization to a unproven educational technique, or research conducted by supervisors involved in employment decisions may not be approvable under this exemption.

Subject population:

- If any subjects are children:
  - Investigators must provide a rationale for why a particular age range was selected, indicate their expertise in working with children, describe the adequacy of their facilities for pediatric research, and indicate whether they will have sufficient numbers of children to adequately address the research question.
  - All study team members must obtain the required clearances before any interaction with children
- Prisoners may be included only if the research involves a broader subject population that only incidentally involves prisoners.

Privacy & Confidentiality:

- "Anonymous" means that no one can identify the subject at any time.
- "Recorded Anonymously" means that recorded data are not linked to the identity of the individual subjects in any way. If there are linkage codes, data is not anonymous.
- "Coded" means that identifiers are recorded, but data are labeled with a code without identifiers. Linkage information is kept in a separate, secure location.
- Data should typically be recorded anonymously or at least coded.
- When identifiers are recorded, and information is of a sensitive nature, exempt review may not be appropriate. ("Sensitive" information is information that has the potential to damage participants' reputation, employability, financial standing, educational advancement, place them at risk for criminal or civil liability, etc.).

Other:

- When children are studied in school or other institutional settings, approval from a relevant school official must be submitted to the IRB.
- If educational records may be accessed, see the Office of the Registrar's guidance on FERPA.

Exemption 2 [45 CFR 46.104(d)(2)]
Tests, Surveys, Interviews, or Passive Observations of Public Behavior
Modified

"The exemption applies to 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) uninfluenced by the investigator if at least one of three criteria is met:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subject cannot 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; or
- The information obtained is recorded by the investigator in such a manner that the identity of 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 (there must be adequate provisions for protecting privacy and maintaining confidentiality)."

Subject population:

- If any subjects are children:
    - Only educational tests or passive observation of behavior with no interaction is permitted
    - Investigators must provide a rationale for why a particular age range was selected, indicate their expertise in working with children, describe the adequacy of their facilities for pediatric research, and indicate whether they will have sufficient numbers of children to adequately address the research question.
    - All study team members must obtain the required clearances before any interaction with children
- Prisoners may be included only if the research involves a broader subject population that only incidentally involves prisoners.

Procedures:

- Interventions cannot be included.
- Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
- Focus groups can be considered to be open-ended interviews, and may be approved for adults, provided the basic exempt criteria are met.
- Passive observation means that there is no interaction or intervention between the subjects and the study team.
- Public means that the setting or location is accessible to anyone in the general public without the need for any special permissions or privileges. Individuals being observed have no reasonable expectation of privacy.

Privacy & Confidentiality:

- "Anonymous" means that no one can identify the subject at any time.
- "Recorded Anonymously" means that recorded data are not linked to the identity of the individual subjects in any way. If there are linkage codes, data is not anonymous.
- "Coded" means that identifiers are recorded, but data are labeled with a code without identifiers. Linkage information is kept in a separate, secure location.
- Data should typically be recorded anonymously or at least coded.
- When identifiers are recorded, and information is of a sensitive nature, exempt review may not be appropriate. ("Sensitive" information is information that has the potential to damage participants' reputation, employability, financial standing, educational advancement, place them at risk for criminal or civil liability, etc.).

Exemption 3 [45 CFR 46.104(d)(3)]
Benign Behavioral Intervention
New

"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:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subject cannot 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; or
- The information obtained is recorded by the investigator in such a manner that the identity of 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 (there must be adequate provisions for protecting privacy and maintaining confidentiality)."

  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."

  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.

<u>Subject Population:</u>

- This exemption applies only to adult subjects.
- Adults with decisional impairment cannot be purposefully included
- Studies with interventions involving children do not meet the exempt criteria.
- Prisoners may be included only if the research involves a broader subject population that only incidentally involves prisoners.

<u>Procedures:</u>

- Behavioral interventions must be brief in duration. Although there is no specific amount of time that is defined as brief, OHRP guidance suggests the intervention must be brief in nature, even if subsequent data collection takes longer.
- Interventions may not be harmful, painful or distressing. Risk to subjects is low.
- Interventions must be unlikely to have significant emotional discomfort or adverse lasting impact
- Study content and procedures must not be offensive or embarrassing to subjects
- Medical interventions and procedures are not permissible in this exemption
- Physical (bodily) tasks and physical exercise should not be included in this exempt category.
- Deception can only be used if the subject prospectively agrees to the use of deception. Subjects must be informed prior to initiating the intervention that they will be unaware of, or misled regarding the true nature or purpose of the research. They will also be told whether further information will be provided at the conclusion of the research activities. Researchers should consider de-briefing subjects.

- Research procedures in this exempt category should generally be limited to:
    - communication or interpersonal contact with the subject,
    - the performance of a cognitive, intellectual, educational or behavioral task, or
    - manipulation of the subject's physical, sensory, social, or emotional environment
- Data collection in this exempt category is limited to:
    - verbal (oral) or written responses by the subject
    - data entry by the subject
    - observation of the subject
    - audiovisual recording

Privacy & Confidentiality:

"Anonymous" means that no one can identify the subject at any time.

- "Recorded Anonymously" means that recorded data are not linked to the identity of the individual subjects in any way. If there are linkage codes, data is not anonymous.
- "Coded" means that identifiers are recorded, but data are labeled with a code without identifiers. Linkage information is kept in a separate, secure location.
- Data should typically be recorded anonymously or at least coded.
- When identifiers are recorded, and information is of a sensitive nature, exempt review may not be appropriate. ("Sensitive" information is information that has the potential to damage participants' reputation, employability, financial standing, educational advancement, place them at risk for criminal or civil liability, etc.).

Exemption 4 [45 CFR 46.104(d)(4)]
Secondary Research with Data and/or Specimens
Modified

"Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
- 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 applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act."

Criterion 1 - Publicly available data/specimens:

Publicly available refers to data and/or specimens that are accessible to anyone in the general public, without the need for special permissions or privileges. In these cases, the subjects do not have a reasonable expectation of privacy of their data/specimens. Examples include data/specimens available for purchase, searchable online, or available at a library. Researchers may be subject to an agreement with the entity releasing data/specimens.

Criterion 2 - Non-public data:

Non-public data which may or may not contain identifiers but are not clinical data subject to HIPAA regulations. Study team members may access identifiable private information, but cannot record / obtain data in a way in which it could be linked back to identifiers, even temporarily. Any individuals accessing the identifiable data must already have access to that information (e.g. by means of their involvement with the original collection). The data will not be able to be linked to the identity of the subjects at any time.

Criterion 3 - Data subject to HIPAA regulations:

An acceptable method for collection of these data include:

1. Direct access to identifiable medical records by the researcher team / Waiver of HIPAA Authorization is required: Identifiable data can be recorded and a waiver of the requirement to obtain signed HIPAA Authorization is requested and sufficiently justified.
    - Note that it must be accurately stated in the protocol that the only individuals who will access identifiable data are those who already have access to the identifiable data, related to their job responsibilities, granted by the privacy office.
    - The IRB will not approve a waiver of HIPAA Authorization if the data desired are not in some way related to the patient care responsibilities of the listed PI.
    - Although it is no longer required that data be "retrospective" as of the date the protocol was submitted, the waiver justifications must pertain to all subject populations, dates, and variables that are to be collected.

Criterion 4 – Research conducted on behalf of Federal Agencies:

Option 4 pertains to research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected data obtained for non-research activities. The study team must demonstrate compliance with the policies detailed in the regulation, specified above.

The 2018 changes significantly broaden the type of secondary research that can be done under this exemption category:

- The requirement that all study data be existing at the time of IRB submission has been eliminated. Data under this exemption may be both retrospective and prospective.
- The requirement that the study involves data only has been eliminated. The research may also involve the use of specimens.
- Creating a de-identified dataset for analysis is still an approvable option and continues to be the most straight-forward approach.
- If investigators need to retain data that contains any HIPAA elements or need to retain a linking list, then appropriate HIPAA protections could make the project approvable. Depending on the circumstances of the data, the HIPAA protections might include a Business Associate Agreement, a Data Use Agreement or a waiver of HIPAA authorization with accounting of disclosures.
- Certain sources of publicly available data require the recipient to sign an agreement outlining restrictions on access, use, security and transfer. These agreements may need review by general counsel.

Additional Requirements for all secondary analysis studies:

- The data and/or specimens have been or will be collected for purposes unrelated to the proposed study (e.g. “secondary” analysis).
- Specimens can only be included in Criterion 1 only. However, a “no human subjects” determination can be made for studies involving specimens if criteria are met.
- Note that as of January 21, 2019, it is no longer a requirement that all data/specimens be retrospective (previously collected as of the date the protocol is submitted).
- "Source" of data/specimens refers to the entity (research study, data/specimen bank, lab, external entity, etc.) from which data/specimens will be directly obtained for this study.

Privacy & Confidentiality:

- “Anonymous” means that no one can identify the subject at any time.
- “Recorded Anonymously” means that recorded data are not linked to the identity of the individual subjects in any way. If there are linkage codes, data is not anonymous.
- “Coded” means that identifiers are recorded, but data are labeled with a code without identifiers. Linkage information is kept in a separate, secure location.
- Data should typically be recorded anonymously or at least coded.
- When identifiers are recorded, and information is of a sensitive nature, exempt review may not be appropriate. (“Sensitive” information is information that has the potential to damage participants’ reputation, employability, financial standing, educational advancement, place them at risk for criminal or civil liability, etc.).

Exemption 5 [45 CFR 46.104(d)(5)]
Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency Modified

"Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants."

The scope of this category has been broadened. Prior rules required that the Federal demonstration projects be conducted by the Federal agency. This category has been updated to allow projects that are simply funded by a Federal agency. The scope has been expanded to include purposes not only to study and evaluate but also to improve these programs. Note that projects eligible for this exemption will be posted on a Federal website.

Exemption 6 [45 CFR 46.104(d)(6)]
Taste and Food Quality Evaluation and Consumer Acceptance Studies
Unchanged

"Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture."

> This exemption category was not changed in the revised Common Rule. Note that it is the only exemption that is allowable for FDA-regulated research.

Applicability to vulnerable populations:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.
- Research involving decisionally-impaired persons could be allowed if their inclusion was justified.