All Pepperdine University human subjects research projects must undergo review and approval by an IRB prior to initiation of research activities. There are 3 categories of review (exempt, expedited, and full board) defined by the Federal Regulations for Protection of Human Research Subjects (45 CFR 46).

Exempt reviews are conducted by at least one reviewer. To qualify for review at the exempt level, the research must not be greater than minimal risk* and must fall into one or more of the exempt categories described below.

Exempt Category 1: Education Research

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Examples:

- Evaluating the use of accepted or revised standardized tests
- Testing or comparing a curriculum or lesson
- A program evaluation of pharmacy continuing education

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.

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.

Exempt Category 2 – Surveys, interviews, educational tests, public observations

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Examples:

- Surveying teachers, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style or best practice
- Conducting a focus group about an experience or an opinion of a community program

This category involves interactions (verbal and written responses) and data collection only. The data collection can include audio or video recordings. Research involving "interventions" would not be approvable under this category. Interventions include manipulation of the environment or physical procedures to collection information, such as a cheek swab.

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 only when it related to educational tests or observations in which the investigators don't participate in the activities being observed. Additionally, children are not eligible for this exemption if the project requires limited IRB review.

Category 3 – Studies of public officials

Research involving the use of educational tests/ benign behavioral interventions (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

This exempt category is completely new in the 2018 revisions to the federal regulations. There are limits on the interventions that are considered 'benign' and requirements on IRB review of this type of research.

Applicability to vulnerable populations:
- Pregnant women who are adults may be included in this type of research
- Research that targets a prisoner population is not eligible for this exemption.
- Research that could include children 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 decisionally-impaired persons is not eligible for this exemption.

Example: Interviewing public officials about a local or global issue.

Category 4 – Analysis of previously-collected, anonymous data

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Example:

- Analyzing existing tissue samples or data set which are recorded by the investigator without identifiers

Category 5 – Public benefit or service program

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- Federal Guidance: Exemptions for Public Benefit and Service Programs

Category 6 – Consumer acceptance, taste, and food quality studies

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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.

Category 7 – Secondary Research Data Collection and Storage

1. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance to IRB approval; (ii) Documentation of informed consent or waiver of documentation of consent was obtained.(iii) An IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.

Research with vulnerable populations may be approvable with this exemption:
- 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.

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review. This exemption is new with the 2018 Common Rule.

2. Research with vulnerable populations may be approvable with this exemption:
   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.

***Important note on Broad Consent:** Because there is no guidance from OHRP and because of the implications of tracking individuals who do not provide consent and excluding their data from all future research, **Pepperdine will not mandate nor implement broad consent at this time**. *Exemption categories 7 and 8, which rely on Broad Consent will not be available in the Pepperdine eProtocol system.* Investigators can continue to use biospecimens that are coded or to seek waiver of consent for use of biospecimens with identifiers retained consistent with current practices.

Category 8 – Secondary research for which consent is not required

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: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) 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; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated for the purposes of "health care operations" or "research" or for "public health activities and purposes ; or (iv) 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.

Effective January 19, 2018, the Revised Common Rule changes significantly broaden the type of secondary research that can be done under this exemption category:

1. 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.
2. The requirement that the study involves data only has been eliminated. The research may also involve the use of specimens.
3. Creating a de-identified dataset for analysis is still an approvable option and continues to be the most straight-forward approach.
4. 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.
5. Certain sources of publicly available data require the recipient to sign an agreement outlining restrictions on access, use, security and transfer. Most often, those agreements will need review by the university's general counsel.

It is important to note the Exemption Category 8 only applies to the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records or existing repositories of clinical specimens. No contact between investigator and subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another approval path would be required.

Applicability to vulnerable populations:
-Data/specimens from pregnant women would be allowed
- Data/specimens from prisoners could be allowed as long as the research wasn't designed to recruit prisoners and prisoners were only incidental subjects of the research.
- Data/specimens from children would be allowed
- Data/specimens from persons with decisional impairment would be allowed

***Important note on Broad Consent:** Because there is no guidance from OHRP and because of the implications of tracking individuals who do not provide consent and excluding their data from all future research, **Pepperdine will not mandate nor implement broad consent at this time**. *Exemption categories 7 and 8, which rely on Broad Consent will not be available in the Pepperdine eProtocol system.* Investigators can continue to use biospecimens that are coded or to seek waiver of consent for use of biospecimens with identifiers retained consistent with current practices.