University of La Verne Institutional Review Board
Policy and Procedure for Exempt Review
Updated May 12, 2017, Amended December 8, 2017

1. Exemptions Policy

Research that does not require either a Standard Review or an Expedited Review is reviewed by the IRB under the Exempt Review Category. There are two types of review an exempt application can undergo, which is stipulated by the exemptions. There are eight categories of research that fall under exempt review in compliance with §__.104. These are described below. Applicants may apply for an exemption under one of these categories.

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, or classroom management methods.

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:
    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. This includes the triangulation of demographics that can narrow responses down to 3 or fewer likely participants.

    OR

    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 § __.111(a)(7) (La Verne IRB Limited Review Policy: https://sites.laverne.edu/institutional-review-board/files/2015/02/La-Verne-IRB-Limited-Review-.pdf)

3. 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. This includes the triangulation of demographics that can narrow responses down to 3 or fewer likely participants;

OR

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 § __.111(a)(7) (La Verne IRB Limited Review Policy: https://sites.laverne.edu/institutional-review-board/files/2015/02/La-Verne-IRB-Limited-Review-.pdf)

* 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.

4. **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:
    a. The identifiable private information or identifiable biospecimens are publicly available;

OR

b. 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. This includes the triangulation of demographics that can narrow responses down to 3 or fewer likely participants;

OR

c. 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

d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch 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.

5. 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. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.:

   a. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the

research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:

    a. if wholesome foods without additives are consumed

    OR

    b. 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

7. 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 and makes the determinations required by § __.111(a)(8) (La Verne IRB Limited Review Policy: https://sites.laverne.edu/institutional-review-board/files/2015/02/La-Verne-IRB-Limited-Review-.pdf)

8. 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:
    a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § __.116(a)(1) through (4), (a)(6), and (d) (La Verne IRB Informed Consent Policy: https://sites.laverne.edu/institutional-review-board/files/2017/12/Informed-Consent.pdf);

    AND

    b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § __.117 (La Verne IRB Informed Consent Policy: https://sites.laverne.edu/institutional-review-board/files/2017/12/Informed-Consent.pdf);

    AND

    c. An IRB conducts a limited IRB review and makes the determination required by § __.111(a)(7) (La Verne IRB Limited Review Policy: https://sites.laverne.edu/institutional-review-board/files/2015/02/La-Verne-IRB-Limited-Review-.pdf) and makes the determination that the research to be

conducted is within the scope of the broad consent referenced in paragraph (8)(a) of this section;

AND

d. 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 abiding by any legal requirements to return individual research results.

2. Exempt Research and Vulnerable Subjects in Subparts B-D Policy

Following the written regulations in Subparts B-D of 45 CFR 46 exempt reviews may include vulnerable populations. With proper protections for confidentiality/anonymity, the following vulnerable populations may qualify as exempt under the following categories using the protections set forth in the Subpart specific to the type of vulnerable subject:

a. **Subpart B**: The eight categories may apply to pregnant women and fetuses
b. **Subpart C**: The eight categories do not apply to prisoners, except for research not specifically targeting prisoners and which only incidentally includes prisoners.
c. **Subpart D**: Exemptions 1 and 4-8 may apply to children. Exemption 2 only applies for a and b when educational tests are implemented or the observation of public behavior when the investigator(s) are not involved in the activities. Part C of exemption 2 does not apply.
d. **Adults with cognitive impairment**: Category 4 may apply
e. **Non-English speakers (may include English Language Learners)**: Categories 1-3 and 5-6 may apply, researchers must include procedures to ensure materials are in the primary/preferred language of the participants.
f. **All other categories** of vulnerable populations will be determined by the IRB on a case-by-case basis.

Procedures

Applicants will complete an exempt Initial IRB Application in IRBManager, which is a streamlined application approved by the La Verne IRB. The application will undergo a pre-review by the IRB Analyst to ensure completion. The Analyst or Chair will conduct an Exempt Review of the application and ask for further clarifications if needed from applicant. If a limited review is deemed necessary by the exemption, the limited review will be conducted as per the limited review policy (La Verne IRB Limited Review Policy: https://laverne.edu/irb/wp-content/uploads/sites/28/2018/08/La-Verne-IRB-Limited-Review.pdf).

Note: If applicants wait more than six months to submit revisions, they will be required to submit a new application in IRBManager and undergo a new review. The outcome may change with the new review, necessitating more revisions from the applicant.

For anonymity purposes, the Analyst and Chair should consider what current demographics are in low frequencies at University of La Verne when protocols are submitted to study the small community. For proposed collection of low frequency

demographics, or a combination of demographics that can triangulate back to 3 or fewer participants, the study should be considered confidential.

Once the application is complete, the Analyst or Chair will make an exempt determination (unless it falls under limited review, in which case the Chair makes the exempt determination following the reviewers' input), document the exempt category under which the research falls, and issue a letter to the applicant. Exempt letters will specify if the research underwent an exempt or limited review.

3. Information Sheet

While an informed consent is not required for exempt research, an information sheet is required unless a broad consent is proposed. An information sheet must contain the following elements (see template on the La Verne IRB website):

1. Study Purpose
2. Procedures
3. Risk
4. Name of PI and contact information (including Chair if a graduate student)
5. Statement about the research being voluntary
6. IRB Office information