**La Verne Institutional Review Board Policy and Procedure for Non-Exempt Review Categories**
**Updated May 12, 2017, Amended December 8, 2017 & December 14, 2018**

There are two non-exempt categories for review by the La Verne IRB under which researchers may choose to submit their application. These categories reflect the nature and the level of potential risk to participants. All non-exempt research must have a closure form filed upon completion of the project. Before selecting the appropriate review type, review the definition of minimal risk below.

**Minimal risk: "**the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45.CFR.46.102(i)).

1. **Standard Review Category**

Research is required to be submitted under Standard Review category if one or more of the following conditions is involved:

1. More than minimal legal, physical, or psychological risk, or
2. Studies that are minimal risk, but do not fit in an expedited review category, or
3. Studies that include vulnerable* individuals identified in Subparts B-D of 45 CFR 46, which include pregnant women and fetuses, prisoners, and minors (under the age of 18) may be subject to standard review. Further, situational vulnerability must be considered. The federal regulations state at ____.111(a)(3), "research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons" qualify as vulnerable populations. Examples of vulnerable populations include, but are not limited to, adults who are under legal guardianship, persons with intellectual or developmental disabilities, frail elderly, low income when the study has a high incentive.
4. If a study is submitted as expedited/exempt but contains elements not in line with current policy.

2. **Expedited Review Category**

Research which does not require a Standard Review, but which involves minimal risk, should be submitted under the Expedited Review category. The 9 Expedited Review categories as identified through OHRP (1998) (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/), along with examples, are reproduced below:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

1. hair and nail clippings in a nondisfiguring manner;
2. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
3. permanent teeth if routine patient care indicates a need for extraction;
4. excreta and external secretions (including sweat)
5. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
6. placenta removed at delivery
g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
7. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
8. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
9. sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

    1. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
    2. weighing or testing sensory acuity
    3. magnetic resonance imaging
    4. electrocardiography, electroencephalography, thermography, detections of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
    5. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
    1. the research is permanently closed to the enrollment of new subjects
    2. all subjects have completed all research-related interventions
    3. the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through

eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**The La Verne IRB will re-categorize reviews if a study fits better in a particular category of review, including exempt determinations.**

**Procedures**

Applicants will complete an Expedited or Standard Review Initial IRB Application in IRBManager. Applicants will attach recruitment materials, necessary permissions, instruments, protocols, and an informed consent (an assent is also required for working with minors; see the La Verne IRB policy on informed consents).

The application will undergo a pre-review by the IRB Analyst to ensure completion. For an Expedited Review: the Area (College) and Chair will conduct an Expedited Review of the application and ask for further clarifications if needed from applicant. The Analyst or Chair will manage the revisions, but the Chair will approve the final application.

For a Standard Review: the Area (College) and Chair will conduct a review of the application and ask for further clarifications, if needed, from the applicant and prior to the meeting. The Chair will manage the revisions and make sure clarifications are made prior to the meeting. If the applicants make substantial changes after College has reviewed the application, but before the IRB has reviewed the application, the application will be re-reviewed by the College. The Board will review and provide feedback at the meeting or reject the application. The Chair will send notice of rejection within 2 business days of the meeting conclusion. The Chair will put the Board's feedback into the application and send it back to the applicant for revision. The Chair will manage the revisions until all are made. Then, the Chair will return the application to the Area for final approval of the revisions.

**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.

**Most likely applications will require several sets of revisions at all stages of review (**pre-review, Area, full board, Chair) in order to clarify content and address reviewer comments. Once the application is complete, and revisions approved, the Chair will request an approval letter signed by the Chair be issued to the applicant by the Analyst.

* The IRB will determine the final review type for applications that include vulnerable populations.