Currently, institutional research activities, (also known as university-wide/program assessment or quality improvement/assurance) conducted at the University of La Verne (ULV) or with affiliated institutions does not satisfy the definition of “research” under 45 CFR 46.102(d). Research is defined by U.S. Department of Health and Human Services (HHS) as, “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...” Therefore, the HHS regulations for the protection of human subjects do not apply to such activities and no requirement for IRB approval or to conduct the activities with an informed consent is needed.

An example of implementing an evaluation and collecting student data for non-research program or administrative purposes include: The Athletics Department at ULV uses a database to help monitor and forecast attendance at sporting events to assess if fans are happy with the parking and restroom accessibility at the venue. This practice is intended to better the access to facilities and to possibly increase attendance for those supporting the athletic teams and ULV.

If an individual has any questions as to whether an activity/evaluation also constitutes human subject research, it is **strongly recommended** that the individual contact the ULV IRB (irb@laverne.edu) to obtain an official ruling as to whether IRB approval is required before the activity/evaluation commences.

However, there are instances where the university-wide/program assessment or quality improvement/assurance conduct at ULV or affiliated institutions does fall under the purview of the IRB and applicants may need to complete an IRB application for approval. When the program evaluation and/or collection of data are to be presented or published to the generalizable population (conference, publication, entity outside ULV...), IRB approval is required.

An example of implementing an evaluation and collecting student data for generalizable knowledge includes: The La Verne Experience (LVE) program at ULV would like to present a poster at the next Association of American Colleges and Universities Conference on retention outcomes
related to implementation of the LVE across the main and regional campuses at ULV.

If you believe your university-wide/program assessment or quality improvement/assurance conduct at the ULV or with affiliated institutions does fall under the purview of the IRB, the following steps will help you with your IRB application.

Steps to the IRB application university-wide/program assessment or quality improvement/assurance conduct at the ULV or with affiliated institutions

- Follow the same procedures for any IRB application
  - Exempt, Expedited, or Standard Review
    - Based on risk, you will need to choose the most appropriate type of review for the application
    - Most of the university-wide/program assessment or quality improvement/assurance conduct at the ULV or with affiliated institutions applications will be **EXEMPT**
      - No risk – deidentified archival data (date range specified) with permission* from the program to the researcher
        * Authorized personnel allowed to give permission for program must authorize permission in writing
      - If the researcher is not affiliated with the program, the program will de-identify the data for the researcher
      - If the researcher is affiliated with the program, the program will need to provide de-identify data to the researcher through a third party (registrar, another individual with access to the information).