



**University of La Verne Institutional Review Board
Policy and Procedure on Member Positions and Duties
Amended May 12, 2017, and May 11, 2018**

The La Verne IRB is a social and behavioral research (SBER) board currently comprised of an IRB Chair/Director, Chair Elect (when necessary), Past Chair (when needed), IRB Analyst(s), and IRB Committee Members. Other personnel associated with the La Verne IRB include consultants and faculty members overseeing student research. The IRB Chair/Director primarily oversees IRB Administration, runs meetings, and approves non-exempt and non-Not Human Subjects Research (NHSR) protocols. The Chair Elect and Past Chair can fill in for the current IRB Chair/Director when conflicts of interest arise or the current IRB Chair/Director is unavailable. The Members main responsibility is reviewing non-exempt and non-NHSR protocols and offering feedback. The committee works 12 months a year and protocols sometimes are reviewed over the summer.

IRB Chair/Director Position Description

The IRB Chair/Director, herein referred to as the IRB Chair, manages IRB meetings, including standard reviews of human subject's research, and oversees reviews of human subject's research in accordance with ethical standards outlined by federal and state regulations and the policies of the University of La Verne. The duties of the chair include but are not limited to the following: training, management of the IRB meetings, review of proposals, ensuring review of applications is in compliance with the policies and procedures for the board, communicating IRB feedback for applications, and liaising with the greater community on IRB matters. The IRB Chair works collaboratively with IRB Committee Members (hereafter IRB Members), research administrators, and the greater community to maintain and promote an ethical research climate at the La Verne. The usual term of appointment is for three years.

Responsibilities:

A. Training

- a. Completes initial and ongoing IRB training in a timely fashion
 - i. Must display proficiency in human subject's research training as identified by the La Verne IRB
 - ii. Expected to be familiar with the policy guidelines of the Human Research Protections Program (HRPP) and university
 - iii. Expected to be familiar with the Ethical Principles of the Belmont Report and other regulatory documents
- b. Identifies training for IRB members and ensures members participate in initial and continuing IRB education
 - i. Documents training of IRB Members, including basic human subjects research training.

- c. Provides IRB training/workshops to the La Verne community on a limited basis

B. Proposal Review

- a. Communicates with the Director of Research and Sponsored Programs (DRSP) in advance of IRB meetings of the IRB meeting agenda, identifies protocols appropriate for full-board review, and determines that protocols submitted are ready for review
- b. Identifies need for external consultation
- c. Identifies conflicts of interest as it relates to applications for self, IRB members, related personnel, or the institution
- d. Reads proposals thoroughly and evaluates them within the context of the federal regulations, and the ethical standards of La Verne
- e. Reviews applications from unaffiliated or outside researchers submitted under the exempt and expedited Categories
 - i. May seek additional review from the pertinent College Committee or other relevant members
- f. Secondarily reviews proposals for exempt (performed by IRB Analyst) and expedited reviews (performed by College Lead and College Second Reviewer)
- g. Secondarily reviews standard reviews (performed by College Committee and full board) in preparation of the application for the meeting
- h. Ensures applications are reviewed expeditiously and reassigns applications to a different reviewer if reviews are not performed in a timely manner as dictated by the policies and procedures of the IRB

C. Responsibilities in conducting full board meetings

- a. Arranges for Chair Elect/Past Chair to conduct meeting if s/he will be absent or must leave the room because of conflict of interest on particular applications
 - i. Regularly attends meetings
- b. Ensures that attendance at the prospective meeting will provide adequate review of all protocols
- c. Determines that a quorum is present a majority of the board is present
- d. Convenes meeting
- e. Executes the agenda
- f. Promotes discussion of research protocols regarding protection for human research participants
- g. Endeavors to complete the agenda in a timely manner
- h. Conducts voting in regard to protocol disposition
- i. Protects the confidentiality of all discussions surrounding decisions whether written, electronic or verbal and adheres to protections afforded under Family Educational Rights and Privacy Act (FERPA), as amended and the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

D. IRBManager

- a. Maintains and updates IRBManager as needed
- b. Develops new versions of applications to meet the IRB's needs
- c. Troubleshoots IRBManager for IRB, applicants, and IRB Administration

- d. Provides system support for applicants
- E. Reporting
- a. Reports to the DRSP and/or Vice Provost under the supervision of the Provost (Institutional Official).
 - b. Signs letters of approval
 - c. Provides evaluative comments about IRB members to DRSP and/or Vice Provost needed to maintain an effective /adequate IRB membership
 - i. These comments will be available for review and comments by IRB members as a supplement to the self-evaluation processed.
 - d. Prepares other reports as requested for the DRSP, Vice Provost, Provost, and others
- F. Handling Allegations, Complaints, and Noncompliance
- a. Reports allegations, complaints, and noncompliance to the Provost, DRSP, and/or Vice Provost
 - b. Works with the DRSP and/or Vice Provost to apply the La Verne policies regarding noncompliance, including the IRB policies and procedures dated September 20, 2012
- G. Assistance to Faculty and Investigators
- a. Provides information to investigators about the need for IRB review and IRB policy and procedures
 - b. Relays information about faculty and investigator concerns or needs for IRB guidance to the IRB or the DRSP
- H. Assurance of IRB Independence
- a. Reports and responds to notice of any attempts to exert undue influence on self, investigators, or IRB members to the Provost, DRSP, and/or the Vice Provost
- I. Management of Staffing and Infrastructure
- a. Oversees an IRB Analyst and manages all aspects related to the hiring, carrying out of the day to day operations, and performance of the Analyst
- J. Personnel and Members
- a. Works with an IRB Analyst for effective IRB Administration
 - i. Addresses any concerns raised by IRB Analyst, and if needed, communicates with institutional officials to address areas of improvement
 - b. Issues informal written warnings to IRB Members for correcting of misconduct
 - c. Documents instances of IRB Member misconduct
 - d. Reports instances of IRB Member and IRB Personnel misconduct to the DRSP and/or Vice Provost
 - i. IRB Member has the opportunity to respond to written warning of misconduct
 - e. Makes recommendations for remedies of misconduct to the DRSP and/or Vice Provost
 - i. The outcome will be communicated to the IRB Member
- K. Appointment of new IRB Members
- a. Works with college Deans to identify and nominate new members for appointment by the Vice Provost as detailed in the IRB Members (Other Than IRB Chair) Position Description, below
 - i. Discusses potential IRB membership with DRSP, Vice Provost and/or Provost (when necessary) prior to approval

1. For staff position, direct supervisor should be involved in the process.

L. Budget

- a. Works within a budget to pay for software, member pay, training, and additional expenses incurred by the board
 - i. Member pay will be issued as a pay advice processed by Human Resources

M. Policy

- a. Complies with federal regulations and La Verne IRB policies and procedures
- b. Writes and suggests policies for adoption by the board and in consultation with the board
- c. May facilitate IRB subcommittees to work through large policy revisions

Qualifications and Appointment

- A. Member of the La Verne faculty and/or research staff
- B. For faculty members and professional research staff, a record of teaching, research, or other scholarship, or ethical expertise is warranted
- C. It is highly recommended that the IRB Chair be a tenured faculty member to protect the IRB Chair from undue influence and to protect their tenure and promotion process
- D. Thorough knowledge of OHRP, DHHS, and/or FDA regulations or willingness to acquire as needed
 - a. If knowledge is not possessed at time of appointment, the IRB Chair will identify and assign CITI or PRIM&R trainings for the incoming IRB Member
 - b. If knowledge is more than 5 years old or training was completed prior to federal regulation changes, then the IRB Chair will identify and assign CITI or PRIM&R trainings for the incoming IRB Member
- E. Commitment to the advancement of research through the ethical treatment of human research participants
- F. Ability to work collaboratively with other IRB members, DRSP, Vice Provost, and other related personnel
- G. A two-year minimum past IRB membership is required and experience as a Lead reviewer is highly preferred
- H. Priority will be given to tenured faculty
- I. The IRB Chair is appointed by the Provost, the designated institutional official for the University
- J. The IRB members, current IRB Chair, and the DRSP will advise the Vice Provost in the nomination and selection of the IRB chair, Chair Elect, and Past Chair. If the IRB Chair, DRSP, and Vice Provost are unable to develop a suitable nomination pool, college Deans can then be consulted for nominations.
 - a. The Vice Provost, with the help of the current La Verne IRB Chair and DRSP, should consider 2-4 individuals from the college that meet the requirements described herein for the La Verne IRB Chair position, and who could serve the committee and university while maintaining their other faculty related/assigned responsibilities. The individuals may be identified by IRB Members, the IRB Chair, the Provost's Office, or college Deans

- i. The Vice Provost, in coordination with the current La Verne IRB Chair and DRSP, will determine which individual would be best suited for the Chair position, based on the committee/university needs and individual names given
- ii. Once those individual(s) have been decided upon, the Department Chair for those individual(s) should be consulted, along with the nominated individual(s) and the area Dean about serving in the 3-year La Verne IRB Chair position
- iii. If all parties agree to the arrangement, the Vice Provost will notify all parties of the appointment
- iv. The current Vice Provost will communicate the final appointment information (Position Description Questionnaire) with the individual and acknowledge acceptance for chair position

Evaluation

- A. Completes annual self-evaluation, including performance, needs, and accomplishments in IRB-related self-development
- B. Files updated copy of CV/resume with DRSP annually

Chair Elect Position Description

The Chair Elect position has essentially the same responsibilities and qualifications as the IRB Chair, but serves on an occasional (ad hoc) basis when the IRB Chair is absent or a conflict of interest with a project arises. This 1-year position requires learning and mentorship from the Past Chair and should include training to prepare for the 3-year term as IRB Chair. The usual term of appointment is for 1 year to be served immediately prior to their transition into the IRB Chair.

Responsibilities:

- A. Responsible for and assists the Chair in all responsibilities outlined above
- B. Management of the IRB Analyst when established
- C. Oversees all aspects of the IRB Analyst in accordance with policies and procedures for the IRB

Training

- A. Completes initial and ongoing IRB training (through CITI and/or PRIM&R and NIH will be accepted but no longer assigned) in a timely fashion
 - a. Must display proficiency in human subject's research training as identified by the La Verne IRB
- B. Participates in ongoing continuing education related to IRB matters
 - a. Expected to be familiar with the policy guidelines of the HRPP

- b. Expected to be familiar with the Ethical Principles of the Belmont Report and other regulatory documents
- C. Qualifications and Appointment
 - i. See Qualifications and Appointment for IRB Chair

Past Chair Position Description

The Past Chair serves as a mentor in all aspects of the La Verne IRB and may on occasion assist the Chair Elect in times of need when the current Chair is unavailable for La Verne IRB duties. The usual term of appointment is for 1 academic year.

- A. Qualifications and Appointment
 - i. See Qualifications and Appointment for IRB Chair

IRB Analyst Position Description

The Analyst provides support for IRB Administration through protocol review, meeting assistance, and completing La Verne IRB Office tasks. Federal Work Study students may also work as Analysts.

- A. Training
 - a. Completes initial and ongoing IRB training in a timely fashion
 - i. Must display proficiency in human subject's research training as identified by the La Verne IRB
 - b. Participates in ongoing continuing education related to IRB matters and as identified as the La Verne IRB Chair
 - i. Expected to be familiar with the Ethical Principles of the Belmont Report and other regulatory documents, including the La Verne IRB policies and procedures
 - c. Assists in providing IRB training to the La Verne community on a limited basis
- B. Proposal Review
 - a. Conducts pre-reviews on all incoming La Verne IRB applications
 - i. Provides feedback to applicants as part of the pre-review process
 - b. Reviews proposals to determine if exempt, expedited, or standard review (in consultation with the Chair or Chair Elect of the IRB)
 - c. Identifies and reports conflicts of interest to the La Verne IRB Chair for self, the investigator, or the institution
 - d. Reads exempt proposals thoroughly and evaluates them within the context of federal regulations and the La Verne IRB policies and procedures
 - i. Some Analysts will be empowered to make exempt determinations without Chair review
 - e. Requests, obtains, and manages revisions from expedited and standard reviews
 - i. Obtains final Chair approval on revisions
 - f. Some Analysts will be empowered to make NHSR determinations without Chair review
 - g. Issues determination and approval letters

- C. Full Board Meetings
 - a. Attends IRB meetings on a regular basis
 - b. Records minutes in IRB meetings
 - c. Assists Chair in various tasks for meeting preparation, including duties related to teleconferencing and projection
- D. La Verne IRB Office Support
 - a. Answers IRB inquiries via emails and phone calls as needed
 - b. Communicates with potential, actual, and past applicants
 - c. Performs website maintenance and revises website as requested by Chair
 - d. Creates reports as requested by Chair
 - e. Completes other tasks, as assigned, in support of IRB Administration
- E. Assistance to Faculty and Investigators
 - a. Provides information to investigators about the need for IRB review, perspectives, and resources from the Office of Research and Sponsored Programs
 - b. Relays concerns from students, faculty, staff, external Principal Investigators, or the public to the Chair of IRB
- F. IRBManager
 - a. Maintains and updates IRBManager as needed
 - b. Develops new versions of applications to meet the IRB's needs
 - c. Troubleshoots IRBManager for IRB, applicants, and IRB Administration
 - d. Provides system support for applicants
- G. Assurance of IRB Independence
 - a. Reports attempts to exert undue influence on self or others to the La Verne IRB Chair, DRSP, and/or the Vice Provost
- H. Evaluation
 - a. Completes annual self-evaluation of performance, including identification and description of IRB-related self-development
 - b. Completes a self-evaluation for IRB when asked
- I. Qualifications and Hiring
 - a. It is preferred the Analyst holds a bachelor's degree or higher in an SBER discipline
 - b. Is detail-oriented
 - c. Works independently
 - d. It is preferred they have current knowledge of OHRP, DHHS, and/or FDA regulations or willingness to acquire as needed, if more than 5 years old, or training occurred prior to federal regulation changes
 - e. As this is a staff position, there is no appointment term.
 - f. Staff will be hired using University of La Verne staff hiring practices and the final candidate will be selected by the IRB Chair, DRSP, and Vice Provost.

IRB Members (Other Than IRB Chair) Position Description

There are several roles in the IRB including Staff/Administration Members, Members without University Affiliation, Lead Reviewers, Second Reviewers, and First Year/Observational Reviewers. The reviewers are considered Area Members that represent each of the four colleges.

The duties differ depending on role, and are briefly defined below. For Area reviewers (Lead, Second, and Observational), the roles rotate every July 1st in the following order: Observational → Second → Lead. Lead Reviewers have the option to rotate back to the Observational role when full term not yet completed. The usual term of appointment is for three years.

Staff/Administration Members: Similar to the structure of the Area Members, the Staff/Administration Members have a voting member and an alternate member. The voting member is the first reviewer (similar to the Lead Reviewer) for applications and the alternate member is the second reviewer (similar to the Second Reviewer) of applications. Staff/Administration Members review institutional research, as well as standard reviews that go before the full board. Their responsibilities include A-F below.

External Members: External members are those individuals who are not employed by the University of La Verne and who have content expertise in an area needed on the board (e.g., public health). One external member is the voting member, while other external members are alternates. External members review standard reviews that go before the full board. Their responsibilities are included in A-F below.

Lead Reviewers – Each college/Area maintains at least one Lead Reviewer position. The Lead Reviewer is the voting member, and in cases of Areas with multiple Lead Reviewers, one vote is shared among the Lead Reviewers (a single Lead Reviewer will vote in Areas with multiple Lead Reviewers; the vote is rotated among the Lead Reviewers after each IRB Meeting so that a different Lead Reviewer votes at each subsequent meeting, unless arrangements are made otherwise and in consultation with the IRB Chair). Lead Reviewers are typically very experienced and trained. Lead Reviewers are responsible for reviewing Area applications first and making the bulk of the comments on the protocols. For standard reviews, Lead Reviewers present applications they have reviewed to the full board with a brief summary of the protocol and any concerns they have identified that should be discussed. Their responsibilities are listed in A-F below.

Second Reviewers – Each Area maintains at least one Second Reviewer position. The Second Reviewer is an alternate who can vote in the absence of all Area Lead Reviewers. Area Second Reviewers are responsible for reviewing Area applications after the Lead Reviewer and making additional comments, as identified and needed. With prior notice, the Second Reviewers can present standard review applications to the full board in the same vein as the Lead Reviewer when the Lead Reviewer cannot attend a full board meeting. In cases of conflict of interest of the Lead Reviewer with an application, the Second Reviewer reviews the application first and provides the bulk of the comments. Second Reviewer responsibilities are listed in A-F below.

Observational Reviewers – Each Area maintains at least one Observational Reviewer. The Observational Reviewers are alternates and can be divided into individuals with experience on the La Verne IRB and those that have not served on the La Verne IRB. For Observational Reviewers that have not served on the La Verne IRB, the first year is for gaining IRB education, becoming human subjects research trained, and observing applications after the Lead and Second Reviewers and Chair have made comments. For experienced Observational Reviewers (e.g. have served as a Lead and/or Second Reviewer), the role will primarily be for reviewing protocols

when there is a conflict of interest (see next paragraph), continuing education as it relates to the IRB, and updating human subjects research training as applicable. Some Areas may request, in consultation with the IRB Chair, that their experienced Observational Reviewers provide pre-reviews for IRB applicants. In these cases, the Lead and Second Reviewers can refer applicants needing pre-review help to the experienced Observational Reviewers.

Both types of Observational Reviewers may be called upon to review applications in cases where there is a conflict of interest for the Lead or Second Reviewer (using the procedures described in sections B and C, below) or another need arises. In that case, the Observational member would read the application second and provide additional comments not offered during the first review. Both types of Observational Reviewers may vote in cases where the Lead and Second Reviewers are absent from the full board meeting and would be responsible for presenting Area protocols as described in the Lead Reviewer description above if the Observational Reviewer is trained and prepared for a vote(s) of this nature. Prior notice must be provided in cases where the Observational Reviewer will vote and/or present. Both types of Observational Reviewer responsibilities are listed in sections A, and D-F below.

Responsibilities:

A. Training

- a. Must display proficiency in human subject's research training as identified by the La Verne IRB
- b. Participates in ongoing continuing education related to IRB matters
 - i. Expected to be familiar with the Ethical Principles of the Belmont Report and other regulatory documents, including the La Verne IRB policies and procedures

B. Proposal Review

- a. Reads expedited and standard review proposals thoroughly and evaluates them within the context of the federal regulations and the La Verne IRB policies and procedures
- b. Suggests to La Verne IRB Chair that a consultant is needed if s/he considers a proposal to be outside the expertise of the La Verne IRB
- c. Identifies and reports conflicts of interest to the La Verne IRB Chair for self, the investigator, or the institution. Participates in the discussion of whether the proposal provides adequate protection for human research participants. This includes a judgment about whether the application has sufficient scientific merit for the involvement of human subjects.
- d. May suggest the shift of submitted protocols from one review category to another as deemed appropriate by committee
- e. Performs reviews of proposals outside of regular Area or application type when circumstances warrant doing so and as asked by the IRB Chair
 - i. Follows normal procedures for proposal review, including, but not limited to requesting a consultant
- f. Serves as an advocate during review for the community or designated vulnerable population, if needed.
 - i. Advocates (an individual that represent the population) may be needed when an application is relevant to a certain population (incarcerated

individuals, elderly, pregnant women, etc...). In certain circumstances an advocate is either required or recommended to be present during the review of the application to help the board understand in greater detail that population and how they may best be safeguarded through the proposed research.

- g. Votes on applications submitted to full board review, depending on empowerment of the vote (see role descriptions above)
- h. Protects the confidentiality of all discussions surrounding decisions whether written, electronic, or verbal and adheres to protections afforded under Family Educational Rights and Privacy Act (FERPA), as amended and the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

C. Meetings

- a. Attends IRB meetings regularly
 - i. If in a voting role, makes arrangements with an alternate to vote at a missed meeting and informs IRB Chair of the change.
- b. Votes on IRB-related matters as they arise if empowered to vote (see role descriptions above)
- c. Engages in discussion regarding protocols and IRB-related matters

D. Assistance to Faculty and Investigators

- a. Provides information to investigators about the need for IRB review, perspectives, and resources from the Office of Research and Sponsored Programs
- b. Offers support to La Verne potential, present, and past applicants by answering questions, and providing tips for successful application approval
 - i. Acts as a college liaison for the La Verne IRB Committee
- c. Relays concerns from students, faculty, staff, external Principal Investigators, or the public to the Chair of IRB

E. Assurance of IRB Independence

- a. Reports attempts to exert undue influence on self or others to the IRB Chair, DRSP, and/or the Vice Provost

F. Evaluation

- a. Completes annual self-evaluation of performance, including identification and description of IRB-related self-development
 - i. A template will be used that has been shown to be in line with best practices from the IRB peer-reviewed literature or from PRIM&R related resources
- b. Completes evaluation form for IRB when asked
- c. (La Verne Faculty and staff members): Files updated copy of CV/resume with DRSP annually

Qualifications and Appointment

- A. Member of the faculty or professional staff at La Verne, or a representative of the community
 - a. For faculty members, a record of teaching, research, or ethical expertise is needed

- b. For community representatives, the qualifications can include being a resident of the community who is not affiliated with the university and is not part of the immediate family of an affiliated person, primary expertise that is in non-scientific areas, and an ability to present community perspectives on research
 - c. Commitment to the advancement of research and the ethical treatment of human subject's research participants
 - d. Ability to work collaboratively with other board members and IRB administrative staff
 - e. A willingness to serve on one of the busiest committees at La Verne
 - f. An understanding and willingness to review applications on a 12-month basis
- B. Appointment of a La Verne IRB Member is facilitated with understanding of the committee expectations
- a. The appropriate Area Dean(s) will be notified by the IRB Chair in late March/early April if there will be vacancy that needs to be filled. Area Deans will be notified sooner if a vacancy arises outside of the July 1st rotation date and there is need for the position to be filled prior to July 1st.
 - i. The Dean should nominate 2-4 people who meet the aforementioned qualifications in an email to the IRB Chair
 - 1. The Dean will facilitate and complete any needed discussions with those nominees and the Department Chairs of the nominees
 - ii. The nominations will be provided to the Vice Provost in an email including recommendations by the IRB Chair
 - iii. The Vice Provost will communicate the selection to the IRB Chair, who will communicate the name of the appointed individual to the Dean
 - 1. The Dean will notify the nominees who were not selected
 - iv. The IRB Chair will communicate the terms of the appointment to the appointed individual
- C. Typically, community members contact the IRB Chair (or vice versa) who will facilitate appointment through the board, DRSP, and Vice Provost.
- i. If the board is in need of a community member, the IRB Chair will contact local institutions to identify someone qualified and interested in the role. The IRB Chair will facilitate appointment through the board, DRSP, and Vice Provost.

Office of Research and Sponsored Programs (ORSP) Consultant

The ORSP Consultant attends meetings and advises the board on policy and procedure as it relates to the ORSP and greater La Verne. The ORSP Consultant also discusses protocols for review in meetings to ensure compliance with ORSP and La Verne policy and procedure.

External Consultants

If the board is in need of an External Consultant, the IRB Chair will contact the appropriate entity to identify someone qualified and interested in the role. The role is limited to a period of time related to the need and no appointment is necessary.

Liability Coverage for IRB members

- A. La Verne will indemnify and defend University faculty and staff performing within the course and scope of their employment with regard to IRB responsibilities. This coverage extends to those under the supervision of faculty and staff (i.e., students) and volunteers (i.e., unaffiliated IRB members) for the University. According to California Statute (Government Code) 995: Except as otherwise provided in Sections 995.2 and 995.4, upon request of an employee or former employee, a public entity shall provide for the defense of any civil action or proceeding brought against him, in his official or individual capacity or both, on account of an act or omission in the scope of his employment as an employee of the public entity.

Faculty Advisor(s)/Mentor(s)/Investigator(s)/Chair(s), Research Coordinator(s)/Staff Who Oversee Classroom-Based Student Research

Herein referred to as Mentor(s), this role is for those individuals who oversee undergraduate (inside or outside the classroom) or graduate capstone research (whether for a class or faculty driven scholarship) involving human subjects at La Verne. The Instructor Guidance Document dated January 5, 2017 contains the detailed responsibilities and procedures for this type of research and is considered a part of this master document.

- A. Reviews and approve IRB applications/documentation for student projects in compliance with La Verne IRB policies and procedures, along with federal regulations, within their approval limits, and in accordance with the Instructor Guidance Document
- a. Will submit student projects for IRB review as appropriate and in accordance with the procedures in the Instructor Guidance Document
 - i. Is responsible for shepherding the protocol through the IRB review process and serves as the point of contact for the IRB and the student as described in the Instructor Guidance Document
- B. Reviews and approves IRB applications/documentation for student projects in compliance with La Verne IRB policies and procedures, along with federal regulations, prior to submission to the La Verne IRB for review
- a. Ensures students complete the Initial Application or Mentor Approved Application (whichever is applicable) in IRBManager appropriately
 - b. Works with students and monitors progress in making revisions requested by the La Verne IRB
 - c. Reads and approves all submissions to the La Verne IRB (including the submission of the initial application and revisions)
 - d. Ensures applications are clean of errors and filled out correctly to minimize delays and maximize IRB approval at resubmission for revision, amendment, annual continuing review, or completion of the supervised protocol.
 - e. Works with the La Verne IRB to ensure appropriate content and protocol are contained in the Initial Application and subsequent study
- C. Maintains own human subjects research training as identified by the La Verne IRB
- D. Assures the student(s) have completed human subject's research training as identified by the La Verne IRB
- E. Maintains knowledge of the direction and status/completion of the students' projects

- F. Ensures the student will promptly file for revision, amendment, annual continuing review, or completion of the supervised protocol
- G. Agrees to promptly report, in conjunction with the student, any significant or untoward adverse events to the IRB
- H. Understands and agrees that if at any time the Mentor who oversees student research is unable to proceed in that role, an alternative Mentor will be appointed for the remainder of the study and this change reported in writing the La Verne IRB as soon as possible

Faculty Advisor(s)/Mentor(s)/Investigator(s)/Chair(s), Research Coordinator(s)/Staff who Oversee Graduate Student Theses or Dissertations

Herein referred to as Graduate Mentor(s), this role is for those individuals who oversee graduate students completing master's theses and doctoral dissertations involving human subjects at La Verne.

- A. Reviews and approves IRB applications/documentation for student projects in compliance with La Verne IRB policies and procedures, along with federal regulations, prior to submission to the La Verne IRB for review
 - a. Ensures students complete the Initial Application in IRBManager appropriately
 - b. Works with students and monitors progress in making revisions requested by the La Verne IRB
 - c. Reads and approves all submissions to the La Verne IRB (including the submission of the initial application and revisions)
 - i. Graduate Mentor(s) can return applications to students for modification when necessary
 - d. Works with the La Verne IRB to ensure appropriate content and protocol are contained in the Initial Application and subsequent study
 - e. Ensures applications are clean of errors and filled out correctly to minimize delays and maximize IRB approval at resubmission for revision, amendment, annual continuing review, or completion of the supervised protocol.
- B. Maintains own human subjects research training as identified by the La Verne IRB
- C. Assures the student(s) have completed human subjects research training as identified by the La Verne IRB
- D. Maintains knowledge of the direction and status/completion of the students' projects
- E. Ensures the student will promptly file for revision, amendment, annual continuing review, or completion of the supervised protocol
- F. Agrees to promptly report, in conjunction with the student, any significant or untoward adverse events to the IRB
- G. Understands and agrees that if at any time the Graduate Mentor who oversees student research is unable to proceed in that role, an alternative Graduate Mentor will be appointed for the remainder of the study and this change reported in writing the La Verne IRB as soon as possible.