



# University of La Verne Institutional Review Board

## Application for Initial IRB Review of Research Protocol

### PART A – To Be Completed For ALL CATEGORIES of Research

#### General Instructions

The IRB Application becomes the permanent record of the compliance of the investigator(s) with laws and regulations protecting the rights and welfare of human participants in research. Sufficient detail of the proposed protocol must be included to permit the IRB to render a decision about whether the safeguards in the research protocol protect the rights and welfare of human participants and benefits justify any risks. Applications with insufficient detail will be returned, without review.

Please print or type information on this form. Forms are available for download from the IRB website ([www.ulv.edu/irb](http://www.ulv.edu/irb)) or you may follow the format using a computer text editor (Microsoft Word, preferably).

Student researchers must obtain faculty advisor review, approval and signature prior to IRB submission. Faculty advisors must have completed U.S. Department of Health and Human Services and ULV IRB Certifications, which can be accessed via the IRB website ([www.ulv.edu/irb](http://www.ulv.edu/irb)). Consult the website or your research supervisor for more information on research protocols that may be considered exempt, qualify for expedited review, or require full standard IRB review

Submit two (2) copies of the Application for Exempt and Expedited Review Categories, or seven (7) copies for the Standard Review Category, to the Office of the IRB c/o The Provost’s Office, University of La Verne, 1950 Third Street, La Verne, CA 91750. Please include an Approval Action Form with your application.

#### Identifying Information

##### 1. Title of proposed research study:

**Researcher’s Assurance:** I certify that the information provided in this application is complete and correct. I understand that as principal researcher, I have ultimate responsibility for the conduct of the study, adherence to ethical standards, and protection of the rights and welfare of human participants. I agree to: (1) Conduct the study according to the approved protocol; (2) Make no changes to the approved study without prior IRB approval; (3) Use the approved procedure and form(s) for obtaining informed consent; and, (4) Promptly report any significant adverse events to the IRB within five working days of occurrence.

\_\_\_\_\_  
Researcher’s Signature

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date

**Faculty Advisor/Sponsor’s Assurance:** By my signature, I certify that the student or guest researcher has sufficient knowledge to conduct the study in keeping with the protection of human participants. Further, I agree to: (1) monitor study progress; (2) Supervise the researcher in solving problems in the research as they arise; (3) Ensure that the researcher promptly report significant adverse events; (4) Identify an alternate advisor or sponsor in the event that I am unavailable (on leave or sabbatical) and advise the IRB in writing of such arrangements.

\_\_\_\_\_  
Faculty Advisor/Sponsor’s Signature

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date

##### 2. Type of Review Requested: (See description of research protocol categories under III.F of Policies & Procedures.)

- Exempt Review (submit two copies)
- Expedited Review (submit two copies)
- Standard Review (submit seven copies)

##### 3. Type of Application:

- New Proposal
- Modified Protocol/Application Resubmission (Research Project No. \_\_\_\_\_)

##### 4. Principal Researcher Position:

- Professor
- Doctoral Student
- Masters Student
- Undergraduate

Other: \_\_\_\_\_

**5. Principal Researcher's College Affiliation:**

- College of Arts and Sciences (Program/Major \_\_\_\_\_)
- College of Business and Public Management (Program \_\_\_\_\_)
- College of Education and Organizational Leadership (Program \_\_\_\_\_)
- College of Law

**6. Principal Researcher's Contact Information:**

Name	
Mailing Address	
Daytime Phone	
E-mail Address	

**7. If Student, Advisor/Faculty Supervisor Contact Information;**

**OR, If Unaffiliated Researcher, ULV Contact Faculty/Administrator Information:**

Name	
University Phone Number	
University E-mail Address	

**8. Check the category that applies to your research:**

- Doctoral Dissertation
- Masters Thesis/Project
- Undergraduate Research/Senior Project
- Graduate Student Research Project (non-degree)
- Faculty or Staff Professional/Academic Research
- ULV Institutional Research
- Outside Research by non-affiliated researcher

**9. Briefly describe the purpose(s) of the study (include research questions and key variables):**

*Protocol Methods/Procedures*

**10. Describe the expected sample size and characteristics of the sample of human participants:**

- a. Please check any of the following “**vulnerable populations**” included in your sample (Requires full IRB review and completion of Part B questions):
- Children (if children are involved state age, legal parent/guardianship status)
  - Persons with Intellectual or Developmental Disabilities
  - Frail Older Adults
  - Adults with Physical Disability or Mental Illness
  - Adults with legal guardians
  - Specific targeted Racial Subgroups or Ethnic backgrounds
  - Other special populations targeted in the study protocol

**11. Describe how participants will be recruited or selected:** (From what source(s), i.e., hospital, institution, school, class, shopping mall, etc.? Attach letters of approval from all participating organizations on their official letterhead, or IRB approval from the organization. Attach any recruitment materials, e.g., letters, postcards, flyers, for IRB review and approval.)

**12. Data will be collected by:**

- Mail Survey/Questionnaire
- Telephone Survey/Interview
- In-person Interview
- In-person Questionnaire
- Observation
- Experimental Procedure – direct measure/self report
- Standardized/Educational Test
- Archival or Secondary Data Source (abstracted/analyzed)
- Participant Observation
- Sound/Video Recording and Content Analysis
- Focus Group Interview
- Other: \_\_\_\_\_

**13. What will you do with the human participants?** (Briefly describe the research methods and procedures that involve human participants.)

**14. State when (approximate dates) and where** the activities involving human participants will take place. The beginning date must be after approval by IRB. If location(s) require permission(s), please **attach authorization letters**.

Start Date:	End Date:
Locations:	

**15. List the title and attach copies of any copyrighted tests, questionnaires, or other materials to be used.** Attach evidence of permission to use the copyrighted material (i.e., purchase invoice, letter or email from author or publisher). If security or copyright prohibits attachment, explain. If none, state "No copyrighted tests or questionnaires."

**16. List the title and attach copies of any specially designed tests, assessments, questionnaires, or interviews or other public domain materials to be used.** (If none, state "No specially designed or public domain materials are being used for this research.")

*Consent Issues – Risks and Safeguards*

**17. Are inducements being offered to participants?**

- NO**
- YES** What are the inducements?

**18. What level of risk** does this research present to the dignity, rights, health, welfare, or privacy of the participants?

- No Risk to Participants – Justify your rating below
- Minimal Risk to Participants – Justify your rating below
- More than Minimal Risk to Participants – Explain and Specify Risks below (Complete Part B)

**19. Describe the safeguards to protect against or to minimize ANY risk** (Minimal or More than Minimal):

If, as part of your management of risk, you are referring participants to an agency that is not a part of the University of La Verne, please list the name of the agency here and attach a letter from that agency stating its qualifications and granting you permission to use its name.

**20. Describe any benefits to the participant(s)** that may reasonably be expected from the research, including providing summary of research findings where appropriate, benefits to organizations, professionals, or others.

**21. Briefly describe the procedures for protecting the confidentiality of participants** both during the project and after the research is completed. (Include where you will keep and how you will dispose of signed consent forms, if applicable. Include pseudonyms for participants, organizations and/or communities that you will use in reporting your results.)

**22. Briefly describe the procedures you will use to obtain Informed Consent.** Attach your proposed consent form(s) and include the text of oral explanations, if applicable, and any additional Informed Consent forms required by other participating organization(s). (See General Requirements for Informed Consent and Sample Informed Consent Form attached as Appendices D and E of the IRB Policies & Procedures.)

- Protocol does not require Informed Consent (i.e., de-identified secondary data analysis, direct observation in public places, educational settings/standardized educational tests, public/elected officials)
- Request for Waiver of Informed Consent (Complete Section in Part B)

**Checklist of Possible Attachments for Part A**

- Letter from agency granting permission to use their name.
- Letters of approval from participating organizations on official letterhead.
- Copyrighted tests, questionnaires, etc. Include evidence of permission to use.
- All other specially designed or public domain tests, questionnaires, interview protocols, etc.
- Proposed Consent Forms, including text of oral explanations.

**PART B**

**To be completed for Standard Review Category Applications or Requests for Waiver of Informed Consent**

***Standard Full IRB Review Supplemental Questions***

**23.** To your knowledge, are there any **laws or regulations relevant to the special nature of your population** (e.g., prisoner populations, people with legal guardians)? If so, explain how your research design deals with these laws or regulations.

**24. If the study includes participants from vulnerable populations** describe how your protocol protects or accommodates their special vulnerabilities.

**25. If the study targets specific racial or ethnic minority communities**, explain why, and describe how language and cultural sensitivity issues are addressed in your protocol.

**26.** If **sensitive issues** are raised in the research protocol, or if **deception is used**, describe the nature of any debriefing of subjects. (If not, state "No debriefing", and justify your decision.)

**27. Briefly describe the training and experience that qualifies you** to carry out the proposed research that involves more than a minimal risk to participants or includes vulnerable populations.

***Request for Waiver of Informed Consent***

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to document informed consent, provided one of the following sets of conditions exists and is documented. The federal regulations do not allow a waiver of informed consent simply because the conditions of informed consent are difficult to carry out or because the conditions make it difficult to enroll subjects into the research. However, the IRB may grant a waiver of informed consent under the following conditions:

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants; and
3. The research could not practicably be carried out without the waiver or alteration, and whenever appropriate, the participants will be provided with additional pertinent information after participation.

**28. Explain why** the proposed research could not be practicably carried out without the proposed waiver or alteration of the informed consent form or procedure.

**29. Describe any protocol for providing participants with additional pertinent information** after their participation.

**30. State any risks to participants** caused by their participation in this research, and justify that the requested waiver or alteration to usual informed consent procedures will not adversely affect the rights or welfare of the participants.