**Initial Application for University of La Verne Institutional Review Board Review**

Bottom of Form

***PART A – To Be Completed for ALL CATEGORIES of Research***

**Application for Initial IRB Review of Research Protocol**

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

**General Instructions**

The Institutional Review Board (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 University of La Verne (ULV) 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 to the applicant, without review.**

Please type information on this form. Forms are available for download from the ULV IRB web site in Word. Student researchers must obtain faculty advisor/mentor approval prior to ULV IRB submission. Researchers must complete human subjects training prior to conducting research. Please check the ULV IRB website for further information. Consult the website or your research supervisor/advisor/mentor for more information on research protocols that may be considered exempt, qualify for expedited review, or require full standard ULV IRB review.

Submit an electronic copy of the Application for Standard, Exempt and Expedited Review Categories, Review Category, to the relevant ULV College IRB representative or irb@laverne.edu. You may check the ULV IRB website to find your College’s representative. **Additional information is available on the website on how to compile and submit your application.** [**http://sites.laverne.edu/institutional-review-board/**](http://sites.laverne.edu/institutional-review-board/)

***Identifying Information***

1. **Title of proposed research study: (**All titles should be in standard mixed case, where the first letter of each word is capitalized and followed by lower case letters.)

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Researcher’s Assurance: I certify that the information provided in this application is complete and correct. I understand that as principal investigator (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 ULV IRB approval; (3) use the approved procedure and form(s) for obtaining informed consent; and, (4) promptly report any significant adverse events to the ULV IRB within five working days of occurrence.

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Researcher’s Name Date

Faculty Advisor/Sponsor’s Assurance: By my approval by either electronic signature below or email with the application, the advisor/mentor certifies that the student or guest researcher has sufficient knowledge to conduct the study in keeping with the protection of human participants. Further, the advisor/mentor agrees to: (1) monitor study progress; (2) supervise the researcher in solving problems in the research as they arise; (3) ensure that the researcher promptly reports significant adverse events; (4) identifies an alternate advisor/mentor or sponsor in the event that the current is unavailable (on leave or sabbatical) and advises the ULV IRB in writing of such arrangements.

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Advisor/Mentor/Supervisor/Sponsor Name Date

***In order to complete this and other ULV IRB forms, place an “X” in the appropriate box to the left of each selection, throughout this and the other ULV IRB forms.***

1. **Type of Review Requested:** (See description of research protocol categories on ULV IRB website)

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|  | Exempt Review |
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|  | Expedited Review |
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|  | Standard Review |

1. **Type of Application:**

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

1. **Principal Researcher Position:**

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| --- | --- | --- | --- |
|  | Professor/Faculty  |  |  |
|  |  |  |  |
|  | Doctoral Student ……………………………………… | Anticipated Graduation |  |
|  |  |  |  |
|  | Masters Student ………………………………………. | Anticipated Graduation |  |
|  |  |  |  |
|  | Undergraduate ………………………………………... | Anticipated Graduation |  |
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|  | Other (write in ULV or external position):  |  |
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1. **Principal Researcher’s Affiliation:**

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| --- | --- | --- | --- |
|  | College of Arts and Sciences…………………………… | Program/Major |  |
|  |  |  |  |
|  | College of Business and Public Management………….. | Program |  |
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|  | LaFetra College of Education………………………….. | Program |  |
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|  | College of Law |
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|  | Other (write in ULV or external affiliation):  |  |

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

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| --- | --- |
| Name: |  Degree: |
| Daytime Phone: |  |  | E-mail Address: |  |

1. **If Student, ULV Advisor/Mentor/Supervisor Contact Information;**

**OR**

**If External Researcher, Contact Information:**

|  |  |
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| Name: |  Degree: |
| Daytime Phone: |  | E-mail Address: |
| External Researcher Institution: |  |
| External Researcher ULV Contact: |  |

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

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| --- | --- |
|  | ULV Doctoral Dissertation |
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|  | ULV Masters Thesis/Project |
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|  | ULV Undergraduate Research/Senior Project |
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|  | ULV Graduate Student Research Project (non-degree) |
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|  | ULV Faculty or Staff Professional/Academic Research |

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|  | ULV Institution or Program Research |
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|  | Outside Research by External ULV Researcher |

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

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***Protocol Methods/Procedures***

1. **Describe the expected sample size and characteristics of the sample of human participants:** (Consider age range, total number of participants, inclusion or exclusion criteria, and how you plan to gain access to the potential participants.)

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1. Please check any of the following **“vulnerable populations”** included in your sample (Requires ULV IRB standard review and completion of Part B questions):

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|  | Minors/Children (if children are involved state age, legal parent/guardianship status) |
|  |  |
|  | Persons with Intellectual or Developmental Disabilities  |
|  |  |
|  | Frail Older Adults |
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|  | Adults with Physical Disability or Mental Illness |
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|  | Adults with legal guardians |

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|  | People who are economically or educationally disadvantaged  |
|  |  |
|  | Other special populations (prisoners, pregnant women, etc.)  |

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

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

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|  | Mail Survey/Questionnaire |  | Telephone Survey/Interview |
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|  | 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 |  | Electronic Survey |
|  |  |  |  |
|  | Other |  |

**13. What will you do with the human participants?** (Describe all the research methods and procedures that involve human participants. This section should help the ULV IRB Committee understand from initial contact to completion of the research protocol what will happen to participants. If you are NOT engaging in the research on ULV campus consider if you need location/on-site permission to perform the research and provide permission letter. For any interventions to be performed not on the ULV campus, a risk management waiver supplied by the IRB will need to be included in the research protocol, see ULV IRB website.)

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

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| Start Date: | End Date: |
| Locations: |

**15. List the titles of any tests, questionnaires, or other instruments to be used** **that were developed by another person,** along with the source where you obtained the material. Attach copies of all these materials and evidence of permission to use the material (i.e., purchase invoice, letter or e-mail from author or publisher, general permission on a website, PsycTests, Creative Commons license). If security or copyright prohibits attachment, explain. If none, state “No materials designed by another person are being used for this research.”

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**16. List the titles and attach copies of any surveys, tests, assessments, questionnaires, or interviews that you developed**. If none, state “No specially designed materials are being used for this research.”

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***Consent Issues – Risks and Safeguards***

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

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|  | **NO** |
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|  | **YES** – What are the inducements? |

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**18. What level of risk does this research present to the dignity, rights, health, welfare, or privacy of the participants?** Consider physical (more than the participant may encounter on a daily basis), psychological (involves a response to participation in a psychological way), social or group risk (when a participant belongs to a group, is employed, or is a student and their status is in jeopardy or impacted by participating or not in the research).

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|  | 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) |

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

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1. If, as part of your management of risk, you are referring participants to an agency that is not a part of ULV, 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. The ULV IRB Committee requires a minimum of **three** referrals.

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**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.

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**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. Signed consent forms must be archived for three years after the conclusion of the study.) Include any procedures for keeping data secure and location of secured data.

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**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 ULV IRB web site for template and examples. Your program or College ULV IRB may also have samples.)

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|  | Consent required |
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|  | Consent not required (i.e., de-identified secondary data analysis, direct observation in public places, |
| educational settings/standardized educational tests, public/elected officials) |
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|  | Informed Consent obtained/Information Sheet at the beginning of telephone interview or  |
| online survey or research (attach copy of either oral or electronic versions of informed consent.) |

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|  | Request for Waiver of Informed Consent (Complete Section in Part B) |

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# Checklist of Attachments for Part A (some may be optional for some applicants

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

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|  | Final format for online/electronic tests, questionnaires, etc. (link and/or PDF copy are acceptable) |
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|  | Human Subjects Protections Certificate (NIH or CITI) for anyone engaged in the research |

***PART B***

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

***Standard Full ULV 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.

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**24. If the study includes participants from vulnerable populations** describe how your protocol protects or accommodates their special vulnerabilities. Appropriate additional safeguards are necessary if potentially vulnerable subjects are to be involved in your research. Potentially vulnerable subjects include the elderly, prisoners, children, cognitively impaired people, people who are economically or educationally disadvantaged, pregnant women, neonates, or persons with impaired decisional capacity. For further information and clarification contact your ULV College’s IRB representative or refer to the NIH website on the guidelines for the use of human subjects at <http://grants.nih.gov/grants/policy/hs/index.htm>.

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**25.** 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.)

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**26. 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.

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

The ULV 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 ULV 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.

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

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

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**29. 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.

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