View xForm - Initial ULV IRB Application

Please use this form for all new initial applications for the Institutional Review Board.

Initial Application Data Entry

Application Header and Instructions

Choose the most appropriate option for this submission.

No answer provided.

Submitter

Chrisco, Kanya Godde Ph.D.

Email: kgodde@laverne.edu **Phone:**

Title of proposed research study:

No answer provided.

Principal Investigator (PI) email address: the name will populate once you move to the next question

No answer provided.

Please enter the email address of the principal investigator. If you are the principal investigator please enter your own email address.

Principal Investigator (PI) Position:
No answer provided.

Enter the appropriate position for the principal investigator.

PI CITI Human Subjects Training Expiration Date

PI NIH Human Subjects Training Certificate Expiration

Attach your human subjects training certification.

No answer provided.

If your human subjects training certification is not listed above or has expired, attach your renewed certificate here.

Choose the most appropriate research category for this application.

No answer provided.

Do you have a funding agency associated with this proposed research study.

No answer provided.

Choose the most appropriate ULV or on-campus department/program.

No answer provided.

Have you reviewed the ULV IRB policies and procedures located on the on the ULV IRB website?

No answer provided.

If you have not reviewed the website, please make sure to review it (http://sites.laverne.edu/institutional-review-board/policies-and-procedures/) prior to submission of your application.

Do you have additional proposed research personnel associated with this study?

No answer provided.

Additional proposed research personnel may include; advisor, students, mentor, other investigators, research coordinators, etc...

Study Details

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

No answer provided.

Give as many details as possible for study purpose.

Describe the characteristics of the expected sample of human participants:

No answer provided.

Please make sure to include all characteristics associated with population (e.g. age range, total number of participants, gender, inclusion or exclusion criteria, how you plan to gain access to the potential participants, etc...)

What is your expected (maximum) sample size?

No answer provided.

Number of total (or maximum) participants expected to recruit for this study.

Please check any of the following "vulnerable populations" included in your proposed sample.

No answer provided.

Proposing to study any of these populations may require full (standard) ULV IRB review.

Recruitment

Participant Recruitment Description

No answer provided.

Describe how participants will be recruited or selected.

Recruitment Sources

No answer provided.

From what source(s) will you be recruiting, e.g., hospital, institution, school, class, shopping mall, etc.?

Attach organizational permissions for recruitment purposes.

No answer provided.

Attach letters of permission from all participating organizations/off site locations on their official letterhead and/or IRB approval from the organization related to recruitment. Will you be naming the organization in the presentation/publication/dissemination of the findings? If so, seek out permission to use the organizational name.

Recruitment Materials

No answer provided.

Attach any recruitment materials, e.g., letters, postcards, flyers, for IRB review and approval.

Proposed Protocol

Data Collection Method (check all that apply)

No answer provided.

What will you do with the human participants?

No answer provided.

*Describe in detail all the 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 and is the **most important part of your application**. State the following in chronological order: 1) what the participants will be asked to do, 2) where the research will occur, 3) what measures will be used (e.g. test), 4) what data and information will be collected and how, 5) whether participants will be identified (further elaborated on in the confidentiality section), 6) whether participants will receive an incentive to participate and if so describe, and 7) how long it will take to complete the instrument and/or task (if multiple items, break down by item).*

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. For on campus research use "ULV," otherwise state location.

Location	Start Date	End Date

Type in the location, select the appropriate dates, and click "Save."

Are location permissions needed for the proposed research?

No answer provided.

*Will the research take place at a location off-campus (any ULV campus) that may require permissions. Examples could include, school districts, institutions of higher education, businesses, etc... This is **different** than recruitment locations.*

Is an off-site location IRB involved with the review of this application?

No answer provided.

Are there any study material(s) created by non-ULV Researcher(s)

No answer provided.

Do you have study materials designed/created/developed by you or another to attach with your protocol?

No answer provided.

Inducements

Are incentives being offered to participants?

No answer provided.

Will you offer money or other incentives for participants time?

Proposed Risk

What type of risk is present in the proposed study?

No answer provided.

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).

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

No answer provided.

No Risk to Participants may require an Exempt IRB review

Minimal Risk to Participants may require an Expedited IRB review

More than Minimal Risk to Participants may require a Standard IRB review

If unsure what you should select, please visit the ULV IRB policy webpage for more detailed explanations.

Please justify why this level of risk is selected.

No answer provided.

State whether the discomfort is more than every day life. Consider other factors, as well.

Describe the safeguards to protect against or to minimize ANY risk.

No answer provided.

For minimal and more than minimal risk.

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 if applicable attach a letter from that agency stating its qualifications and granting you permission to use its name.

Referral agency for participants.	Referral Agency Attachment

*The ULV IRB requires a minimum of **three** referrals if you are referring participants to a non-ULV agency.*

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, the discipline, or others.

No answer provided.

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 3 years after the conclusion of the study). Include any procedures for keeping data secure and the location of secured data.

No answer provided.

Will a form of debriefing be needed for this study protocol or for this population?

No answer provided.

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.)

Standard Review Supplemental Questions

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)?

No answer provided.

An example for this would be for research involving minors (USA <18 years) and the fact that they are required to have parental or legal guardian consent prior to participation along with their assent.

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

No answer provided.

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 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.

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.

No answer provided.

Human subjects training (CITI or NIH Certification), certification in profession or field, experience from internship/practicum, etc...

Informed Consent

Choose your informed consent option.

Please note, if you choose the waiver or alteration in the usual informed consent process option, you will need to state any risk(s) to participants caused by their participation in this research and justify that the requested waiver or alteration to the usual informed consent procedures will not adversely affect the rights or welfare of the participants.

No answer provided.

An Informed Consent is the standard (typical) format (paper, oral, electronic, etc.) for informing future participant(s) of all procedures, risks, benefits, etc.

Confirm you have met the required categories for informed consent by visiting the ULV IRB website for more information.

A Waiver of Informed Consent is proposed in situations that may require an altered consent form (studies involving deception, etc.).

Briefly describe the procedures you will use to obtain Informed Consent for participants.

No answer provided.

If Informed Consent is not required (e.g., de-identified secondary data analysis, direct observation in public places, educational settings/standardized educational tests, public/elected officials) please explain that in more detail here.

See ULV IRB Forms and Examples webpage for template and examples.

Optional Informed Consent Oral Explanation/Script.

No answer provided.