Initial La Verne IRB Application V3

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Initial Application Data Entry

-- Instructions --

Most applications at La Verne fall under exempt review. Please review our exempt decision charts website and exempt application policy before starting your application to ascertain if you have an exempt study.

-- Human Subjects Research --

Is this human subjects research? (Required)
Select "No" if this is a secondary data study or other type of research that does not use human subjects (e.g., analysis of policy).

⇒ Select either 'Yes' or 'No'

-- Review Type Determination --

Are you a researcher who is NOT affiliated with University of La Verne? (Required)

⇒ Select either 'Yes' or 'No'

The worksheet below will help you determine if you should apply for an exemption (exempt review) or if your application is better suited for an expedited or standard review.

Does your study completely fall into any of the exemption categories listed below? (Required)
You must have reviewed the federal regulations at 45 CFR 46.101(b) prior to making a selection as the categories are summarized from the regulations and are not comprehensive.

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Category 1: Research conducted in educational settings, involving normal educational practices. ‡Category 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. ‡Category 3: Research involving the activities in category 2 and the human subjects are elected or appointed public officials or candidates for public office. ‡Category 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. ‡Category 5: Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine materials for (click on this category to see

the options). ‡Category 6: Taste and food quality evaluation and consumer acceptance studies. ‡None of these categories apply.

Mark which of the following apply. (Required)

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Research on regular and special education instructional strategies ‡Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods ‡None of these

Mark which of the following apply. (Required)

⇒ Select *one* of the following options from the list of radio buttons presented: ‡The human subjects are elected or appointed public officials or candidates for public office ‡Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter ‡None of these

Mark which of the following apply. (Required)

⇒ Select *one* of the following options from the list of radio buttons presented: ‡This is research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available ‡The information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects ‡None of these

Mark which of the following apply. (Required)

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Public benefit or service programs ‡Procedures for obtaining benefits or services under those programs ‡Possible changes in or alternatives to those programs or procedures ‡Possible changes in methods or levels of payment for benefits or services under those programs ‡None of these

Mark which of the following apply. (Required)

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Wholesome foods without additives are consumed ‡A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture ‡None of these

Please select the appropriate description of your study. (Required)
*If you have designed a study that is **only** confidential **or** anonymous, please be consistent throughout the application and only use the appropriate term (i.e., don't use the terms interchangeably)*

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Anonymous - this means there is no identifiable information in the data that can be traced back to a specific individual ‡Confidential - identifiers are present in the data, but you will not be sharing this information in a manner that can be traced back to a specific individual, thus protecting the participant

Would "any disclosure of the human subjects' responses outside the research... reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation" in your study? (Required)

Select either 'Yes' or 'No'

⇒**Does your proposed study target prisoners or adults with cognitive impairment? (Required)**

⇒ Select either 'Yes' or 'No'

Does your proposed study target prisoners, adults with cognitive impairment, or non-English speakers (could include English Language Learners)? (Required)

⇒ Select either 'Yes' or 'No'

Does your proposed study target prisoners? (Required)

⇒ Select either 'Yes' or 'No'

Does your study contain children (persons under the age of 18)? (Required)

⇒ Select either 'Yes' or 'No'

Does the following apply to your study? The study only includes "educational tests or observation of public behavior where the investigators do not participate in the activity being observed... also ... the data are recorded without individual identifiers, or the condition that disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation." (Required)

⇒ Select either 'Yes' or 'No'

Your study appears to be qualified to apply for an exemption. As such you may use an information sheet in lieu of an informed consent. Please see examples of information sheets on the La Verne IRB website.

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Please check the Exempt box to continue. (Required)
Please check the Exempt box to continue.

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Exempt

Please check the Exempt box to continue. (Required)
Please check the Exempt box to continue.

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Exempt

Please check the Exempt box to continue. (Required)
Please check the Exempt box to continue.

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Exempt

Please check the Exempt box to continue. (Required)
Please check the Exempt box to continue.

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Exempt

Please check the Exempt box to continue. (Required)
Please check the Exempt box to continue.

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Exempt

-- Application Header and Instructions --

Greetings,

This form has been returned to you for substantial revisions. Please open the attached PDF which contains your previously submitted form followed by the comments from the reviewers. Please make the required changes in this xForm and then resubmit for review by the IRB.

⇒ Display the answer to a previous question.

Under which of the following expedited categories does your application qualify for an expedited review? (Required)
*Please refer to the **nonexempt policy** for more information on each category.*

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Clinical studies of drugs and medical devices... ‡Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture... ‡Prospective collection of biological specimens for research purposes by noninvasive means ‡Collection of data through noninvasive procedures... ‡Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis) ‡Collection of data from voice, video, digital, or image recordings made for research purposes ‡Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies ‡Continuing review of research previously approved by the convened IRB... ‡Continuing review of research, not conducted under an investigational new drug application.or investigational device exemption where categories two (2) through eight (8) do not apply.but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. ‡None of these

Is your study more than minimal risk? (Required)

⇒ Select either 'Yes' or 'No'

Does your study specifically target vulnerable populations or individuals who are experiencing situational vulnerability? (Required)

⇒ Select either 'Yes' or 'No'

Your study appears to qualify for a standard review. Please mark standard below.

Your study appears to qualify for a standard review. Please mark standard below.

Your study appears to qualify for a standard review. Please mark standard below.

Your study appears to qualify for an expedited review. Please mark expedited below.

Please mark the review type populated in the box above this question. (Required)

Review the nonexempt policy to determine your review type.

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Expedited ‡Standard

Submitter

⇒ Displays the name of the user who submitted this form.

Title of proposed research study: (Required)

⇒ Enter an unlimited amount of text.

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

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

⇒ Enter the e-mail address of an existing contact.

Choose the most appropriate research category for this application (Required)

*If you are an **external researcher wishing to conduct research at La Verne,** select "Outside Research by Non-Affiliated Researcher"*

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Doctoral Dissertation ‡Masters Thesis/Project ‡Undergraduate Research/Senior Project ‡Graduate Student Research Project (non-degree) ‡Faculty or Staff Professional/Academic Research ‡Outside Research by Non-Affiliated Researcher

Principal Investigator (PI) Position: (Required)

Enter the appropriate position for the principal investigator.

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Professor ‡Administrator/Staff ‡Doctoral Student ‡Masters Student ‡Undergraduate ‡Other

Please describe the other PI Position (Required)

⇒ Enter an unlimited amount of text.

Chair/Advisor/Mentor email address: (Required)

Provide the email address of your supervisor. If you receive a message stating "Contact not found." it simply means your Chair/Advisor/Mentor does not yet have an IRBManager login. You can click here to create a new contact for them right now, and then continue filling out this form.

⇒ Enter the e-mail address of an existing contact.

Mentor Email Status

⇒ Display value of UDF for contact.

What type of project are you proposing? Consider if this is affiliated with a class or class assignment.

(Required)
A classroom project could include: observation, interview, survey, intervention, or other.

*Select Faculty/Staff Mentored Research Project if this is a **Senior Thesis** or **Graduate Capstone** that requires IRB review because you will be **publishing/presenting**.*

⇒ Select *one* of the following options from the list of radio buttons presented:
‡Undergraduate or Graduate Classroom Project ‡Faculty/Staff Mentored Research Project (Outside of the Classroom) ‡Master's Thesis ‡Master's Capstone Experience

Please list the names of all members of your Masters or Dissertation Committee (Required)

⇒ Enter an unlimited amount of text.

Stop filling out this application. You need the Mentor Approved Application.
Please click on the link below to complete the Mentor Approved Application.
Do NOT click "Next" or "Save for Later".

⇒ User had the option to start a different form here.

Did you verify you have a human subjects training certificate (NIH or CITI) on file with the La Verne IRB? Please read and follow the instructions to the right of the drop down list. If you fail to follow these instructions, your application will be returned unread. (Required)
If an expiration date for your human subjects training certification is listed in your settings (Click on Settings in the top right hand corner, and then My Expirations), select Yes. Otherwise, select "No."

⇒ Select either 'Yes' or 'No'

Attach your required current human subjects training certification. (Required)
If an expiration date for your human subjects training certification is not listed in your settings (Click on Settings in the top right hand corner of the Dashboard, and then My Expirations), attach your renewed certificate here. Certificates must be less than 5 years old.

⇒ Attach a file of type "Required Human Subjects Training Certification" to this xForm.

Please attach your required "current" human subjects training certificate. (Required)

⇒ Attach a file of type "Required Human Subjects Training Certification" to this xForm.

Which type of training did you complete? (Required)

⇒ Select *one* of the following options from the list of radio buttons presented:
‡CITI ‡NIH

Human Subjects Training Attachment (Required)

Attach your NIH or CITI training certificate here.

⇒ Attach a file of type "Required Human Subjects Training Certification" to this xForm.

Do you have a funding agency associated with this proposed research study? (Required)

⇒ Select either 'Yes' or 'No'

Choose the most appropriate La Verne on-campus department/program. (Required)

⇒ Select a department from the list of valid departments.

In which doctoral program are you enrolled? (Required)

⇒ Select *one* of the following options from the drop down list presented:
‡DPA ‡EdD ‡PsyD

In which college is your program/department housed? (Required)

⇒ Select *one* of the following options from the list of radio buttons presented:
‡College of Arts and Sciences ‡College of Business and Public Management ‡College of Law ‡La Fetra College of Education ‡University-Wide (for administrative, library, and staff applications) ‡Not Applicable

What is your anticipated semester of graduation? You may round to the first of the month. (Required)

⇒ Enter a valid date.

Have you reviewed the La Verne IRB policies and procedures located on the on the IRB website? (Required)

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.

⇒ Select either 'Yes' or 'No'

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

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

⇒ Select either 'Yes' or 'No'

This field automatically populates the date of your first submission. No action is required by you.

⇒ Enter a valid date.

-- NHSR 1 --

Study Description (Required)

Please describe the study you will be conducting with the data.

⇒ Enter an unlimited amount of text.

Does your study include any of the following La Verne IRB approved public use datasets? (Required)

Check all that apply.

** indicates this is a database and all datasets from this database are approved, provided they follow the criteria listed in the **Secondary Data Analysis Policies and Procedures**.*

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Agency for Health Care Research and Quality (AHCRQ) ‡Healthcare Cost and Utilization Project (HCUP) ‡Medical Expenditure Panel Survey (MEPS) ‡American Changing Lives ‡Autism Brain Imaging Data Exchange (ABIDE) ‡Better Access to Data for Global Interdisciplinary Research (BADGIR) ‡California Department of Education ‡California Health Interview Survey (CHIS) ‡Center for AIDS Prevention Studies (CAPS) ‡Center for Disease Control and Prevention (CDC) ‡National Behavioral Risk Factor Surveillance System (BRFSS) ‡National Health and Nutrition Examination Survey (NHANES) ‡National Health Interview Survey (NHIS) ‡National Youth Risk Behavior Survey (NYRBS) ‡Center for Medicare and Medicaid Services (CMS) ‡Demographic and Health Surveys ‡Health and Retirement Study ‡Survey of Health, Ageing, and Retirement in Europe (SHARE) ‡Health Reform Monitoring Survey (HRMS) ‡Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey ‡Integrated Public Use Microdata Series (IPUMS-International) ‡Integrated Public Use Microdata Series (IPUMS-USA) ‡Integrated Public Use Microdata Series (IPUMS-CPS) ‡Inter-University Consortium for Political and Social Research (ICPSR)* ‡Luxembourg Income Study (LIS) ‡Medical Expenditure Panel Survey (MEPS) ‡Medicare Hospital Value-Base Purchasing (HVBP) program ‡Midlife in the United States (MIDUS) ‡Monitoring the Future ‡National Center for Education Statistics ‡National Center for Health Statistics ‡National Election Studies ‡National Hospital Ambulatory Medical Care Survey (NHAMCS) ‡National Longitudinal Surveys ‡National Nursing Assistant Survey (NNAS) ‡National Nursing Home Survey ‡National Survey on Drug Use and Health (NSDUH) ‡New Immigrant Survey ‡Panel Study of Income Dynamics (PSID) ‡Child Development Supplement (CSD) ‡Transition into Adulthood Supplement (TAS) ‡Roper Center for Public Opinion Research ‡Surveillance Epidemiology and End Results Cancer Registry (SEER) ‡Treatment Episode Data Set-Admissions (TEDS-A) ‡University of Wisconsin-Madison Data and Information Services Center (DISC) ‡U.S. Bureau of the Census ‡Vaccine Adverse Event Reporting System (VAERS) ‡None of these

Are you ONLY using a dataset listed above? Mark no if you are using datasets not listed. (Required)

⇒ Select either 'Yes' or 'No'

Do any of the datasets you are using from the list above include identifiers? (Required)

Identifiers could include names, SSN, or demographics that triangulate back to a specific person.

⇒ Select either 'Yes' or 'No'

Because the data you are using contains identifiers, you cannot run your application as not human subjects research. Please click "Human Subjects Research" from the Application Header in the middle of the top of the screen. Then, change your answer to "Yes."

-- NHSR2 --

Do any of the datasets you are using include identifiers? (Required)

Identifiers could include names, SSN, or demographics that triangulate back to a specific person.

⇒ Select either 'Yes' or 'No'

What is the sample size of the dataset you are using? (Required)

⇒ Enter a valid number. It must be a whole number.

What is the name of the dataset you are using? (Required)

⇒ Enter an unlimited amount of text.

Please attach the permissions you received to use the data.

⇒ Attach a file of type "Secondary Data Permission" to this xForm.

Please provide the website from which you requested the data. (Required)
This should be the URL explaining how to access the data and describing the data. If none, state none.

⇒ Enter an unlimited amount of text.

Please list all variables you will obtain with the dataset. (Required)

⇒ Enter an unlimited amount of text.

Please list all the variables you will use from the dataset. (Required)
If the variables used are the same as the variables obtained from the dataset, you may write that you will use all variables obtained.

⇒ Enter an unlimited amount of text.

Check all confidentiality/anonymity and security procedures you have put in place. (Required)
Check all that apply.

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Use of pseudonyms ‡Use of protocol numbers that do not link participants ‡No identifiers collected/provided ‡Data will be reported in aggregate/summary ‡Storage will be in researcher's office ‡Storage will be in researcher's home ‡Storage will be in mentor/chair/advisor's office ‡Data will be stored in a locked cabinet ‡Data will be stored on a password protected computer ‡Data will be stored in a password protected file ‡Data will be stored on a password protected disk ‡Data will be stored in a secure and confidential online storage (also password protected)

Because the data you are using contains identifiers, you cannot run your application as not human subjects research. Please click "Human Subjects Research" from the Application Header in the middle of the top of the screen. Then, change your answer to "Yes."

-- Additional Proposed Study Personnel --

Click the link provided below if your contact is not found in IRBManager. You will know this is the case if the email address cannot be found in the table where you are adding the researchers.

⇒ User had the option to start a different form here.

Enter details for any proposed Co-Investigator(s) below. You are *required* to attach a human subjects training certificate if the new personnel does not have one on file with the IRB. You must click "Save" after inputting each Co-Investigator's information.

⇒ Displays a table containing existing Question Types in a repeat group.

Enter details for any proposed Non Co-Investigator(s) below. You must click "Save" after inputting each Non Co-Investigator's information.

⇒ Displays a table containing existing Question Types in a repeat group.

-- Non-Affiliated (External) Applicant --

Non-Affiliated Applicant Institution (Required)

⇒ Enter an unlimited amount of text.

Provide your institution's IRB contact name, phone number, and email address. (Required)

We will be contacting the other IRB to enter into a reliance agreement, so please account for the time needed to enter into the agreement.

⇒ Enter an unlimited amount of text.

Input the email address of your faculty sponsor affiliated with the proposed application. (Required)

*Provide the email address of your supervisor. If you receive a message that "Contact not found." it simply means your Advisor/Mentor does not yet have an IRBManager login. You can **click here** to create a new contact for them right now, and then continue filling out this form.*

⇒ Enter the e-mail address of an existing contact.

Please attach the IRB Approval letter from your home institution. (Required)

⇒ Attach a file of type "Non-Affiliated Applicant IRB Approval" to this xForm.

Please attach the approved IRB application and all materials submitted to the IRB from your home institution. (Required)

This is the approved IRB application and materials after all revisions were made and approved.

⇒ Attach 1 to 10 files of type "Any" to this xForm.

Please upload your non-affiliated applicant informed consent/assent/information sheet. (Required)

⇒ Attach 1 to 5 files of type "Any" to this xForm.

Do you plan to use the La Verne name in any publications and/or a dissertation? (Required)

⇒ Select either 'Yes' or 'No'

-- Proposed Study Funding Details --

Enter the name of your funding agency (NIH, NSF, DOE) and the total amount funded. If you have a detailed budget with monies for human subjects or for the research protocol, provide a general explanation for those funds. (Required)

⇒ Enter an unlimited amount of text.

Have you submitted your ORSP application? (Required)

⇒ Select either 'Yes' or 'No'

-- Study Details --

Briefly describe the purpose(s) of the study: (Required)

*Give as many details as possible for study purpose. If this is a **Senior Thesis** or **Graduate Capstone** that you plan on publishing/presenting, you are **required** to state this in your application, here.*

⇒ Enter an unlimited amount of text.

What are your research questions, hypotheses, and key variables? (Required)
*If your study does **NOT** have research questions, hypotheses, and/or variables as a result of experimental design, please state this for auditing purposes (e.g. state, "A XX (study type) study does not require the use of variables").*

⇒ Enter an unlimited amount of text.

Will all participants be age 18 or older? (Required)

⇒ Select either 'Yes' or 'No'

Describe the characteristics of the expected sample of human participants (i.e., inclusion and exclusion criteria):
(Required)
Please make sure to include all characteristics associated with the 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...)

⇒ Enter an unlimited amount of text.

What is your expected (maximum) sample size? (Required)
Number of total (or maximum) participants expected to recruit for this study.

⇒ Enter a valid number. It must be a whole number.

Select any of the following vulnerable populations/populations that require special considerations included in your proposed sample. (Required)
Proposing to study any of these populations may require full (standard) La Verne IRB review.

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Children/Minor ‡Persons with intellectual or developmental disabilities ‡Frail older adults ‡Adults or legal representatives of individuals with physical disability or mental illness ‡Adults with legal guardians ‡People who are economically or educationally disadvantaged ‡American Indian/Alaskan Native Populations ‡International Populations ‡Non-English Speakers ‡Other populations that require special consideration (prisoners, pregnant women, patients, undocumented individuals, etc.) ‡No Vulnerable Populations

Include the other vulnerable population(s) proposed in the text box provided. (Required)

⇒ Enter an unlimited amount of text.

Have you been in contact with the Tribe? (Required)

⇒ Select either 'Yes' or 'No'

Have you received permission from the Tribe? (Required)

⇒ Select either 'Yes' or 'No'

Does the Tribe have a Tribal IRB? (Required)

⇒ Select either 'Yes' or 'No'

Please provide the Tribal permissions and IRB approval, including the application, all supporting materials, and the approval letter. (Required)

⇒ Attach 1 to 10 files of type "Approval Letter" to this xForm.

Please describe the geographic location (including country and other regional designations), performance site, and other relevant information regarding where

the study will be conducted. Number multiple locations for ease of understanding. (Required)

⇒ Enter an unlimited amount of text.

Provide a statement showing review and comprehension of The International Compilation of Human Research Standards, and compliance with local context laws, regulations or guidelines that govern research involving human participants. (Required)

*Refer to the policy on **international research** for more information.*

⇒ Enter an unlimited amount of text.

Is there a local IRB? (Required)

⇒ Select either 'Yes' or 'No'

Please attach the IRB approval and all materials submitted for approval (Required)

⇒ Attach 1 to 20 files of type "Any" to this xForm.

Provide information about the current social, economic and political conditions for the local context in which research will be conducted. (Required)

⇒ Enter an unlimited amount of text.

Provide information about any potential additional risks that participants might face as a result of participation. These should be different than the proposed risks component of the application. Mark N/A if there are no additional risks. (Required)

⇒ Enter an unlimited amount of text.

How are you taking into consideration factors relevant to obtaining informed consent from research participants including their literacy levels, confidentiality concerns and local context cultural climate? (Required)

⇒ Enter an unlimited amount of text.

I understand that the La Verne IRB will have all materials not in English translated and this may cause increased processing times. (Required)

⇒ Enter your password to create your signature.

-- Recruitment --

Will you be recruiting participants (asking people to take part in your study)? (Required)

⇒ Select either 'Yes' or 'No'

Participant Recruitment Description (Required)

Describe how participants will be recruited or selected. This should include describing how flyers will be posted, how participant emails will be obtained for emails to be sent, etc.

⇒ Enter an unlimited amount of text.

Recruitment Sources (Required)

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

⇒ Enter an unlimited amount of text.

Attach your recruitment materials. (Required)
Attach any recruitment materials, e.g., letters, postcards, flyers, for IRB review and approval. Generally, any advertisement to recruit subjects should include: 1. ***The title of the study,*** *2.* ***The purpose of the research and, in summary form, the eligibility criteria that will be used to admit participants into the study,*** *3. A straightforward and truthful* ***description of the benefits (e.g., payments or free treatment)*** *to the participant from participation in the study, 4.* ***The location of the research and the person (the researcher/investigator) to contact for further information,*** *5. The following statement: "****Approved by the Institutional Review Board, #.....****" [Include IRB Approval Number].*

All materials are required to be attached to the application during submission if you plan to email, post flyers, or use any other written materials for recruiting participants.

Please refer to the Advertising Procedures for information regarding this policy.

⇒ Attach 1 to 26 files of type "Recruitment Materials" to this xForm.

Will you need permission to recruit from institutions/agencies from where you are recruiting participants and/or to name the organization in presentation/publication/dissemination of the findings? (Required)
All permissions to recruit participants or name the institutions/agencies during dissemination are required to be submitted with your application.

Please refer to the IRB Policies and Procedures for more information.

⇒ Select either 'Yes' or 'No'

Attach organizational permissions for recruitment purposes. (Required)
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. Our permission letter templates can be individualized to fit your study and signed by the organization. Our templates can be found ***here****.*

⇒ Attach 1 to 27 files of type "Off-Site Letters of Approval/Permissions" to this xForm.

Contact details for the affiliated organization (for recruitment purposes).
Please include affiliated organization name and contact (person affiliated with research and organization) details (including email address and phone number).

⇒ Enter an unlimited amount of text.

By signing below you are agreeing to the following: 1) you have reviewed the University policies prohibiting misappropriation of research and agree to conduct your proposed research in accordance with such policies; 2) you understand that it is your responsibility for determining and obtaining appropriate and correct permission(s) for recruiting participants, using an organization's name, employees, and/or other resources, and to conduct your research at a specific location; 3) that you have already determined and obtained the appropriate permissions for the items listed in 2) and which you also describe in this IRB application; 4) you understand that the La Verne IRB does not provide approval for or take any responsibility for the acquisition of necessary permissions for the items in 2); and 5) you agree to indemnify and hold harmless the University, the La Verne IRB and individual members of the La Verne IRB for any claims and liabilities

resulting from your failure to obtain the necessary and correct permissions for the study as submitted in this application.

(Required)

⇒ Enter your password to create your signature.

-- Proposed Protocol --

Data Collection Method (check all that apply)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡*Other (provide more information when prompted) ‡Archival Data ‡Class Project/Assignment ‡Device ‡Drug ‡Electronic Survey ‡Experimental Procedure Direct Measure/Self Report ‡Focus Group ‡In person interview ‡Intervention - Behavioral ‡Intervention - Dietary/Ingestables ‡Intervention - Exercise ‡Interview - In Person (face to face) ‡Interview - Telephone ‡Mail survey/Questionaire ‡Observation ‡Questionnaire Administered In Person ‡Questionnaire Administered Via Email ‡Questionnaire Administered Via Mail ‡Questionnaire Administered Via Qualtrics/Online ‡Questionnaire Administered Via Telephone ‡Skype Interview ‡Sound/Video recording ‡Standardized/Educational Test ‡Telephone Interview ‡Telephone Survey

Provide a link to your electronic survey. (Required)

⇒ Enter an unlimited amount of text.

Provide your online survey as a PDF here. This should reflect both the informed consent/information sheet and the final questions as loaded into the electronic questionnaire program of your choice. (Required)

⇒ Attach 1 to 10 files of type "Online Survey Attachment" to this xForm.

Please attach the final version of the survey, interview script, focus group materials, etc. you propose to administer. (Required)

⇒ Attach 1 to 10 files of type "Survey/Interview Script" to this xForm.

Please attach the final version of the survey, interview script, focus group materials, etc. you propose to administer. (Required)

Attach any tests, questionnaires, surveys, interview scripts or other instruments to be used.

⇒ Attach 1 to 5 files of type "Survey/Interview Script" to this xForm.

Please provide approval to use archival data. (Required)

⇒ Attach 1 to 3 files of type "Secondary Data Permission" to this xForm.

If you selected "other" above please describe your method here. (Required)

⇒ Enter an unlimited amount of text.

What online program do you plan to use for the online dissemination/implementation of your survey? (Required)

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Qualtrics (provided for all ULV faculty, staff, students, and alumni) ‡Survey Monkey ‡Other

Please list the name of the online program you will be using. (Required)

⇒ Enter an unlimited amount of text.

What will you do with the human participants? (Required)
*Describe in detail all the methods and procedures that involve human participants. This section should help the La Verne 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 and number your answer: 1) what the participants will be asked to do, 2) where the research will occur, 3) what measures will be used (e.g. test), what data and information will be collected, and how, and 4) how long it will take to complete the instrument and/or task (if multiple items, break down by item).*

⇒ Enter an unlimited amount of text.

Will you be using audio/visual recording? (Required)

⇒ Select either 'Yes' or 'No'

What type of recording will you be using? (Required)

⇒ Select *one* of the following options from the list of radio buttons presented:
‡Audio ‡Visual

Will participant name be recorded? (Required)
It is highly suggested to not record participant name as it increases the identity risk if the recordings were ever obtained outside of your study.

⇒ Select either 'Yes' or 'No'

How will you identify participants on the recordings? (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented:
‡Use of a pseudonym ‡Use of a study number ‡Use of their actual name ‡Other

Please describe how you will identify the participant on recording. (Required)

⇒ Enter an unlimited amount of text.

If participants do not agree to be recorded, can they still participate? (Required)

⇒ Select either 'Yes' or 'No'

How will you handle participants who do not wish to be recorded? (Required)

⇒ Select *one* of the following options from the list of radio buttons presented:
‡I will take handwritten notes ‡Other

If you marked Other in the question above, how will you handle participants who do not wish to be recorded? (Required)

⇒ Enter an unlimited amount of text.

State when (approximate dates) and where the activities involving human participants will take place. The beginning date must be after IRB approval. If location(s) require permission(s), please attach authorization letters. For on campus research use "La Verne," otherwise state location. (Required)
Type in the location, select the appropriate dates, and click "Save."

⇒ Displays a table containing existing Question Types in a repeat group.

Are location permissions needed for the proposed research? (Required)
If the research takes place at a location off-campus (any non-La Verne campus), permission may be required for the research to be conducted there. Examples could include school districts, institutions of higher education, businesses, etc. This is different than recruitment locations.

All permissions are required to be submitted with your application. Please refer to the IRB Policies and Procedures for more information.

⇒ Select either 'Yes' or 'No'

If location permission(s) is/are needed, please attach authorization letters. (Required)

⇒ Attach 1 to 30 files of type "Off-Site Letters of Approval/Permissions" to this xForm.

Is an off-site location IRB involved with the review of this application? (Required)
All permissions from the off-site IRB are required to be submitted with your application. Please refer to the IRB Policies and Procedures for more information.

⇒ Select either 'Yes' or 'No'

Off-Site IRB Contact Table (Required)
Click "Save" after entering details for the off-site IRB contact

⇒ Displays a table containing existing Question Types in a repeat group.

Attach Off-site IRB Approval Letter (Required)

⇒ Attach a file of type "Non-ULV IRB Approval Letter" to this xForm.

Are there any study material(s) created by researcher(s) other than yourself? (Required)

⇒ Select either 'Yes' or 'No'

Study Material(s) by Researcher(s) Other than Yourself

(Required)
*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 **click "Save" after completing the table**.*

⇒ Displays a table containing existing Question Types in a repeat group.

Copyright Permissions Signature

By signing below you are agreeing to the following: 1) you have reviewed the University policies prohibiting misappropriation of research and agree to conduct your proposed research in accordance with such policies; 2) you understand that it is your responsibility for determining and obtaining appropriate and correct permission(s) to use instruments, measurements, scales, etc. as dictated by each individual item created by someone other than you that you use in your study, 3) you are following the La Verne policy on Copyright, which can be reviewed by clicking here, 4) that you have already determined and obtained the appropriate permissions for the materials you have attached as a part of this IRB application, 5) you understand that the IRB does not provide approval for or take any responsibility for the acquisition of necessary permissions for using work by someone other than yourself, and 6) you agree to indemnify and hold harmless the University, the IRB and individual members of the

IRB for any claims and liabilities resulting from your failure to obtain the necessary and correct permissions for the study as submitted in this application.

(Required)

⇒ Enter your password to create your signature.

Do you have study materials designed/created/developed by you to attach with your protocol? (Required)

⇒ Select either 'Yes' or 'No'

Attach any study materials designed/created by you to be used in the proposed protocol. (Required)

Attach any tests, questionnaires, surveys, or other instruments to be used that were developed/designed/created by you.

⇒ Attach 1 to 25 files of type "Study Material(s) Created By ULV Researcher(s)" to this xForm.

If you are receiving this message it is because you marked "No" to both study materials questions and you currently do not have any study materials to attach to this application. We cannot process an application without your materials attached in the appropriate area (either as those created by someone else, or by you, or both, as applicable). Please go back to the study materials questions and correct your answers and upload your documents to the appropriate location.

Off-site IRB Contacts

This Group of pages will repeat.

-- Off-site IRB Contacts --

Off-site IRB Contact Prefix (e.g. Dr., Mrs., Mr., etc.) (Required)

⇒ Enter one line of text.

Off-site IRB Contact First Name (Required)

⇒ Enter one line of text.

Off-site IRB Contact Last Name (Required)

⇒ Enter one line of text.

Off-site IRB Contact Email Details (Required)

⇒ Enter a valid e-mail address.

Off-site IRB Contact Phone Number (Required)

⇒ Enter one line of text.

-- Inducements --

Are incentives being offered to participants? (Required)

Will you offer money or other incentives for participants' time?

⇒ Select either 'Yes' or 'No'

What type of incentive are you proposing? (Required)

Please review California law as it relates to each type of incentive to ensure you are following California law. A quick search of the internet will provide you with the law as it pertains to each of the items listed below. You will be asked to provide tax forms, proof of registration, etc. for the items that require these documents under California law.

⇒ Check *one or more* of the following items from the list of check boxes presented:
‡Raffle ‡Opportunity Drawing ‡Other

Please provide more details for the incentive(s). (Required)
Please provide the following information: 1) how much, 2) how often and when will you provide incentives (e.g. every 10 participants), 3) who will be eligible (check state laws to ensure compliance), 4) how you will handle drop-outs and or those that don't continue participation following consent (again, check state laws), 5) how you will confirm receipt of the incentives, and 6) how long you will provide for claiming incentives after the study is completed.

Consider the information on our website as it pertains to incentive amount.

⇒ Enter an unlimited amount of text.

California law requires that opportunity drawings have "general and indiscriminate distributing of tickets." For the La Verne IRB, we interpret this to mean the drawing is open to all who want to join and not just people who participate in your study. Have you updated your informed consent/information sheet and the answer above to account for this portion of the law? (Required)

⇒ Select either 'Yes' or 'No'

Please provide any incentive forms (explanation for debriefing, raffle information, document for receipt of inducement, tax forms if needed) if needed.
Provide all documentation related to the incentive.

⇒ Attach a file of type "Inducement Form" to this xForm.

-- Proposed Risk --

What level of risk does this research present to the dignity, rights, health, welfare, or privacy of the participants? (Required)
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 La Verne IRB policy webpage for more detailed explanations.

⇒ Select *one* of the following options from the list of radio buttons presented:
‡Minimal Risk to Participants ‡More than Minimal Risk to Participants

What type of risk is present in the proposed study? (Required)
*Consider: 1) identifiable (the participants' identities can be traced, which can happen in **confidential** studies), 2) physical (more than the participant may encounter on a daily basis), 3) psychological (more than the participant may encounter on a daily basis), and 4) social or group risk (when a **participant belongs to a group, is employed, or is a student** and their status may be in jeopardy or impacted by participating or not in the research).*

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Identifiable ‡Physical ‡Psychological ‡Social Group Status ‡Other - Described below

Describe the "Other" type of risk identified above. (Required)

⇒ Enter an unlimited amount of text.

Select options that describe the identifiable risk in your study. (Required)

Only describe identifiable risk

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Data are confidential, but protected ‡Data are not confidential or anonymous ‡Other

Describe the "Other" identifiable risk marked above. (Required)

⇒ Enter an unlimited amount of text.

Select options that describe the physical risk in your study. (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Risk from ingestion ‡Risk from injury ‡Risk from minor discomfort ‡Risk from pain ‡Risk from illness ‡Other

Describe the "Other" physical risk identified above. (Required)

⇒ Enter an unlimited amount of text.

Select options that describe the psychological risk in your study. (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Discomfort may result from sensitive questions ‡Discomfort may result from recalling past traumatic events ‡Other

Describe the "Other" psychological risk identified above (Required)

⇒ Enter an unlimited amount of text.

Select options that describe the social group risk in your study. (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Employees may experience discomfort answering questions about their employer ‡Teachers may experience discomfort answering questions about their institution ‡Students may experience discomfort answering questions about their institution/teacher/or other school official ‡Other

Describe the "Other" social group risk identified above (Required)

⇒ Enter an unlimited amount of text.

Will you be adding the following safeguard (altered to match your study) to your study and specifically state it in the informed consent? Safeguard: The participants' positions with their [write either employer, institution, school, etc. that is specific to your study] will not be jeopardized by participating or not, nor by the content of their answers. (Required)

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Yes ‡No ‡N/A

Will you be adding the following safeguard to your study and specifically state it in the informed consent? Safeguard: The participants' positions with their employer, institution, school, etc. will not be jeopardized by participating or not, nor by the content of their answers. (Required)

⇒ Select *one* of the following options from the list of radio buttons presented:
‡Yes ‡No ‡N/A

Is the risk more than everyday life in your study? (Required)
Please select the appropriate answer for your study. If it is more than everyday life, referrals are required by the IRB.

⇒ Select either 'Yes' or 'No'

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

⇒ Displays a table containing existing Question Types in a repeat group.

Please select what you will implement in your study from the following safeguards (check all that apply): (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented:
‡Using anonymity procedures ‡Using strong confidentiality procedures (see Confidentiality Procedures below for more information) ‡A waiver of consent is requested to protect identifiable information ‡Referral to CAPS ‡Referral to 3 community psychological referrals ‡A debriefing process will be implemented ‡Certification/licensure/expertise in physical activities participants will perform ‡Certification/licensure/expertise in any activities participants will perform ‡Compensation is provided to offset cost of participating in research ‡Other

Please describe the certification selected above. (Required)
What certifications/licensures, etc. do you hold? Please name.

⇒ Enter an unlimited amount of text.

Describe the other safeguards to protect against or to minimize ANY risk. (Required)
For minimal and more than minimal risk.

⇒ Enter an unlimited amount of text.

Does the proposed research involve any of the following? (mark all that apply) (Required)
The Institutional Review Board follows University of La Verne required training initiatives in compliance with the Office of Research and Sponsored Programs for any research involving human subject's. Additional training within specific risk areas may be required in order to comply with all federal regulations and university policy.

⇒ Check *one or more* of the following items from the list of check boxes presented:
‡Research regulated by the Food and Drug Administration (FDA) ‡Research involving participants who do not speak English ‡Research involving genetic testing ‡Research with prisoners ‡Research with children ‡Research with pregnant women ‡Research in public elementary and secondary schools ‡Research outside the United States or governed territories

Based on what you indicated in the previous question, additional CITI training is required. Complete the CITI training modules corresponding to your specific research and include your Supplemental CITI Training Certificate here. (Required)

Your Supplemental CITI Training Certificate should include the additional training modules required by the IRB and mandated by the Office of Research and Sponsored Programs in accordance with university policy. This is required based on the specifics of your proposed research.

⇒ Attach a file of type "Supplmental Human Subjects Training Certification" to this xForm.

Describe any benefits to the participant(s) and/or society that may reasonably be expected from the research. (Required)

Provide a summary of research findings where appropriate, benefits to organizations, professionals, the discipline, or others.

⇒ Enter an unlimited amount of text.

Please select the appropriate description of your study. (Required)

*Most studies are **EITHER** confidential **OR** anonymous. If you have designed a study that is **only** confidential **or** anonymous, please be consistent throughout the application and only use the appropriate term (i.e., don't use the terms interchangeably)*

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Anonymous - this means there is no identifiable information in the data that can be traced back to a specific individual ‡Confidential - identifiers are present in the data, but you will not be sharing this information in a manner that can be traced back to a specific individual, thus protecting the participant

Check all confidentiality/anonymity procedures you have put in place. Per the La Verne IRB Policies and Procedures, signed informed consent forms must be stored for 3 years. (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Use of pseudonyms ‡Use of protocol numbers that do not link participants to answers ‡Data will be reported in aggregate/summary ‡Signed consents will be stored separate from data so they cannot be re-associated ‡My study is Exempt, so I will use an Information Sheet, rather than a consent and no signatures or names will be collected and stored ‡Audio/visual transcription will be conducted by you ‡Audio/visual transcription will be conducted by a service that is confidential ‡Audio/visual recordings will be destroyed upon transcription (REQUIRED FOR EXEMPT APPLICATIONS) ‡Other

Do you need to request permission from La Verne to use their name in your research as the institution at which you conducted the research? (Required)

⇒ Select either 'Yes' or 'No'

Please send an email to irb@laverne.edu with a one paragraph justification for why you want to name the institution in your research. Your request will be reviewed independent of your application and a letter issued to you for your records that will also be attached to your application.

Please mark the box below to add the safeguard that you will not be naming the institution in your research. (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Institution at which research is conducted will not be named

Description of other confidentiality attribute or procedure (Required)

⇒ Enter an unlimited amount of text.

Please sign here to 1) agree to storing the signed consent forms (if applicable) and data for 3 years upon which time they will be destroyed, and 2) agree to put this information in the confidentiality section of your information sheet/informed consent. (Required)

⇒ Enter your password to create your signature.

Name of transcription service (Required)

⇒ Enter an unlimited amount of text.

Are you using an app on a cell phone, tablet, or any unprotected device to record participants? (Required)

⇒ Select either 'Yes' or 'No'

By signing below you are agreeing to: 1) transfer recordings from an unprotected app/software/device to a non-mobile, password protected device upon completion of recording, and 2) describing this process in your informed consent/information sheet. (Required)

⇒ Enter your password to create your signature.

Please describe the device you are using to record participants. (Required)

⇒ Enter an unlimited amount of text.

Describe how the recordings will be protected with the device (e.g., password protected, encrypted, etc.) (Required)

⇒ Enter an unlimited amount of text.

By signing below you are agreeing to: 1) transfer recordings from your device to a non-mobile, password protected device upon completion of recording, and 2) describing this process in your informed consent/information sheet. (Required)

⇒ Enter your password to create your signature.

Survey Confidentiality Procedures (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡The consent form will contain an agree/disagree statement and no names will be collected ‡For surveys with incentives: the email addresses of people wishing to participate in the incentive will be collected using a question that directs the participants to a separate survey so the anonymous responses and email addresses cannot be linked

You have marked in the application that your survey will be anonymous. Please mark the box below to add the safeguard that you will ensure your survey has all of the anonymity settings in place. (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡1) The survey has been set to anonymous in the software & 2) the survey has been set so applicants cannot save and go back to their answers later (which provides true anonymity in combination with the anonymity feature)

Electronic Storage Procedures (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Data will be stored on a password protected computer (DO NOT SELECT THIS OPTION IF YOU ARE STORING PAPER COPIES, ONLY) ‡Consents will be stored on a password protected computer (DO NOT SELECT THIS OPTION IF YOU ARE STORING PAPER COPIES, ONLY) ‡Data will be stored in a password protected file (DO NOT SELECT THIS OPTION IF YOU ARE STORING PAPER COPIES, ONLY) ‡Consents will be

stored in a password protected file (DO NOT SELECT THIS OPTION IF YOU ARE STORING PAPER COPIES, ONLY) ‡Data will be stored on a password protected disk (DO NOT SELECT THIS OPTION IF YOU ARE STORING PAPER COPIES, ONLY) ‡Consents will be stored on a password protected disk (DO NOT SELECT THIS OPTION IF YOU ARE STORING PAPER COPIES, ONLY) ‡Data will be stored in a secure, confidential online storage (also password protected) (DO NOT SELECT THIS OPTION IF YOU ARE STORING PAPER COPIES, ONLY) ‡Consents will be stored in a secure, confidential online storage (also password protected) (DO NOT SELECT THIS OPTION IF YOU ARE STORING PAPER COPIES, ONLY) ‡N/A, nothing will be stored electronically

Location of storage of computers, disks, and/or paper documents. (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Storage will be in researcher's office ‡Storage will be in researcher's home ‡Storage will be in mentor/chair/advisor's office ‡N/A, I'm storing everything in the password-protected cloud/online storage

Storage procedures for paper documents and mobile devices (e.g., laptops, phones, tablets). (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Data will be stored in a locked cabinet (DO NOT SELECT THIS OPTION IF YOU ARE STORING ONLINE OR ON A PASSWORD PROTECTED COMPUTER THAT CANNOT BE LOCKED IN A CABINET) ‡Consents will be stored in a locked cabinet (DO NOT SELECT THIS OPTION IF YOU ARE STORING ONLINE OR ON A PASSWORD PROTECTED COMPUTER THAT CANNOT BE LOCKED IN A CABINET) ‡N/A, I am only storing everything electronically on non-mobile devices and will shred any non-electronic documents I receive after scanning them ‡N/A, I am only storing everything electronically on non-mobile devices

Who all will have access to the data and/or consents/assents? (Required)

Please name all people and their association to this study with access to the data and/or consents/assents.

⇒ Enter an unlimited amount of text.

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

If sensitive issues are raised in the research protocol, or if deception or incomplete disclosure is used, mark "Yes."

⇒ Select either 'Yes' or 'No'

Debriefing Justification (Required)

Either describe the necessity in debriefing for non-deceptive studies or describe why you are using deception or incomplete disclosure. Remember, deception or incomplete disclosure will only be permitted when the researcher documents that an alteration of the usual informed consent requirements is justified under the criteria in the federal regulation (45 CFR 46.116(d)). You must document in your answer that: 1) the research presents no more than minimal risk to subjects, 2) the alteration will not adversely affect the rights and welfare of the subjects, 3) the research could not practicably be carried out without the alteration (the use of deceptive techniques must be justified by the study's prospective value and there should be no reasonable alternative method that would be equally effective), and 4) where appropriate, the subjects will be provided with additional pertinent information after participation.

⇒ Enter an unlimited amount of text.

Please provide the debriefing document. (Required)

⇒ Attach a file of type "Debriefing Document" to this xForm.

-- 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)? (Required)

*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. Others include, but are not limited to, **pregnant women, fetuses, and prisoners**.*

⇒ Select either 'Yes' or 'No'

Explain/justify how your research design deals with these laws or regulations.

⇒ Enter an unlimited amount of text.

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

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 Area/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.

⇒ Enter an unlimited amount of text.

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. (Required)

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

⇒ Enter an unlimited amount of text.

-- Informed Consent --

Choose your informed consent/information sheet option (Required)

An information sheet is the minimum required for an exempt review.

⇒ Select *one* of the following options from the list of radio buttons presented:
‡Information Sheet ‡Informed Consent

Choose your informed consent option. (Required)

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 IRB website for more information.

*A **waiver of informed consent** is proposed in situations that may require an altered consent form (studies involving deception, situational vulnerable populations, etc.).*

***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.

⇒ Select *one* of the following options from the list of radio buttons presented: ‡Informed Consent and/or Informed Assent required ‡Request for Waiver of Informed Consent

Please mark all conditions that are contained in your study for obtaining informed consent. (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡If collecting surveys, interviews, focus groups, etc. in person/signature will be obtained: the consents and completed instruments will be collected and stored separately so they cannot be re-associated ‡If collecting surveys online/no signatures obtained: the participants will click to agree or disagree to the consent/information sheet prior to taking the online survey ‡No signatures are required on the Information Sheet I am providing (Exempt Reviews)

Briefly describe when and how you will get informed consent (or an altered informed consent) from the participants. If using an information sheet in an exempt study, describe when and how you will provide it. (Required)
See the La Verne IRB Forms and Examples webpage for template and examples.

⇒ Enter an unlimited amount of text.

The federal regulations state that adequate time must be given to participants to review and accept the informed consent. Please describe the amount of time given in your study and indicate how it is proportional to your research design. (Required)
For example, an informed consent is provided to the participants and they are told that your study is accepting participants until a particular date, at which time they will turn in an informed consent. That time frame is 10 days from the date they are provided the informed consent. 10 days is provided as it is a clinical trial testing the effectiveness of a medical device.

⇒ Enter an unlimited amount of text.

Will you go over the informed consent/information sheet? (Required)

⇒ Select either 'Yes' or 'No'

Will the potential participants have an opportunity to ask questions? (Required)

⇒ Select either 'Yes' or 'No'

Will participants be in a confidential location? (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡Yes, if they choose to be (typical of surveys administered in SurveyMonkey, Qualtrics, and similar media) ‡Yes ‡No

Do all of the sections in your consent/assent/information sheet match the content of the answers in your application? (Required)

⇒ Select either 'Yes' or 'No'

Is the language appropriate to your participants (e.g. it is at a level of understanding appropriate for their education level)? (Required)

⇒ Select either 'Yes' or 'No'

In order to be reviewed and approved, the information in the application and informed consent/assent/information sheet protocols must match (e.g. confidentiality procedures).

It is advised to copy and paste answers to questions in the application that correspond to a particular section of the informed consent/assent.

For information sheets, it is not advised to copy and paste answers.

Is the language in your consent/assent/information sheet directed to your audience? In other words, if you copied and pasted text from your dissertation or paper, did you change the language so that it no longer reads as your dissertation/paper and instead reads as a document directed to the participants? (Required)

⇒ Select either 'Yes' or 'No'

Is the IRB contact information in your consent/assent/information sheet listed exactly as follows: IRB Office, University of La Verne, 1950 Third St, CAFE 112, La Verne, CA 91750, irb@laverne.edu, 909-448-4564. (Required)

⇒ Select either 'Yes' or 'No'

Is your mentor/chair/advisor listed as your supervisor in the Identification of Investigators section of the consent/assent/information sheet (including their contact information, specifically phone number)? (Required)

⇒ Select either 'Yes' or 'No'

Were you consistent in using the appropriate term (confidential or anonymous) in the application and the consent/assent/information sheet? In other words, if your study is confidential, did you only use that term throughout? Refer to the prior question (previous page) that defines confidential and anonymous in order to ensure you are using the terms correctly. (Required)

⇒ Select either 'Yes' or 'No'

Do you have a separate section in the consent/assent below the description of your protocol that contains a checkbox to agree or disagree to the audio or visual recording and an area for the participants to initial next to their selection (i.e. agree or disagree)? (Required)

⇒ Select *one* of the following options from the list of radio buttons presented:
‡Yes ‡No ‡Not Applicable - I don't have audio/visual recording in my study ‡Not Applicable - my study uses an information sheet

Is your protocol (procedures in your study) described in detail in the informed consent or briefly in the information sheet? (Required)

⇒ Select either 'Yes' or 'No'

Did you describe *ALL* of your inclusion/exclusion criteria? (Required)

⇒ Select *one* of the following options from the list of radio buttons presented:
‡Yes ‡No ‡Not Applicable - I'm using an information sheet

Did you describe *ALL* of your inclusion/exclusion criteria? (Required)

⇒ Select either 'Yes' or 'No'

Please mark the following items that are applicable to your study. (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented:
‡The content of your study may cause psychological discomfort (either more or less

than everyday life) ‡Your study was designed to sample participants who are employees/teachers of a particular company/institution you targeted, or are students of a particular educational institution ‡N/A

Have you listed the psychological risk (and that it is more or less than everyday life) in your informed consent or information sheet? (Required)

⇒ Select either 'Yes' or 'No'

Have you stated there is social group risk by being an employee/teacher/student and added the following safeguard to your study (modified to fit the details of your study) and specifically stated it in the informed consent or information sheet? Safeguard: The participants' positions with their [write either employer, institution, school, etc. that is specific to your study] will not be jeopardized by participating or not, nor by the content of their answers. (Required)

⇒ Select either 'Yes' or 'No'

You have indicated that your study is confidential. Did you list that you have identity risk in your informed consent/information sheet and how you will be protecting the participants' data? (Required)

⇒ Select either 'Yes' or 'No'

You must identify all the the risks of your study in the information sheet/informed consent. Please do so and then change your answer(s) above to "Yes"

Informed Consent Attachment. Please *CHANGE* the document type to match the type of document you are uploading (e.g. consent, assent, information sheet, etc.). (Required)
If you have multiple consent forms *in your study, please upload all consent forms prior to application submission. All consent forms are required to be submitted prior to review.*

Please only upload Word versions of the consent/information sheet.

⇒ Attach 1 to 20 files of type "Any" to this xForm.

Informed Consent/Information Sheet Attachment. Please *CHANGE* the document type to match the type of document you are uploading (e.g. consent, assent, information sheet, etc.).
If you have multiple consent forms/information sheets *in your study, please upload all consent forms prior to application submission. All consent forms are required to be submitted prior to review.*

Please only upload Word versions of the consent/information sheet.

⇒ Attach 1 to 20 files of type "Any" to this xForm.

Attach your informed consent/assent. Please *CHANGE* the document type to match the type of document you are uploading (e.g. consent, assent). (Required)
If you have multiple consent forms/information sheets *in your study, please upload all consent forms prior to application submission.*
All consent forms are required to be submitted prior to review.Please only upload Word versions of the consent/information sheet.

⇒ Attach 1 to 20 files of type "Any" to this xForm.

Informed Consent/Information Sheet Attachment. Please *CHANGE* the document type to match the type of document you are uploading (e.g. consent, assent, information sheet, etc.).
If you have multiple consent forms/information sheets *in your study, please upload all consent forms prior to application submission. All consent forms are required to be submitted prior to review.*

Please only upload Word versions of the consent/information sheet.

⇒ Attach 1 to 20 files of type "Any" to this xForm.

Optional Informed Consent Oral Explanation/Script.

⇒ Attach 1 to 10 files of type "Informed Consent Oral Explanation/Script" to this xForm.

In order to be reviewed and approved, the IRB Office information in the consent/assent/information sheet must match the information listed in the prior question.

In order to be reviewed and approved, your mentor/chair/advisor must be listed as a supervisor in the Identification of Investigators section of the consent/assent/information sheet (along with phone number).

In order to be reviewed and approved, you must use confidential or anonymous consistently, and not interchagably, throughout the application and consent/assent/information sheet.

In order to be reviewed and approved, the informed consent/assent must contain a separate section with checkboxes to agree or disagree to recording, and an area for the participant to initial for their choice.

In order to be reviewed and approved, the language must be appropriate for the pool of participants from which you will be sampling.

In order to be reviewed and approved, the language in your consent/assent/information sheet must be directed to the participants in your study.

In order to be reviewed and approved, you must describe your protocol in the consent/assent in detail, including, for example, time to complete tasks and measures. For information sheets, this should be a brief description.

In order to be reviewed and approved, you must list *ALL* of the inclusion/exclusion criteria in your study (e.g. over the age of 18, a particular degree, etc.).

Please attach your information sheet (Required)

⇒ Attach 1 to 10 files of type "Information Sheet" to this xForm.

Error! You have marked that you are using an informed consent in the question at the top of the page, but in the question above you stated you are using an information sheet. Please change one of your answers so they match each other and match which document you are using. The application will unlock once you have done this.

In order to be reviewed and approved, you must list *ALL* of the inclusion/exclusion criteria in your study (e.g. over the age of 18, a particular degree, etc.).

-- Waiver of Consent Supplemental Questions --

The research could not be practicably carried out without the waiver of consent because (check all that apply): (Required)

⇒ Check *one or more* of the following items from the list of check boxes presented: ‡The investigator does not have a reasonable opportunity to obtain consent (e.g., the investigator has no existing or continuing professional relationship with the subjects). ‡The risk to a participant signing an informed consent is more than minimal ‡Other

Explain why the proposed research could not be practicably carried out without the proposed waiver or alteration of the informed consent form or procedure. (Required)
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(s) the requirement to document informed consent. The waivers are approved in rare circumstances and does not include the reason it is difficult to enroll participants. Please refer to the federal regulations for information on the conditions allowable for a waiver of informed consent.

⇒ Enter an unlimited amount of text.

Describe any/all protocol(s) for providing participants with additional pertinent information following their participation. (Required)

⇒ Enter an unlimited amount of text.

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. (Required)

⇒ Enter an unlimited amount of text.

You will need to describe any/all protocol(s) for providing participants with additional pertinent information following their participation in the debriefing portion of this application. Please review your answer to whether a debriefing document will be provided and ascertain the appropriate option was selected.
To change your answer to the debriefing portion of the application, click on the Application Header in the top center of the screen and select Proposed Risk.

⇒ Display the answer to a previous question.

-- PI Self Submission Signature --

All applications will undergo a pre-review prior to review by IRB Administration and/or the Board. The purpose of the pre-review is to identify areas of the application that need improvement prior to being reviewed for an exempt determination. This is crucial as *exempt* determinations are *only reviewed once* and either accepted or rejected. Please review the following information about the IRB process before signing your application by clicking here.

By signing you are attesting to having reviewed the IRB process on our website and understand there may be multiple revisions in the pre-review process and there is only one review for an exempt determination.

(Required)

⇒ Enter your password to create your signature.

All applications will undergo a pre-review prior to review by IRB Administration and/or the Board. The purpose of the pre-review is to identify areas of the application that may need improvement prior to being reviewed. This will save time and reduce the number of revisions required to gain a determination or approval. Please review the following information about the IRB process before signing your application by clicking here.

By signing you are attesting to having reviewed the IRB process on our website and understand there may be multiple revisions through every stage of the process.

(Required)

⇒ Enter your password to create your signature.

By entering my password (required for submission), 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. (Required)

⇒ Enter your password to create your signature.

After signing, click "Next" and "Submit" to formally submit your application.

Location and Research Dates

This Group of pages will repeat.

-- Location and Date Range --

Location (Required)

⇒ Enter one line of text.

Start Date (Required)

⇒ Enter a valid date.

End Date (Required)

⇒ Enter a valid date.

Copyright Permissions

This Group of pages will repeat.

-- Copyright Table --

Title of Material (Required)

⇒ Enter one line of text.

Source of Material(s) (Required)

⇒ Enter one line of text.

Study Material(s) Attachment (Required)

⇒ Attach a file of type "Study Material(s) Created By Non-ULV Researcher(s)" to this xForm.

Referral Agency

This Group of pages will repeat.

-- Referral Agency Table --

Referral agency for participants.

⇒ Enter one line of text.

Referral Agency Attachment

⇒ Attach a file of type "Referral Agency" to this xForm.

Co-Investigator Group

This Group of pages will repeat.

-- Co-Investigators --

Additional Proposed Research Personnel Contact Email (Required)

⇒ Enter the e-mail address of an existing contact.

Attach your current human subjects training certificate (NIH, CITI, etc...)

⇒ Attach a file of type "Required Human Subjects Training Certification" to this xForm.

Choose the most appropriate position for the Co-Investigator(s)/Additional research personnel. (Required)

⇒ Select *one* of the following options from the drop down list presented:
‡Professor ‡Administrator/Staff ‡Doctoral Student ‡Master's Student ‡Undergraduate ‡Faculty Sponsor (if external researcher) ‡Other

If other, describe title/position.

⇒ Enter one line of text.

Non Co-Investigator(s)/Additional Group

This Group of pages will repeat.

-- Non Co-Investigator(s)/Additional Personnel --

Additional Proposed Research Personnel Contact Email (Required)

⇒ Enter the e-mail address of an existing contact.

Attach your required "current" human subjects training certificate (NIH, CITI, etc...)

⇒ Attach a file of type "Required Human Subjects Training Certification" to this xForm.

Additional Proposed Research Personnel Position (Required)

⇒ Select *one* of the following options from the drop down list presented:
‡Professor ‡Administrator/Staff ‡Doctoral Student ‡Master's Student ‡Undergraduate ‡Other

If other, describe title/position.

⇒ Enter one line of text.

-- Mentor Approval Via EMail --

Your mentor is set to approve your application via email. Please attach a PDF of your mentor's approval here. (Required)

⇒ Attach a file of type "Mentor Approval Letter" to this xForm.