Welcome to the Institutional Review Board for Research Involving Human Participants at Lewis-Clark State College. The purpose of this document is to describe, in detail, any research project that intends to recruit human participants. LCSC’s Institutional Review Board (IRB), via a formal review process, will use the information you provide in this document to determine if the rights and welfare of participants will be protected throughout the course of your research project.

The IRB encourages you to look over this IRB application document as you think about potential projects. The questions will help you determine the information needed to complete your project, consider various aspects of the research process, and prepare the protocols and materials needed to complete the project. If you are still in the planning phases of a research project, this document can serve as a guide. To submit this application, it is necessary that you have all background elements of the proposed research prepared or planned (e.g., rationale, design, participant recruitment, methodology, potential risks and benefits), along with any materials (e.g. approach scripts, consent forms, questionnaires, debriefing, permission to collect data at certain locations) created that are necessary to execute the research from start to finish.

While you may need to gain permission from directors, supervisors, or other individuals to conduct your research to fulfill the requirements of this application **it is imperative that you do NOT directly contact any potential participants until this application has been officially approved by the LC-State IRB via a formal approval letter on LCSC letterhead, complete with an approval number.**

Before submitting this document, any researchers working on the proposed research project are required to complete the IRB Training offered on Canvas (adapted from the training previously offered by the NIH Office of Extramural Research). **Have your instructor email** **IRB@lcmail.lcsc.edu** **to request you be added to the IRB Training on Canvas**. If your project is approved, approval is valid for one year from the date of your approval letter. Please note on your application when you anticipate the completion of your research (if applicable/known), as the IRB will contact you about the status of your project.

The questions in the application are both open-ended (short answer) and closed-ended (e.g., multiple choice). A “traffic light” reference is used throughout the application. **Unless specifically indicated otherwise, all questions require an answer**. You may need to skip various questions that do not apply to your project. For multiple choice or yes/no questions you will see a small stop light graphic

🡪 . If the response (usually no), directions are in green, this allows you to skip (go) to the next question. If your response (usually yes) requires additional information, you will see directions in yellow, listing additional questions. You will need to pause (slow down) to explain/answer before moving on. **For questions that have answer choices with brackets [ ], place an X in the bracket for the answer(s) that best represent your research project.**

If you have questions about this application, please refer to the available resources on the [LCSC IRB website](http://www.lcsc.edu/irb/), the Canvas Training Course, or your advisor with any questions before you contact any IRB board member or the IRB Chair, Dr. Heidee McMillin.

Email your **completed research application, saved as a Word document** with the file name of **LastNameofPI\_ARIHP\_Semester\_Year**, to IRB@lcmail.lcsc.edu, copying your research advisor.

**Cover sheets** (page 2) **must be signed** **by the PI (student(s)) and research advisor and** saved with the file name **LastNameofPI\_CoverSheet\_Semester\_Year** and emailed **as a PDF** to IRB@lcmail.lcsc.edu. The signed cover sheet including the date in which all researchers completed the Canvas IRB training (or their Certification number from another training) must be on file with the IRB before a project will be reviewed.

NOTE: If the principal investigator is a student, the cover sheet must be ***digitally*** signed (instructions [here](https://www.lcsc.edu/media/3608/instructions_creating-a-digital-id-signature_adobe-pdf.pdf)) by their advisor. All applications must be sent using official LCSC email addresses and **students must copy their advisor in the emails.**

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| **Cover Sheet** |
| **Title of your research project:**  |
| Name of Principal Investigator (PI): |  | Academic Division (if applicable): |  |
| Email:  |  |  Telephone: |  |
| Address:  |  | State: |  | Zip: |  |
| Relationship to School (student, faculty member): | (If other than student or faculty, please describe your profession and/or affiliations): |  |
| **Principal Investigator (PI):** By signing below, I acknowledge that this application represents an accurate and complete description of the research and that I will ensure that the rights and welfare of the human participants are properly protected. |
|   |  |  |
| **Signature of Principal Investigator** | **Date** | **Date IRB Training Completed** |
|  |  |  |
| IRB Training Information for any Additional Investigators: |
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| --- | --- | --- | --- | --- | --- |
| **Name** | **LC email** | **Date IRB Training Completed** | **Name** | **LC email** | **Date IRB Training** **Completed** |
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| 🡪 Classification of Project (Exempt, Expedited, Full): |  |
| 🡪 Anticipated Completion Date of Research Project: |  |
| **Advisor’s Name** (if PI is a student): |  | Academic Division: |  |
| Advisor’s Email: |  | Telephone: |  |
| Address:  |  | State: |  | Zip: |  |
| **Research Advisor:** I have reviewed this project and I agree to provide the proper management of this project to ensure that the rights and welfare of the human participants are properly protected. |
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| **Signature of Research Advisor** | **Date** | **Date IRB Training Completed** |
| **\* Note: a *digitally* signed copy of this page must be sent in PDF format** to IRB@lcmail.lcsc.edu by the PI, copying the advisor before the application will be reviewed. A **Word format** of the full application must also be submitted so that reviewers can provide feedback within the document. |

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| 1. **Summary of Rationale and Objectives**
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| Explain the rationale for your research project (include ≥ 1 relevant in-text APA/MLA citation).  |
| **Example:** There are four distinct parenting styles which are authoritarian, authoritative, permissive, and neglectful/uninvolved. Each of the parenting styles have a different effect on juvenile delinquency. For example, in a study by Backman, et al., (2021) of 1354 offending adolescents in the US,” self-reported offending was predicted by higher parental hostility and lower maternal warmth” (p. 955). |
| Type your research rationale here: |
| List references (at least one) for the citations in your rationale above.  |
| **APA Example:** Backman, H., Laajasalo, T., Jokela, M., & Aronen, E. T. (2021). Parental warmth and hostility and the development of psychopathic behaviors: A longitudinal study of young offenders. *Journal of Child & Family Studies*, *30*(4), 955–965. https://doi-org.ezproxy.lcsc.edu/10.1007/s10826-021-01921-7 |
| **MLA Example:** Backman, Heidi, et al. “Parental Warmth and Hostility and the Development of Psychopathic Behaviors: A Longitudinal Study of Young Offenders.” *Journal of Child & Family Studies*, vol. 30, no. 4, Apr. 2021, pp. 955–65. *EBSCOhost*, https://doi-org.ezproxy.lcsc.edu/10.1007/s10826-021-01921-7Enter your references for the rationale your provided in question #1 here: |
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| Describe in detail your specific research objectives (What do you hope to accomplish?).  |
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| What is your research question?  |
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| What is your hypothesis (if applicable)? (What do you think will happen?) (If you do not have a hypothesis, enter “N/A” below.) |
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| Briefly describe the type of research you are conducting and your methodological approach to collecting data. [For example, “This will be a descriptive study using a survey to assess client satisfaction with a drug treatment program,” or “This study will use a pre-test/post-test quasi-experimental design to evaluate the effectiveness of a new weight-training program on the body composition of student athletes,” or “This correlational study will use a survey to gauge the relationship between exercise habits and mental health in college students.”] |
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| Will any participants be under the age of 18? Research with minors requires participant assent & parental/ guardian consent. |
| [ ] Yes, participants will be under the age of 18**.** ⮱Both assent & consent forms will be required in the Materials |
| [ ] No, all my participants will be 18 years of age or over. |
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| **Summary of Methodology & Procedures** |
| **Participants** |
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| Describe in detail the population from which you will sample. Describe the group from which you will select or invite participants, the agency from which you will review documents, etc. |
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| Where will the research be conducted (school, hospital, prison, etc.)? |
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| 1. **Projected sample size:**
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|  Describe your sampling technique (how participants, documents, etc. will be selected). |
| (e.g., random assignment, convenience sample, purposive sample, snowball sample, etc.) For example, “The study will use a purposive sample that includes only members of the LC-State men’s baseball team.” |
|  |
|  Select your procedure for recruiting participants or gathering data (check all that apply). |
| [ ] None  | [ ] E-mailed a survey or request  | [ ] Phone solicitation by researcher  |
| [ ] Poster/flyer | [ ] Asked verbally, face-to-face, by researcher | [ ] Asked by caseworker, instructor, administrator  |
| [ ] Mailed a survey | [ ] Other 🡪 Enter another method of recruiting not already listed here. |
|  |
| Regardless of contact method, how will you present the consent form to potential participants? |
| [ ] Individuals will be approached about the research; the consent process will occur if they show interest in participating[ ] Individuals will be approached with consent script/form (no approach script needed)[ ] Not applicable (e.g., my research involves archival analysis)  🡪 **Move to Q16** |
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| What method will be used to deliver the consent form to participants? Click all that apply. Consent script and/or form will be required at the end of this application. [Consent Guidelines](http://www.lcsc.edu/irb/) |
| [ ] A. Read aloud verbally 🡪 By whom? Enter who will read the consent form to participants.[ ] B. Read by participants (e.g., handed sheet, read online) |
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| Are any cultural, language, or special needs (e.g., blind participants) barriers expected? |
| [ ] No, barriers are expected (e.g., LCSC students must pass an English proficiency exam and any other students who need accommodations should already have them available in the classroom).  🡪 **Move to Q16** |
| [ ] Yes, a cultural, language, or special needs barrier may occur 🡪 Answer 15a below.**15a**. Describe the expected barrier(s) & how the(se) barrier(s) will be addressed when going through the consent process. Explain expected barriers and how they will be addressed during the consent process. |
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| **Summary of Methodology & Procedures** |
| **Procedure** |
| Approximate start and end dates of data collection (turn-around time for IRB approving most applications is 2-3 weeks):  |
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| Describe a step-by step procedure of everything participants will experience while involved in the research (e.g., from first contact to debriefing), or your process for collection data. When possible, list stimuli, manipulations, measures, etc. in the order they are presented in IV. Materials (E).  |
| #17 General Procedure **Example**: The primary investigator will meet a potential participant at the appointed time and place and go over the consent form with them. If a participant decides to participate, they will fill out a series of self-report questionnaires, including measures on self-esteem, competitiveness, and anxiety. After the participant has completed the measures, they will be thanked for their participation and dismissed.  |
| **III. Summary of Methodology & Procedures** |
| **Operationalization** |
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| Describe how you will operationalize each research variable (e.g., by using questionnaires, interview questions, specific data taken from files, field research observations, etc.). Include relevant citations for these materials or not if self-created. |
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| **IV. Risks & Costs**  |
| Could participants consider information requested to be private or sensitive? |
| [ ] No 🡪 Move to Q20 |
| [ ] Yes 🡪 19a. Explain what could be considered private or sensitive.  |
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| Will the participants encounter the possibility of stress or psychological, social, physical, or legal risks that are greater than those ordinarily encountered in daily life or during the performance of routine physical activity, exercise, or when completing psychological examinations or tests? |
| [ ] No 🡪 **Move to Q21** |
| [ ] Yes 🡪 20a. Please explain the stress or risk to participants. |
| Will participants consider any of the materials presented to be offensive, threatening, or degrading*?* |
| [ ] No 🡪 **Move to Q22**[ ] Yes 🡪 21a.Explain specifically what participants might find offensive, threatening, or degrading. |
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|  21b. What will the researcher(s) do if a participant becomes distressed? |
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|  Will medical clearance be necessary for participants to participate because of tissue or blood sampling, administration of substances (e.g., food, drugs), or physical exercise conditioning? |
| [ ] No 🡪 **Move to Q23**[ ] Yes 🡪 22a. Explain how the clearance will be obtained below.  |
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| Will you deceive or mislead participants in any way (e.g., cover story, omission of key study details)? Federal regulations prohibit the use of deceptive techniques that places participants at “greater than minimal risk”. Type an X in the bracket next to the appropriate answer below.  |
| [ ] No 🡪 My research design *does not* use an omission of key study details and/or deception 🡪 Move to Q24[ ] Yes 🡪 My research design uses an omission of key study details and/or deception that does not go beyond minimal harm. ⮱A debriefing procedure & script will be required in item F. found later in the **Materials** section of this application.23a. Explain why the deception is necessary below. A debriefing script is required in your materials (Section IV, Item F) if you are using deception in your research. (e.g., when you have an experimental (treatment) group and a control (non-treatment) group, or if you have multiple treatment groups each receiving a different treatment (i.e., different curriculum, program, exercises, vitamin supplement, etc.) where your study relies on participants all having the same assumption so you can accurately test your dependent variable without interference of different participant’ expectations.)  |
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|  23b. Explain your debriefing procedure (how, when, by whom; (see Q #17 and Section IV, Item F). |
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| What level of risk will your participants potentially face if involved in your study? |
| [ ] No anticipated risk 🡪 **Move to Q25**[ ] Minimal risk 🡪 Answer **#24A** below[ ] More than minimal risk 🡪 Answer **#24A** below**24A.** If there is more than minimal risk, describe how you will minimize risks. |
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| What type of data will you be collecting? (Type an X in the bracket next to all answers that apply.) |
| [ ] Tissue or blood samples[ ] Responses or observations (thoughts, feelings, opinions, behaviors)[ ] Other 🡪 Enter the other type of data you will be collecting. |
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| Will data be collected anonymously or kept confidential? (Choose ONLY 1 answer below [A, B, C, or D])  |
| [ ] A. Anonymous (participant data unidentifiable to researchers) 🡪 Move to Q27 |
| [ ] **B. Anonymous** with code (e.g., for projects that need to match measures) 🡪 Answer Q26B.1 & 26B.2 below.**26B.1**. How will the code be generated & matched? |
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| **26B.2.** For how long will you have the code matched before it is destroyed?  |
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| [ ] **C. Confidential w/o names** (identification possible due to small sample size/unique characteristics)🡪Answer only Q26D.2. below. |
| [ ] **D. Confidential w/names** 🡪Answer **26D.1, 26D.2** and **26D.3** below**26D.1.** Will identifying information be removed? [ ] Yes [ ] No**26D.2.** If **confidential**, how will you protect your participants’ identity? |
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| **26D.3**. How do you intend to keep confidential data secure for the duration of the project? (Check all that apply) |
| [ ] Locked office (not private)[ ] Locked cabinet[ ] Coded to a master list 🡪 Answer Q26D.4 below. ⮱ **26D.4.** Will the master list be kept separate from the data? (Type an X next to all that apply.)[ ] Restricted computer[ ] Locked Private office[ ] Encrypted data[ ] Firewall system[ ] Other 🡪 (Please specify.) |
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| Location of data (e.g., laptop computer, locked office, etc.)  |
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| Who will have access to the data and what is their relationship to the research process? (Only the researcher(s) (PIs) and research advisor should have access to the raw data if you have promised participants either anonymity or confidentiality of their identities in your research.) |
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| How long will the data be kept in any form (hard copies, electronic website addresses, electronic file)? (Anonymous data can be kept indefinitely; confidential data must be kept ≥ 3 years).  |
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| Will participants be rewarded or compensated for their participation in any way? |
| [ ] No 🡪 All my participants will be volunteers 🡪 **Move to Q31**[ ] Yes 🡪Answer Q30a below.**30a. What type of reward or compensation will be offered?**[ ] Extra credit for a course 🡪 Alternative methods must be made available to students by instructors to avoid pressure to participate, or in case the student has participated in another class, or just prefers not to participate.[ ] Payment 🡪 Answer Q30b below.**30b. What type of payment?** [ ] Being entered into a drawing (e.g., name randomly chosen from a pool for a gift card)[ ] Cash[ ] Other 🡪 (please specify): |
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| Will the participant’s participation in a specific experiment or study be made a part of any record available to his or her supervisor, teacher, or employer? Note: If course instructors need records of who participated for extra credit reasons, or you are collecting consent forms with a signature, you’ll need to mark “yes”. |
| [ ] No 🡪 **Move to Q32**[ ] Yes 🡪 Answer Q31a & Q31b below.31a. Please explain why the record is needed. |
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| 31b. How will you maintain confidentiality of the record or consent forms? (Records kept in a locked file cabinet, password-protected computer, etc.) |
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|  Describe expected or potential costs to participants (e.g., their time, impact of intervention, transportation). Specify how many minutes it will take to participate in your study. Make sure this answer matches your Consent Form. |
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| **V. Benefits**  |
| Describe how participants may benefit, now or in the future, from engaging in the proposed research.  |
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| Explain how the proposed research may benefit society or your field of study, either now or in the future.  |
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| **Materials** |
| Approach Scripts - What you will say as you approach potential participants BEFORE giving them the consent form.[ ] Not applicable 🡪 Type an X in the bracket if you will **NOT** be using an approach script (See your answers to Q13 & Q14 to match your answer here.) 🡪 **Move to item B.**If using an approach script: Type or paste your approach script here. |
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| Consent Script (What will be said to participants when introducing or guiding them through the consent form?)[ ] Not applicable 🡪 Type an X in the bracket if you will **NOT** be using a consent script 🡪 **Move to item C.**If using a consent script: Type or paste the words that will be said out loud to participants during the consent process. |
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| Consent Form (must be appropriate to audience 🡪 ≤ 9th grade if not college sample; see the example Participant Consent Form under the IRB Guides and Forms section of [LC-State’s IRB webpage](https://www.lcsc.edu/irb)): |
|  |
| Type or paste your consent form here. |
| **C.1.** Consent Form Reading Level[How to determine your Flesch-Kincaid reading level](https://support.office.com/en-us/article/Test-your-document-s-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2) (e.g., 8.2): Type the Flesh-Kincaid reading level here. |
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| Experimenter Script (if applicable; the words and procedures an experimenter will say and follow to lead a participant through an experimental session beyond guiding them through the consent process). |
| [ ] Not applicable 🡪 Check if you will **NOT** be using an experimenter script 🡪 **Move to item E.** |
| If using an experimenter script, type or paste it here. |
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| **Copies of questionnaires, interview questions**; descriptions of stimuli, manipulations, or coding. Present in chronological order. **List the questions or prompts you will use to collect your data here AND paste the link to your online survey (e.g., Qualtrics) here.** Label all materials with a title, along with relevant citation, or whether created for the purposes of the proposed research to match content in procedures (e.g., “The Rosenberg Self-Esteem Scale (Rosenberg, 1965)). These labels can be removed before presenting them to participants based on the discretion of the researcher. |
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| Debriefing Script or Form  |
| [ ] Not applicable 🡪 Check if you will NOT be using a debriefing script (See your answer to Q23 to confirm this answer.) 🡪 Move to item G.If using a debriefing script, type or paste the content said, sent, or handed to participants after the research is complete to debrief them about the purpose of the research, manipulations, cover story, deception, etc. **(Examples include: a)** Participants are asked to take a quiz for research, but they are not told the research question also involves how background noise affects their ability to concentrate; **b)** Participants are told that they are participating in a study about environmental attitudes, but they are not told that the study will also test the effectiveness of different types of persuasive messages on attitude change.) |
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| Signed permission letter from agency to collect data from their records or clients, or from an author to use copyrighted materials for data collection.  |
|  |
| [ ] Not applicable 🡪 Check if you DO **NOT** need permissions to collect data from an agency or to use copyrighted measures (e.g., survey tools) |
| If a permission letter is required, paste here, if possible, otherwise email IRB@lcmail.lcsc.edu as an attachment.**Please note:** If you are conducting a survey and plan on including LC State students, faculty, or staff in your research you **MUST get written approval from** [LC’s Institutional Research & Effectiveness (IRE) office](https://www.lcsc.edu/ir/need-to-conduct-a-survey). To request permission to survey the LC State community, go to <https://lcsc.co1.qualtrics.com/jfe/form/SV_6SF0kn4tOZG8wvj> to submit your request. |