IRB Application for Use of Human Participants/subjects in research

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For use by ORI only:

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IRB Designate Approval:

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(*For use by UCR faculty researchers, students, visiting professors, and postdocs*)

**I – General information**This IRB application must be typed out and submitted via e-mail (irb@ucr.edu) along with all the appendices and signatures. All the applicable questions should be answered. Do not delete or alter any questions on this application form. Try to follow the suggested length requirements and focus on ethical issues.
 **1. Title of Research Study:**

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 **2. Researcher (e.g., UCR faculty, student, postdoc, visiting professor):**

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| Title (e.g., Dr., Mr., etc.):        | Name:       |
| Department:       |
| Phone:        | Institutional e-mail:       |
| Alternate contact (e.g., research coordinator, department administrator) name:       | Alternate contact Institutional e-mail:       |

 **3. UCR Status:**

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| Faculty (50% f/t) [ ]  Doctoral [ ]  Masters [ ]  Undergrad [ ]  Post-Doctoral [ ]   |
| Visiting professor/External researcher [ ]  Other [ ]  (specify:      )  |

 **4. UCR Faculty Advisor or Sponsor**

1. **List the UCR Faculty Advisor or Sponsor. Advisor or Sponsor must meet PI eligibility as defined by** [**UCR Policy #527-3**](http://research.ucr.edu/about/policies-ucr.aspx?k=6). **(Q4a is to be filled out only if person in Q2 is a UCR student, trainee, postdoc, or visiting scholar; for faculty research, this question should be blank):**

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| Title (e.g., Dr., Prof):        | Name:       |
| Department:       | Email:       |

1. **Department information (for UCR faculty or Faculty advisor):**

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| Department chair name:       |

**5. Personnel**

1. **Are co-investigators involved in this project? Y****es** [ ]  **No**[ ]
2. **List all key personnel in the project roster as an appendix.**

**6. Funding**

1. **List all anticipated or secured funding source(s):**
2. **What category do(es) the funder(s) belong to (check all that apply):**

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| [ ]  Industry (e.g., Pharmaceutical, biotech, etc.) | [ ]  Non-profit sponsor (e.g., AHA, Bill & Melinda Gates Foundation, John Templeton, etc.) |
| [ ]  Government funding (e.g., NIH, NSF, CDFA, Riverside County, etc.) | [ ]  Departmental funds |
| [ ]  Other (describe):       | [ ]  Not applicable/unfunded  |

1. **Status of Funding:**

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| [ ]  Funding obtained If YES, provide the PAMIS award number(s):       |
| [ ]  Funding applied for If YES, provide the anticipated start date:       |
| [ ]  No Funding required If YES, explain why no funding is needed:       |

**7. Conflict of Interest**

**Do you or any other study personnel (or the spouse, registered domestic partner and/or dependent children thereof) have a direct or related financial interest that might affect, or even appear to affect, the rights and welfare of participants involved in this research?**

 [ ]  Yes [ ]  No (If Yes, please contact [PRO](https://research.ucr.edu/ori/committees/pro) for a separate review)

**8. Additional Reviews**

1. **Has the research project received a scholarly, scientific, or peer review prior to this submission (this may involve a review by a funder, faculty supervisor, or a departmental committee):**

[ ]  Yes, specify:

[ ]  No (NB: IRB recommends a prior scholarly review for studies that are more than minimal risk)

[ ]  Pending, specify:

1. **Will this research involve any of the following (check all that apply & specify status of review)**:

[ ]  Research using biohazardous materials including any human-derived materials such as blood, body secretions and tissues, primary and established cell lines [Institutional Biosafety Committee ([IBC](http://research.ucr.edu/ori/committees/ibc.aspx))]

[ ]  Research using human pluripotent cells [Stem Cell Oversight Committee ([SCRO](http://research.ucr.edu/ori/committees/scro.aspx))]

[ ]  Research using vertebrae animals [Institutional Animal Care and Use Committee ([IACUC](http://research.ucr.edu/ori/committees/iacuc.aspx))]

[ ]  Promoting Research Objectivity Committee ([PRO](https://research.ucr.edu/ori/committees/pro)) – formerly COIC

[ ]  Other (e.g., UCR or non-UCR entities – such as UC [Reliance](https://irbreliance.ucop.edu/site/about) Registry or another IRB) Specify:

[ ]  None – IRB is the only approval I need

**II – Study Summary**

**9. Location of research: Where will this study take place? If it’s a collaborative study, provide details regarding other site(s). If there is an online component, provide details.**

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| (Max ¼ page)      |

 **10. Abstract (suitable for a lay audience)**

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 **11. What is the scholarly rationale for this study?**

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 **12. What are the study hypotheses or research questions?**

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 **13. Describe the design and methodology specific to how human participants will be involved in the research.**

**If there is to be an intervention or interaction with the participants, describe what the researcher and participants will do, who will conduct the procedures, where and when the procedures will take place, how frequently, for how long, what equipment will be used, etc.**

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**14. a) Does this study involve deception or intentional lack of disclosure?** [ ]  **Yes** [ ]  **No**

**b) If YES, justify and indicate how participants will be debriefed. Indicate if participants are free to withdraw or selectively edit data after being fully debriefed.**

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**15. Provide a list of appendices here for all additional materials submitted with this IRB application (e.g., Appendix A – Informed Consent; Appendix B – Interview Guide; Appendix C – References, Appendix D – Recruitment flyers/materials; Appendix E – Access letters.) at the end of this document. The list should be in the same order as you append the materials at the end of the document with headers for ease of review and referencing.**

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**III – Participants/Subjects**

**16. Study Timelines**

**Estimated start date for involvement of participants:
Estimated completion date for the involvement of participants:**

**17. Please describe the participants/subjects. List the inclusion/exclusion criteria. If applicable, please provide a rationale for your choice in sample size and/or sample size calculation.**

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**18. a) Are there any age, language, gender, or race-related inclusion/exclusion criteria?** [ ]  **Yes** [ ]  **No

 b) If YES, please justify:**

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 **19. a) Will any participants/subjects be specifically recruited from the following categories listed below (check**

 **all that apply):**

[ ]  **Under the age of 18**

[ ]  **Prisoners, probationers, or parolees**

[ ]  **Pregnant women, fetuses, or neonates**

[ ]  **Other characteristics that may cause them to be considered ‘vulnerable’ (e.g., cognitively impaired, educationally/economically disadvantaged, patients, students, staff, history of distrust, etc.) describe:**

 **b) If YES, please justify the use of the above populations, and detailing what additional safeguards will be included in the study to protect the rights and welfare of the subjects and will there be direct benefits. If NO, skip to the next question.**

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**20. Recruitment methods: Describe the mode of communication, how participants will be approached. Any recruitment materials, e-mails, & scripts must be submitted for review and listed as an appendix in Q15.**

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**21.** **[Compensation](#Compensation" \o "Compensation refers to money or item given to the research participatns that acknowledges the time and effort they have provided in participating in the research ): Will participants be compensated for their time? Describe the methods, amount and schedule for payment. If relevant, justify why compensation is not offered. What will happen to compensation if participants chose to withdraw?**

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**22.** **[Reimbursement](#Reimbursement" \o "Reimbursement is money or items given to research participants that reflect out-of-pocket expenses associated with participating in a research study (e.g., child care, bus far, gas money, etc.)): Will participants personally incur any expenses as a result of participation (e.g., fuel, missed work)? If relevant, justify why no reimbursement is offered.**

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**23. If you are recruiting participants through the Psychology Department’s subject pool, please note that you must have a debriefing form (which should be listed in Q15 and appended for review) and be familiar with the procedures and policies approved in the UCR Psychology Subject Pool Protocol (HS-08-045).**

**IV. Consent process - Ensure you are following the** [**UCR Informed Consent Guide**](http://research.ucr.edu/webdocs/RI/Forms/HRRB/UCR%20Informed%20Consent%20Guide.pdf)**. Sample Informed Consent**

**Templates can be found on the** [**ORI Resources page**](https://research.ucr.edu/ori/resources.aspx#IRB)**.**

**24. a) Describe the process that will be used to obtain informed consent. How will it be recorded? Who will be authorized to conduct the process? Note that it’s the quality of the consent that’s most important not the format.**

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**b) If you are applying for a waiver or alteration of the consent process (e.g., verbal, online, etc.), please explain how you are meeting the conditions for waiver or alteration outlined in the** [**UCR informed Consent Guide**](http://research.ucr.edu/webdocs/RI/Forms/HRRB/UCR%20Informed%20Consent%20Guide.pdf)**.**

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**25. Will anyone other than the participants provide consent (e.g., parents, guardians, legally authorized representatives, etc.)? Describe the process by which capacity/competency will be assessed.**

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**26. Where applicable, please describe how participants will be informed of their right to withdraw from the study and outline the procedures that will be followed to allow them to exercise this right. Also, what will happen to the data already collected.**

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**27. If research is taking place within a community or an organizations, describe how access will be obtained. Are there any special considerations for obtaining consent? Access letters may be requested from the community or organization. Sample Access Letter template can be found on the** [**ORI Resources page**](https://research.ucr.edu/ori/resources.aspx#IRB)**. Attach any relevant supporting documentation in Q15.**

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**28. If relevant, please describe what information/feedback, if any, will be provided to the subjects and/or communities after their participation in the project is complete. How will they be able to access the information? If relevant, describe the debriefing process.**

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**29. Possible Risks**

1. **Please check off all potential risks to participants as individuals or as members of a community or to the researchers that may arise from this research.**
	* 1. **Physical Risks (e.g., bodily contact, administration of substance):** [ ]  **Yes** [ ]  **No**
		2. **Psychological/emotional risks (e.g., feeling uncomfortable or upset):** [ ]  **Yes** [ ]  **No**
		3. **Social risks (e.g., economic, loss of status or reputation):** [ ]  **Yes** [ ]  **No**
		4. **Legal risks (e.g., arrest or subpoena):** [ ]  **Yes** [ ]  **No**
2. **Describe the possible risks and consider the probability and magnitude of possible harms and discomforts. Describe the procedures that will be used to minimize potential risks to participants.**

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**30. Possible Benefits**

1. **Describe possible direct benefits to participants. If there are no direct benefits, please state so.**

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1. **Describe possible benefits to communities, society, or scientific knowledge in general.**

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**31.** **[Privacy](#Privacy" \o "Privacy refers to how much control a participants/subject has over the extent, timing, and cirumstances of sharing oneself with others),** **[Confidentiality](#confidentiality" \o "Confidentiality refers to the methods used by researchers to ensrue that information obtained about their participants/subjects is appropriately protected. ) & Data**

1. [**Privacy**](#Privacy)**: Where and how will participants be providing information? Are the researchers collecting identifying information (e.g., names, addressed, phone numbers, DOBs, phone numbers, licenses, audio/video recordings, etc.)? If yes, please describe:**

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1. [**Confidentiality**](#confidentiality)**: Describe the procedures used to protect the confidentiality of participants. If not relevant, describe any limitations to protecting the confidentiality of participants whether due to the law or method used (e.g., confidentiality is not appropriate). For use of electronic identifiable information outside of a secure server environment, the IRB recommends the use of encryption software.**

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1. **Where will the data be stored and for how long? Who will have access to identifying information and for what reason?**

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**32. The US research regulations define ‘Minimal Risk’ as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. (45 CFR 46 & 21 CFR 50)**

1. **Do you believe your proposed research activities meet the above definition of ‘Minimal Risk’?**

[ ]  **Yes** [ ]  **No**

1. **If yes, please elaborate by engaging your particular IRB proposal with the definition above.**

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 **\*\*Final decision of whether an application is minimal risk or higher is up to the IRB\*\***

**IRB application submission instructions:**

**All IRB applications must be submitted via email (****irb@ucr.edu****) with the required signatures in place. The application should be submitted as a single attachment in PDF or Word format. All the appendices are to be inserted in the single attachment in the order that they are listed in question Q15 with descriptive headers to facilitate cross referencing and review of the application.**

**If this application is more than minimal risk, please note the submission deadlines for IRB meetings on our** [**website**](http://research.ucr.edu/ori/committees/hrrb.aspx)**. Ultimately, the IRB may choose to escalate an application for full board review if it deems the level of risk to be more than minimal. While this is a subjective assessment, it is not a haphazard one. For additional guidance and assistance, please visit the ORI IRB** [**FAQ’s**](https://research.ucr.edu/ori/faqs/faq-irb.aspx) **and** [**Resources**](https://research.ucr.edu/ori/resources.aspx#IRB) **pages.**

**For student/trainee or UCR-faculty sponsored research applications, all 3 signatures are required (student/trainee + UCR faculty + chair). For faculty research, only two are required (faculty + chair).**

**V. Signatures (electronic or scanned signatures are acceptable; taking a single picture of all the signatures in place is acceptable; inserting a jpeg of the signature is acceptable, also)**

**My signature as researcher, confirms that this study has been designed to protect human participants. I am responsible for the scientific and ethical conduct of the research and providing all reports and information to the IRB, as well as other related groups. I further confirm that I am not in violation of UCR’s conflict of interest policy while participating in this research. All members of the research team are appropriately credentialed and trained to perform the work undertaken and all the research-related activities. I will provide all continuing review documentation to the IRB.**

**Researcher’s signature ----------------------------------------------- Date: -------------------**

**My signature as UCR faculty advisor and/or supervisor, confirms that this study has been designed to protect human participants. I have read and approved all aspects of this proposal. As a UCR faculty supervisor, I am ultimately responsible for the scientific and ethical conduct of the research and providing all reports and information to the IRB, as well as other groups. I further confirm that I am not in violation of UCR’s conflict of interest policy while participating in this research. All members of the research team are appropriately credentialed and trained to perform the work undertaken and all the research-related activities. I will provide appropriate supervision to the undergraduate / graduate student or postdoc.**

**UCR Faculty advisor’s / faculty sponsor’s signature ---------------------------------- Date: ------------------**

**My signature as departmental chair, confirms that I am aware of the project and that it has received appropriate review prior to submission to the IRB. In addition, my administrative unit will follow guidelines and procedures to ensure compliance with all relevant UCR, state, federal govern research involving human participants. My signature also reflects the willingness of the department, faculty or division to administer the research funds, if there are any, in accordance with University policies.**

**Department chair signature (If chair is the faculty advisor or it is departmental chair’s research, the Dean should sign below; if it is Dean’s research, no additional signatures are required)**

**Chair’s / Dean’s (or designate’ s) signature ------------------------------------ Date: -------------------**