UC RIVERSIDE | Research and Economic Development

For use by ORI only: Expedited #5 & #7 IRB Designate Approval: APPROVED 8/9/2023 CV	HS-23-031

IRB Application for Use of Human Participants/subjects in research

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

Please Note: Both Principles and Framework Guiding a Phased Approach for Ramp-Up and Ramp-Down of On-Campus Research-Related Activity and Research & COVID-19 Guidance should be reviewed before completion of this application.

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. There are embedded resources and tools on our website and throughout this IRB application. **Hand-written applications will not be accepted.**

1. Title of Research Study

Lights Camera Action: Evaluating the Impact of Randomized Preoperative Instructional Video on Patient Preparedness following Minimally Invasive Gynecologic Surgery

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

Title (e.g., Dr., Mr., etc.): M.D.	Name: Janet Cruz
Department: Obstetrics and Gynecology	
Phone: 844-827-8000	Institutional e-mail: Janet.Cruz@medsch.ucr.edu
Alternate contact (e.g., research coordinator, department administrator) name: Sarah Simko, MD	Alternate contact Institutional e-mail: sarah.simko@medsch.ucr.edu

3. UCR Status

Faculty (50% or f/t) ☒ X Doctoral ☐ Masters ☐ Undergrad ☐ Post-Doctoral ☐
Visiting professor/External researcher ☐ Other ☐ (specify:)

4. UCR Faculty Advisor or Sponsor

a) List the UCR Faculty Advisor or Sponsor. Advisor or Sponsor must meet PI eligibility as defined by UCR Policy #527-3. (Q4a is to be filled out only if the person in Q2 is a UCR student, trainee, postdoc, or visiting scholar; for faculty research, this question should be blank):

Title (e.g., Dr., Prof): Dr	Name: Samar Nahas

Department: Obstetrics and Gynecology	Email: Samar.nahas@medsch.ucr.edu

b) Department Information (for UCR faculty or Faculty advisor)

Department chair name: Samar Nahas, M.D.

5. Key Personnel

Are co-investigators involved in this project? Yes ☒ No ☐
List all key personnel in the Project Roster. This is a separate document that must be attached with this IRB application as an appendix.

6. Training: Provide details on your and the research team's experience with this type of research. Please provide details on study-specific training that will be provided (excluding the online CITI course).

(Max ¼ page)

Janet Cruz, M.D.: Dr. Cruz is a assistant clinical professor in the Department of Obstetrics and Gynecology Medicine of UCR. She is also associate program director of the fellowship in Minimally Invasive Gynecologic Surgery. She completed her fellowship training at University College of Riverside California. Dr. Cruz will be involved in subject recruitment, consent process, research procedures, data collection and data analysis and will have access to subject identifiable research data.

Sarah Simko, MD: Dr. Sarah Simko is a an oncoming first year surgical fellow within the Department of Obstetrics and Gynecology Medicine of UCR. Dr. Simko will serve as a primary investigator of this study, Dr. Simko will be involved in subject recruitment, consent process, research procedures, data collection and data analysis (Dr. Simko will finalize consent) and will have access to subject identifiable research data.

Nayo Macauley, M.S.: Nayo Macauley is a medical degree candidate at UCR serving as a co-investigator on this project. Macauley will be involved and be trained in subject recruitment, consent process and will have access to subject identifiable research data.

Mallory A. Stuparich, M.D.: Dr. Stuparich is the Division Director for Obstetrics and Gynecology at UCR. Dr. Stuparich will be co-investigator for this study. Dr. Stuparich is board certified in Obstetrics and Gynecology. Dr. Stuparich has participated in clinical research for years as a principal investigator and co-investigator. As the co-investigator, Dr. Stuparich will be involved in subject recruitment, consent process and will finalize consent and will have access to subject identifiable research data.

Samar Nahas, M.D.: Dr. Nahas is the lead research for this study. Dr. Nahas is the Department Chair of Obstetrics and Gynecology Division at UCR. Dr. Nahas is board certified in Obstetrics and Gynecology. Dr. Nahas has participated in clinical research for years as a principal investigator and co-investigator. As the lead researcher, Dr. Nahas is responsible for the overall conduct of the study but not limited to the following: Subject recruitment, consent process (Dr. Nahas will finalize consent), research procedures, data collection and data analysis. Dr. Nahas will have access to subject identifiable research data.

7. Funding

a) Is this study funded?

☐ 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: Video will be created using a free application service. The follow up questionnaire and data collection can be completed using free programs.

b) If obtained or applied for, what are the type(s) and source(s) of funding (check all that apply)? If No Funding required, skip to the next question. Please note it is your responsibility to update the IRB if your funding status changes.

☐ Government funding (e.g., NIH, NSF, CDFA, Riverside County, etc.) Source:
☐ Industry (e.g., Pharmaceutical, biotech, etc.) Source:
☐ Non-profit sponsor (e.g., AHA, Bill & Melinda Gates Foundation, John Templeton, etc.) Source:
☐ Other Source:
☐ Departmental Funds

8. Conflict of Interest review (Promoting Research Objectivity):

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 ☒ X No (If Yes, please contact PRO for a separate review)

9. Additional Reviews

a) 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: Dr. Stuparich, Dr. Nahas
☐ No (NB: IRB recommends a prior scholarly review for studies that are more than minimal risk)
☐ Pending, specify:

b) Will this research require review by any of the following (check all that apply):

☒None – UCR IRB is the only approval required
☐Other (e.g., UCR or non-UCR entities – such as UC Reliance Registry, SMART IRB or another IRB) *Specify entity and status of review*:
☐ UCR Institutional Biosafety Committee (IBC): Research using biohazardous materials including any human-derived materials such as blood, body secretions, and tissues, primary and established cell lines
☐ UCR Stem Cell Oversight Committee (SCRO): Research using human pluripotent cells
☐ UCR Institutional Animal Care and Use Committee (IACUC): Research using vertebrae animals

II – Study Summary

10. Abstract (suitable for a lay audience)

(Max ¼ page)

In this study we will evaluate the impact of a pre-operative instructional video for patients undergoing a minimally invasive gynecologic surgery. The video will educate patients to understand what to expect and how to take care of themselves after the procedure. The effectiveness of the video will be evaluated via a questionnaire to see if patient's who watched the video had better recovery outcomes, greater understanding, and less anxiety when compared to the group of patients who did not watch the pre-operative video.

11. What is the scholarly rationale for this study?

(Max ½ page)

Minimally invasive gynecologic procedures are considered lower risk than highly invasive surgeries, however, any surgical procedure can be a source of anxiety and fear for patients (1). Studies show that pre-operative videos for various procedures can reduce patient anxiety and increase patient satisfaction (2). Pre-operative video education was shown to increase understanding of their operation and lessen feelings of uncertainty in patients who received a lumbar puncture. Another study found that interaction between the patient and physician in addition to a video was more effective than an interview alone or interview with written material when measuring patient satisfaction and the amount of information gained (3). This is important because pre-operative anxiety and confusion can lead to poorer outcomes and recovery post- surgery. We want to add to this collection of data and see if the same results appear when pre-operative audio-visual material is shown to patients before they undergo their scheduled minimally invasive gynecologic surgery.

12. What are the study hypotheses or research questions?

(Max ¼ page)

1. Will the patients who watch the pre-operative will show decreased anxiety and uncertainty about their procedure when compared to the control group?
2. Will increased understanding of the information shared in the video result in less pain medication usage, less ambiguity and thus increased compliance with post-operative care instructions, and quicker recovery?

III – Study Design and Methodology

13. Study Timelines

Estimated start date for involvement of participants: Upon IRB Approval
Estimated completion date for the involvement of participants: *6 –9 months.*

14. Location of Research

a) 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.

(Max ¼ page)
UCR Women's Health Clinic. Letter of access from Paul Hackman attached

b) If research is taking place within a community or an organization, 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. Attach any relevant supporting documentation as appendices.

(Max ¼ page)
N/A

15. Participant Population: Please describe the participants/subjects. List the inclusion/exclusion criteria. Include any age, language, gender, or race-related inclusion/exclusion criteria and provide a justification for the use of these criteria. If applicable, please provide a rationale for your choice in sample size and/or sample size calculation.

If you are conducting research in languages other than English, translated versions of the participant-facing research materials (e.g., informed consent, recruitment materials, measures, etc.) must be submitted for review along with the Certificate of Translation form.

(Max ¼ page)
Participants/Sample Size: Female patients who have been recommended for minimally invasive gynecologic surgery. A total of 100 patients will be enrolled in this study at UCR Women's Health Clinic. Statistical power. To rationalize the consideration of statistical power, we determined that 100 subjects will be needed to predict a difference of improvement in patient's post-operative experience ranges 20% or greater.

Inclusion criteria:

- Age 18 – 65 years old
- Surgery with UCR Gynecology physician
- Laparoscopic/robotic surgery
- Same day discharge after surgery
- Can read a survey in English
- Female

Exclusion Criteria:

- Receiving postoperative chemotherapy in the 6-week postoperative period
- Minors under the age of 18

- Postoperative overnight stay
- Laparotomy (open surgery)
- Pregnancy

16. Special Populations

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.

(Max ¼ page)

17. Recruitment: Describe the mode of communication and how participants will be approached. Any recruitment materials, e-mails, & scripts must be submitted for review as appendices.
If you are recruiting participants through a subject pool (e.g., Psychology Department subject pool), please refer to the UCR Policy on the Use of Subject Pools in Human Subjects Research.

(Max ¼ page)
All patients undergoing surgery will be asked to participate in the study. No PHI would be needed for randomization. Patients will be approached in the office setting once they have decided to proceed with surgical management. The surgeon, fellow or clinical research team will approach the participants. Please see the roster for a list of participants involved in the consenting process. They will be handed a "study info" pamphlet that describes the purpose, methods and involvement of the study. The participants will then be scheduled for a preoperative visit. All patients who decide to have surgery are scheduled for a preoperative visit in our office, and patients will be reminded of the study and asked if they want to participate. If consent is granted, the patient will be randomized to receive the preoperative instructions verbally or via an instructional video." The surgeon, fellows and clinical research team are part of the research team.

18. Compensation: Will participants be compensated for their time? Describe the methods, amount and schedule for payment. What will happen to compensation if participants chose to withdraw? If no compensation is being offered, please justify why.

(Max ¼ page)
There is no patient compensation. The study involves no cost to subject participation.

19. Reimbursement: Will participants personally incur any expenses as a result of participation (e.g., fuel, missed work)? If no reimbursement is being offered, please justify why.

(Max ¼ page)

Patients will not incur any expenses as a result of participation.

20. Procedures

a) Describe 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.

(Max ½ page)

Patients will be invited to participate in the study by principal investigator or co-investigator or designated study personnel (Appendix Project Roster) when the patient will be undergoing a minimally invasive gynecologic surgery.

Patient will be consenting in the clinic and randomization will take place the same day patient consent is obtained.

The study group of patients will come to the clinic on the day of their surgery and be asked to watch the informational video about what to expect after their procedure and instructions on how to recover. They will be encouraged to ask their provider any follow up questions. The instructional video is approximately 10 minutes long.

The control group of patients will receive the standard patient education in place before the procedure and will also be able to ask to follow up questions from their provider.

Both groups will be scheduled for their routine two-week postoperative visit. Some patients schedule a telehealth postoperative visit, if a telehealth visit is scheduled, then a text or email will be sent. If the patient comes in person, the option of filling out the questionnaire in paper form, receive text or email to complete the survey. The survey will take approximately 10 minutes to complete.

Our primary outcomes will be patient level of satisfaction with the education they received prior to surgery and its impact on post-operative care which will be measured by the standardized likert scale (1 to 5 scale where 1 = strongly disagree and 5= strongly agree). The survey will include the following objective and subjective measures: Tylenol tablets used (over two weeks), Ibuprofen tablets used (over two weeks), pain scale (1 to 5 scale where 1 = none and 5= very severe). Additional information will be collected from the patient's medical records (ie. office visit notes, telephone encounters, hospital laboratory results, pain medication refill requests). Patients should continue any medication regimen as instructed by their physician up to the day of surgery. Patients will be treated for complications as they would have been treated otherwise. Study duration period will be approximately six months.

b) If you are using a dataset, please list out the variables you will be accessing. If you are using the Psychology Subject Pool, please list out the pre-screening data you will be collecting on your participants.

(Max ½ page)

Chart review data: Age, Ethnicity, BMI, Smoking status, Narcotic use before surgery, Pain levels before surgery, Preop hemoglobin, Indication for surgery, Surgical procedure, Diagnosis, Presence of other pain disorders such as Interstitial cystitis, fibromyalgia, Intraoperative complications,

and Intraoperative blood loss.

REDCAP Database will be used for the following purposes:

- Data collection
- Sending links to view the video and questionnaire to patient(s)

21. Deception

a) Does this study involve deception or intentional lack of disclosure?

☐ **Yes** ☒ **X 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. If NO, skip to the next question.

(Max ¼ page)

22. Research Results: 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.

Individual results will not be shared with subjects.

23. Consent Process - Ensure you are following the UCR Informed Consent Guide. Sample Informed Consent Templates can be found on the ORI Resources page.

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.

(Max ¼ page)
Consenting Process:

Patients will be approached when they are scheduling their surgery. Subject will be encouraged to take as much time as necessary to decide on participation on the study. They will be allowed to take an unsigned consent to review and discuss with family member. Subjects will be informed that no matter what they decide regarding participating, the care received from the physician will not be affected. Subjects will be randomized on the same day patient informed consent is obtained.

b) If you are applying for a waiver of documented consent (e.g., verbal, online, etc.) or a waiver or alteration of the consent process (e.g., not obtaining consent at all), please explain how you are meeting the conditions for the waiver or alteration as outlined in the UCR informed Consent Guide.

(Max ¼ page) N/A

24. 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.

(Max ¼ page)
N/A

25. Withdrawal: 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 if data has already collected (e.g. previous data will be kept, all data will be destroyed, etc.)?

(Max ¼ page)
Participants ~~or legal representatives~~ will be informed of their right to withdraw from the study at any time, verbally and via the written informed consent form. If the patient wishes to withdraw from the study, the data collected will be discarded.
Participants may be withdrawn at any time during the study, until its completion, at which point the de-identified data will not be able to be withdrawn because the identifying data will have been destroyed and link between coded and records is deleted, projected end 2024. Also, published coded/de-identified data will not be able to be withdrawn.
Procedures for withdrawal will be as follows: access to the key code by approved personnel on the project roster, removal of that coded data from all files, shredding of written records, deletion of electronic records.

26. Privacy, Confidentiality & Data

a) 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:

(Max ¼ page)
Patient identifying data will be provided via the informed consent and will include name, date of birth, medical record number, address, phone number, email address, and an alternate contact if the patient or legal representative is unavailable. A study number, for example given by REDCAP will be given to each subject P01, with "P" representing patient with a numerical value thereafter will be transcribed on the consent form and the medical questionnaire. The coded medical questionnaire will be completed for pertinent medical history. The documents with identifying information (consent form, HIPAA), will be placed in a sealed envelope for collection, or saved electronically on a password-protected drive, and stored in the office of the clinical PI

b) 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 storage of electronic identifiable information outside of a secure server environment, UCR requires the use of encryption software.

(Max ¼ page)
All measures will be taken by the study team to protect the confidentiality of every subject's personal health information. All study subjects will be assigned a patient ID. Research data collected will be deidentified and stored in a secured data server with access code protection to access the database. Only certified and designated staff is allowed to access, enter and retrieve the data. All paper format data are stored in a secured location with locks to prevent Reporting of confidentiality. The code sheet/file will be stored separately from all other data for an additional layer of confidentiality protection.

c) Data: Where will the data be stored and for how long? Who will have access to identifying information and for what reason?

(Max ¼ page)
Patient consent forms and will be stored as described in section 26b. The patient consent form will be discarded in compliance with HIPAA policy and procedure once all data is collected and analyzed, which is projected for end 2024. The coded data will be stored and analyzed by personnel on the project roster. De-identified data will be stored indefinitely by UCR personnel on the project roster. the consent document and the HIPAA authorization form should be maintained for six years to be in compliance with HIPAA requirements.

27. Possible Risks

a) 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. Please acknowledge risks even if remote or unlikely.

Physical Risks (e.g., bodily contact, administration of substance):	**☐Yes ☒ No**
Psychological/emotional risks (e.g., feeling uncomfortable or upset):	**☐ Yes ☒No**
Legal risks (e.g., arrest or subpoena):	**☐ Yes ☒No**

b) 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.

(Max ¼ page)

A remote unlikely risk is that the patient could feel more anxiety towards surgery despite the educational videos effort to calm patients concerns. The patient will be validated in her fears and reiterate that the video is meant to improve a patient's understanding regarding upcoming surgery. The patient will also be reassured that she can chose to be removed from the study at any point.

Ethical concerns may be associated with reviewing medical records of each participating patient but in order to prevent release of information improperly, each participating individual including physicians, nurses, receptionists, and the principal investigator will be certified under HIPPA and will properly exercise HIPPA regulations throughout the duration of this research.

- Only members of the study team will have access to the study data
- All study documents will be maintained in a secure location (i.e., a locked cabinet in the locked study coordinator's office [with limited access]) with only authorized research personnel affiliated with the study having access to it
- All electronic data will be stored on a password protected database with encryption, firewall, etc.

28. Possible Benefits

a) Describe possible direct benefits to participants. If there are no direct benefits, please state so. Please note that compensation is not a benefit.

(Max ¼ page)

Taking part in this study may or may not make benefit the subject's health. All reasonable efforts will be made to ensure the safety of each participant by following good medical practice guidelines. Any unanticipated risks will be addressed on a case-by-case basis.

b) Describe possible benefits to communities, society, or scientific knowledge in general.

(Max ¼ page)

The information from this study might help to develop better post operative experience after receiving concise information via video for future patients undergoing similar surgeries.

29. 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)

a) Do you believe your proposed research activities meet the above definition of *'Minimal Risk'*?
☒ X Yes ☐ No

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

(Max ¼ page)

Patients will be counseled on any risks associated with watching the pre-operative video.

The only problems that are anticipated are data collection loss to follow up.

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

c) 30. 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). 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.

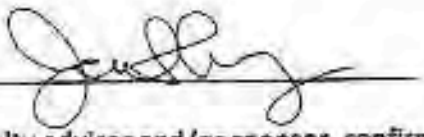
REFERENCES:

1. Soydaş Yeşilyurt, Duygu BSN, MSc; Yildiz Findik, Ümmü PhD, BSN, MSc Effect of Preoperative Video Information on Anxiety and Satisfaction in Patients Undergoing Abdominal Surgery, CIN: Computers, Informatics, Nursing: August 2019 - Volume 37 - Issue 8 - p 430-436 doi: 10.1097/CIN.0000000000000505
2. Snyder-Ramos, Stephanie A. MD*; Seintsch, Henrik*; Böttiger, Bernd W. MD, DEAA*; Motsch, Johann MD*; Martin, Eike MD, FANZCA*; Bauer, Martin MD, MPH* Patient Satisfaction and Information Gain After the Preanesthetic Visit: A Comparison of Face-to-Face Interview, Brochure, and Video, Anesthesia & Analgesia: June 2005 - Volume 100 - Issue 6 - p 1753-1758 doi: 10.1213/01.ANE.0000153010.49776.E5
3. Babapour Mofrad, R., Fruijtier, A. D., Visser, L., Hoogland, N., van Dijk, M., van Rossum, F., Bouwman, F. H., Smets, E., Teunissen, C. E., & van der Flier, W. M. (2021). Lumbar puncture patient video increases knowledge and reduces uncertainty: An RCT. *Alzheimer's & dementia (New York, N. Y.)*, *7*(1), e12127. https://doi.org/10.1002/trc2.12127

IV. Signatures

(If you have already provided signatures for this project in a previous application, there is no need to complete this section again. Electronic or scanned signatures are acceptable. Submitting a single picture/screenshot of all the signatures in place is acceptable. Inserting a jpeg of the signature is also acceptable.)

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: 2/21/23

My signature as UCR faculty advisor and/or sponsor, 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 Mahan Date: 2/21/23

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.

If the 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 Mahan Date: 2/21/23

IRB application submission instructions:

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 Q30 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. 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 and Resources pages.

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