Initial Review Application (IRA) Updates
Impact to Applications

Existing Studies

- No impact until IRA edits are needed
- Use the pencil icon to edit the IRA
  - Previously entered responses carry forward
  - New questions require responses
  - Old questions that have been removed are no longer present
    - Exceptions: Vulnerable Populations have single checkbox remnant

Work in Progress

- Use the pencil to update to the new IRA
- Complete required fields

New Studies

- Click “Start a Wizard” and select “UC Davis - Initial Review Application”
- Complete required fields
Substantial Updates

• Administrative Approval
• Other IRB Project Information ➔ Reliance Section
• Study Information ➔ Ancillary Reviews
• Request for Waiver of Consent ➔ No Consent Process
• Consent Language
• Medical Device(s) Information
• Vulnerable Participants
• Targeted Participants
Key to Document

• Any instructions, questions, or answers removed or rewritten are in [red]
• Any updated or new instructions, new questions, or answers are in [green]
General Instructions

Previous Version

Please download and use the "IRBNet User Manual" in the Forms and Templates Library to complete this application.

All research personnel must complete required training. Please answer all questions. You can save your work, so you do not need to complete the submission in one sitting. When you complete the form, a checklist will appear to assist with compiling required documents. Please update this form as changes are made to this project.

Changes

- Instructional text rewritten for increased submitter understanding

Current Version

Welcome to the UC Davis Initial Review Application (IRA). You should complete one IRA for this project and update the IRA when changes are made to the project. Please review the "Initial Review Application User Manual" for guidance. The IRA is a dynamic form; you may not see all questions that appear in the User Manual.

The IRA does not need to be completed in one sitting. Your work automatically saves each time you advance a page. You can save and exit the IRA at any time. After exiting the application, the Initial Review Application will be listed under the heading "Documents in This Package." Click the pencil icon to re-open the IRA and resume work or make edits. Use the "Jump To" button at the top right of the screen to revisits or make changes to completed pages.

Once complete, the IRA will provide a list of documents that should be submitted for this project. Use this list to build a complete submission.

Warning: Do not click the red X to the right of the document. This will permanently delete your work. Once deleted, it cannot be recovered.
Changes

- **PI Attestation** page has replaced the **PI Assurance** page (previously the last page of the form)
- Instructional text expanded to include itemized list of specific requirements
Administrative Approval page has replaced the HRP-226 Administrative Approvals form

What does this mean for submitters?
- HRP-226 Administrative Approvals form is no longer accepted
- All signatories must provide electronic signature on IRBNet

Back to the list of substantial changes
Principal Investigator Information

Please enter the following information for the PI, Name Name.

**Principal Investigator Information**

**PI Title**

**PI Degrees**

**PI Department**

**PI Department - Other**
If you selected "Other," please specify the PI's department.

**PI Phone**

**PI Email**

**PI Consent**
Will the Principal Investigator be involved in the consent process?

- Yes
- No

**UCD Investigator**
Is the PI listed on this application a UC Davis Investigator (UCD faculty, staff, student, visiting scholar, volunteer, etc.)?

- Yes
- No (Non-UC Davis Investigator - reliance agreement required)
Changes

• Page added to collect institutional information from non-UCD Pis submitted to the UC Davis IRB under a reliance agreement.
Co-Principal Investigator

**Previous Version**

<table>
<thead>
<tr>
<th>Co-Principal Investigator *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there a Co-Principal Investigator? A Co-PI is required for all clinical trials.</td>
</tr>
<tr>
<td>○ Yes</td>
</tr>
<tr>
<td>○ No</td>
</tr>
</tbody>
</table>

**Changes**

- Outdated requirement for all clinical trials to have a Co-Principal Investigator removed
- Instructional text rewritten for increased submitter understanding

**Current Version**

<table>
<thead>
<tr>
<th>Co-Principal Investigator *</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Co-PI can sign IRB submissions after the initial approval and may assume responsibility for research if the PI becomes unavailable. The Co-PI should be from the same institution as the PI. A Co-PI is not required. Is there a Co-Principal Investigator (Co-PI)?</td>
</tr>
<tr>
<td>○ Yes</td>
</tr>
<tr>
<td>○ No</td>
</tr>
</tbody>
</table>
Co-Principal Investigator Information

**Previous Version**

- Co-PI First Name *
- Co-PI Last Name *
- Co-PI Degrees *
- Co-PI Title *
- Co-PI Department *
- Co-PI Department - Other
  If you selected “Other,” please specify the Co-PI’s department.
- Co-PI Phone *
- Co-PI Email *
- Co-PI Obtain Consent *
  Will the co-Principal Investigator be involved in the consent process?
  - Yes
  - No

**Current Version**

- Co-PI First Name *
- Co-PI Last Name *
- Co-PI Degrees (List completed degrees or write “None”) *
- Co-PI Title (Enter the professional title, e.g. Associate Professor, Nurse Manager, PhD Student, Medical Resident, Visiting Scholar, etc.) *
- Co-PI Department *
- Co-PI Department - Other
  If you selected “Other,” please specify the Co-PI’s department.
- Co-PI Phone *
- Co-PI Email *
- Co-PI Consent *
  Will the co-Principal Investigator be involved in the consent process?
  - Yes
  - No
No changes were made to this page

Primary Contact *
Is the Principal Investigator the primary contact for this study?

- Yes
- No
**Changes**

- UC Reliance and UC Reliance Number questions removed
- Questions about UC Davis IRB relying on another IRB or acting as the reviewing IRB for an external site rewritten for increased submitter understanding
- Explanatory text about IRB reliance agreements added
• Many questions from this page have been transferred to other sections of the Initial Review Application.

• Additional questions specific to studies involving reliance agreements have been added to this page.

• The previous Initial Review Application would end immediately after this page for studies involving reliance agreements. The current version will now continue to collect some additional study details.

Back to the list of substantial changes
No changes were made to this page.

Additional Personnel *
Are there additional personnel for this study?

- Yes
- No
Additional Personnel Information

Please provide the following for each additional personnel for this study.

- **Person 1**
  - First Name *
  - Last Name *
  - Degrees *
  - Title *

Consent *
Will this person participate in the consent process?
- Yes
- No

Sub-Investigator *
Is this individual a sub-investigator?
- Yes
- No
Previous Version

**Related Financial Interest**

Do any personnel involved in the design, conduct or reporting of the protocol have a Related Financial Interest?

- Yes
- No

Current Version

**Outside Financial Interest**

Information:

SFI: Significant financial interest (per UC Davis PPM 230-05 III.J) - anything of significant monetary value, including but not limited to salary or other payments for services, equity interests (e.g. stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); or holding a position as an officer, director agent, or employee of a business entity. "Significant financial interest" includes such interests held by a Principal Investigator or other Investigators and by their spouses, domestic partners and/or dependent children.

Related: (per UC Davis PPM 230-05, Exhibit A III.B) When completing the Supplemental Form for a project sponsored by the federal government or other agency for which Form 800 is required, Principal Investigators and other Investigators shall consider all significant financial interests to determine if any are related to the (sponsored) project.

Examples include but are not limited to the following:

1. Financial interest in a business entity that develops, manufactures, or improves a product of offers services related to the research project.
2. Financial interest in a business entity that might manufacture or market a drug, device, procedure, or any other product used in the project that will predictably results from the research project.
3. Consulting income from a business entity where the consulting activity could reasonably appear to be related to the research project.
4. Financial interest in a business entity where the consulting activity could reasonably appear to be related to the research project.
5. Financial interest in a business entity that relates to the intellectual property in which the investigator is named as an inventor if the research project could reasonably appear to be affected by the interest.

Question:

Do any personnel responsible for the design, conduct or reporting of the protocol have any ‘Significant Financial Interests’ (as defined in PPM 230-05 II.G) RELATED to the work to be conducted under the proposed project that was received within the last twelve months or that you expect to receive in the next twelve months? Include financial interests of the spouse, registered domestic partner, or dependent children of such personnel. See examples below. More information about conflicts of interest in human research can be found here.

- Yes
- No
Changes

• Questions eliminated and replaced with directions for submitting appropriate financial interest disclosure forms
Changes

• Questions removed because they did not add value to the review process.

• *Study Procedures* question added to assist in assessing risk level of the research based on procedures required by the protocol.
### Funding Information

#### Previous Version

**Funding Information**

How is this study funded or supported?

- [ ] Industry Sponsored
- [ ] Federal Grant
- [ ] Other Grant
- [ ] Department Funded
- [ ] Other

#### Current Version

**Funding Information**

Here is a list of sponsors from the Project Overview page:

If there is no sponsor for this research, enter the word "Departmental" in the sponsor field on the Project Overview page.

Indicate the type of funding. Select all that apply.

- [ ] Industry Sponsored
- [ ] Federal Grant
- [ ] Other Grant
- [ ] Department Funded or No Funding
- [ ] Other
This page was removed. Sponsor name will be pulled directly from the Project Overview.
Grant Information

Previous Version

Current Version

Federal Funding *
- Yes
- No

Grant Status *
- Funded
- Still seeking funding
- This research is federally funded but the grant was awarded to an institution other than UC Davis
No changes were made to this page

**Other Funding** *

As you selected "Other" as a funding source, please specify.
Clinical Trial Billing ➰ UC Davis Health Billing and Compliance

Changes

• Policy & Procedure 2317 information added
• Question updated, but previous answer will carry forward
Research Location Information

Previous Version

Research Location Information

Research Setting

Resources Available

Current Version

Research Location Information

Research Setting

Describe the locations where recruitment, consent, and research procedures will take place.

Resources Available

Describe any special credentials, licensing, or training needed to perform research procedures. For example: Only trained phlebotomists will conduct blood draws; Physiological assessments will be conducted by certified clinicians, etc. If no specific training is required, write "NA."
Changes

- Question rewritten to increase submitter understanding
### Changes

- Question rewritten to increase submitter understanding
Coordinating Study

This page was removed

Coordinating Study *
Is UC Davis the Coordinating Center for this study?

- [ ] Yes
- [ ] No
This page was removed

Investigator Initiated *

Is this research investigator-initiated?

- Yes
- No
UC Davis Clinical and Translational Science Center

Previous Version

**UC Davis Clinical and Translational Science Center** *

Is this research supported by the UC Davis Clinical and Translational Science Center (CTSC)?

- Yes
- No

Current Version

**UC Davis Clinical and Translational Science Center** *

Is this research supported by the UC Davis Clinical and Translational Science Center (CTSC)? This includes Biostatistical support, REDCap databases, Coordinators for Hire (CCRC), Regulatory support, Study Start-up and management, Clinical Research Center.

- Yes
- No
Changes

• This page has been reformatted and extensive explanatory text has been added to increased connect submitters with groups and committees responsible for ancillary reviews.

• Additional details can be found on the next two pages.

Back to the list of substantial changes
Changes

*Due to the high number of edits, only removed questions are marked on this page.
**Changes**

- **Hazardous Material**
  Split into two questions to ensure appropriate ancillary review.

- **Due to the high number of edits, only new questions are marked on this page.**

### Educational Records
- Does your study involve access to educational records or student health records for research?
  - Yes, FERPA guidance
  - No

### Community Engaged Research
- Does your study involve community participation or community member involvement in study design, implementation, or sharing of results?
  - Yes
  - No

### IT Evaluation
- Does your study involve electronic applications, systems, or devices that collect or transmit Personally Identifiable Information (PII)?
  - Yes
  - No

### UC Davis Campus
- Does your study involve UC Davis campus (on or off campus) or UC Davis specific resources?
  - Yes
  - No

### Material Data Transfer
- Does your study involve the transfer or receipt of tangible research material or non-tangible data from or to another institution, in whole, or in part?
  - Yes
  - No

### Pathology
- Does your study involve the Clinical Laboratory Improvement Amendments, where, or analysis specimen?
  - Yes
  - No

### Prospective Interlocutors
- Does this study involve a defined trial to assist with the most two questions?
  - Yes
  - No

### Effects on Health-Related Outcomes
- Does this study evaluate the effects of an intervention on health-related outcomes?
  - Yes
  - No

### NCT Number
- If applicable, what is the NCT number (ClinicalTrials.gov number) for this study?
Recruitment Information

Previous Version

<table>
<thead>
<tr>
<th>Recruitment Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment Methods *</td>
</tr>
<tr>
<td>Please check any of the following methods that will be used to identify and recruit participants for this study:</td>
</tr>
<tr>
<td>□ Advertising</td>
</tr>
<tr>
<td>□ Medical record review</td>
</tr>
<tr>
<td>□ From a database of participants who have given prior permission to be contacted for research studies</td>
</tr>
<tr>
<td>□ From personal contact (i.e. patients, former research participants, friends, etc.)</td>
</tr>
<tr>
<td>□ Referrals</td>
</tr>
<tr>
<td>□ Clinical Trials Websites</td>
</tr>
<tr>
<td>□ Internet</td>
</tr>
<tr>
<td>□ Social Media</td>
</tr>
<tr>
<td>□ Other</td>
</tr>
<tr>
<td>Recruitment Methods - Other</td>
</tr>
<tr>
<td>If you selected “Other,” please specify</td>
</tr>
</tbody>
</table>

Current Version

<table>
<thead>
<tr>
<th>Recruitment Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment Methods *</td>
</tr>
<tr>
<td>Please check any of the following methods that will be used to <strong>identify and recruit</strong> participants for this study:</td>
</tr>
<tr>
<td>□ Advertising (flyers, social media, clinical trials websites, etc.)</td>
</tr>
<tr>
<td>□ Medical record review</td>
</tr>
<tr>
<td>□ From a database of participants who have given prior permission to be contacted for research studies</td>
</tr>
<tr>
<td>□ From personal contact (i.e. patients, former research participants, friends, etc.)</td>
</tr>
<tr>
<td>□ Referrals</td>
</tr>
<tr>
<td>□ Other</td>
</tr>
<tr>
<td>Recruitment Methods - Other</td>
</tr>
<tr>
<td>If you selected “Other,” please specify</td>
</tr>
</tbody>
</table>

Study Pages Contact

If your study is a clinical trial at UC Davis it will automatically be posted to UC Davis Study Pages to advertise for recruitment. Provide the email address of the study team’s primary contact for subject recruitment.

Changes

• Question rewritten to increase submitter understanding
Changes

- Answer choices expanded to increase submitter understanding.
- Answers will carry forward for existing research.
# Waiver of HIPAA Authorization

## Previous Version

**Waiver of HIPAA Authorization**

You will need a Waiver of Research Authorization to use or share private health information for this research or for recruitment. Please answer the following questions so the IRB can make the determinations needed to approve this waiver.

**Protected Health Information**

Does the use or disclosure of PHI involve no more than a minimal risk to the privacy of the individual based on at least the presence of the following? Please confirm below.

- [ ] Only authorized persons will be given access to the identifiers and/or data-storage devices will be encrypted and password protected; identifiers maintained in paper format will be kept in a locked area accessible by only research staff who require access.
- [ ] I will destroy the identifiers at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or as otherwise required by law.
- [ ] Protected health information from this research will not be released or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI.
- [ ] I will use Quick Disclosure Activity in EMR to track all medical records accessed as defined by P&P 2446.

**Elements of Health Information**

Please list the specific elements of health information for which you are requesting the waiver.

**Reasons for the Waiver**

What specific information will this waiver cover and why do you need this waiver to be able to conduct the research?

## Changes

- Research team now attests to following Policy & Procedure 2446

## Current Version

**Waiver of HIPAA Authorization**

You will need a Waiver of Research Authorization to use or share private health information for research or recruitment. Please answer the following questions so the IRB can make the determinations needed to issue this waiver.

**Protected Health Information**

Does the use or disclosure of PHI involve no more than a minimal risk to the privacy of the individual based on at least the presence of the following? Please confirm below.

1. [ ] I confirm that minimum necessary information is accessed under this waiver. If this is a partial waiver for recruitment, only information required for recruitment purposes. If this is a full waiver for the study, all information required for the research will be included.
2. [ ] I confirm that any authorized persons will be granted access to the identifiers, identifiers stored on computers, electronic notebooks, mobile devices, or data storage devices will be encrypted and password protected; identifiers maintained in paper format will be kept in a locked area accessible by only research staff who require access.
3. [ ] I confirm that all identifiers will be destroyed at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or as otherwise required by law.
4. [ ] I confirm that protected health information from this research will not be released or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI.
5. [ ] I will use Quick Disclosure Activity in EMR or the Disclosure Tracking Database to track all medical records accessed as defined by P&P 2446.

**HIPAA Waiver Rationale**

- [ ] No

If you selected “Other”, please explain why you will not obtain prior authorization.
No changes were made to this page

**Screening Scripts**
Are you using any written or verbal screening scripts to screen participants prior to obtaining consent (such as telephone call scripts, web-based questionnaires, etc.)?

- [ ] Yes
- [ ] No
Consent

Changes

• Answer choices rewritten to increase submitter understanding, but previous answer will carry forward.
### Previous Version

**Request for Waiver of Signed Consent**

You indicated that you want the IRB to waive the requirement for a signed consent form. To help the IRB determine whether the signature can be waived, please answer the following:

**Minimal Risk Rationale**
Please explain how this research involves only minimal risk.

### Current Version

**Information Sheet or Oral Consent Request**

You indicated that there will be no signed consent document. To help the IRB determine if this is appropriate, please answer the following:

**Written Consent**

Does the research involve any procedures for which written consent is usually required?
- [ ] Yes
- [ ] No

**Consent Document**

Is the consent document the only document linking the participant to the research?
- [ ] Yes
- [ ] No

**Confidentiality**

Is the only risk involved with this research to the participant’s confidentiality?
- [ ] Yes
- [ ] No

**Distinct Cultural Group**

Are the research subjects members of a distinct cultural group or community in which signing forms is not the norm?
- [ ] Yes
- [ ] No
### Previous Version

**Request for Waiver of Consent**

You indicated that you want the IRB to waive the requirement for consent. To help the IRB determine whether consent can be waived, please answer the following:

**FDA Regulation**
- Is this research regulated by the FDA? (If yes, consent cannot be waived.)
  - Yes
  - No

**Minimal Risk Rationale**
- Please explain how this research involves only minimal risk.

**Participants’ Rights**
- Please explain how waiving consent does not adversely affect the participants’ rights.

**Reasoning for Waiver**
- Please explain why this research cannot be conducted without this waiver.

### Current Version

**No Consent Process**

You indicated that you will not obtain informed consent from participants. To help the IRB determine if this is appropriate, please answer the following:

**Rationale for No Consent Process**
- What is your rationale for conducting this project without consent from participants? Select all that are true:
  - The research team will have no direct contact with potential research subjects.
  - Obtaining consent could pose a risk to subjects’ privacy, physical safety, or psychological wellbeing.
  - Failure to obtain a complete or representative data set would prevent this study from drawing reliable conclusions.
  - Other

**Rationale for No Consent Process - Other**
- If you selected "Other", please explain why you will not obtain consent.

---

[Back to the list of substantial changes](#)
Consent Process

This page was removed

Consent Process *
Will you follow HRP-090 and HRP-091 when obtaining consent?

- [ ] Yes
- [ ] No
Consent Language

Previous Version

<table>
<thead>
<tr>
<th>Consent Language *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will you be enrolling participants who are unable to speak or read English?</td>
</tr>
<tr>
<td>☐ Yes</td>
</tr>
<tr>
<td>☐ No</td>
</tr>
</tbody>
</table>

Current Version

<table>
<thead>
<tr>
<th>Consent Language *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information: When preparing your study for initial review, consider whether you may enroll individuals who cannot read the English consent document because their native language is not English. Generally, any research that holds the prospect of direct benefit should allow the enrollment of those unable to read English. There are two processes available to enroll subjects who are unable to read English because it is not their native language:</td>
</tr>
<tr>
<td>- Translated Documents</td>
</tr>
<tr>
<td>- Short Form Consent Process</td>
</tr>
<tr>
<td>Question: Is it possible you will enroll participants who are unable to speak or read English?</td>
</tr>
<tr>
<td>☐ Yes, open to non-English speakers</td>
</tr>
<tr>
<td>☐ No, non-English speakers will be excluded</td>
</tr>
</tbody>
</table>

Changes

- A statement that, in general, any research that holds the prospect of direct benefit should allow enrollment of participants who cannot speak or read English has been added.
- Explanatory text related to how to enroll participants who cannot speak or read English has been added.
- The question on this page has been clarified for increased understanding.
- Answers will carry forward for existing research.

Back to the list of substantial changes
Changes

• Instead of justifying the inclusion of non-English speaking subjects as in previous versions of the Initial Review Application, the IRB is requesting justification for the exclusion of non-English speaking subjects.

• The inclusion of non-English speaking subjects, particularly in research with the prospect of direct benefit, is aligned with the basic ethical principle of justice found in the Belmont Report.
Language Barriers

Overcoming Language Barriers *
How will you (1) conduct the consent discussion in a language understandable to the participant; and (2) conduct ongoing communication with the participant throughout the research and in case of emergency?

☐ At least one member of the research team is fluent in the language that will be used for communication and will be available during emergencies;

☐ The research team has 24-hour access to a translation service with sufficient medical expertise to discuss the research in this study;

☐ Other

Overcoming Language Barriers - Other
If you selected "Other", please specify

Translation of Consent Form *
Will you have the consent form (and other approved documents) translated into a language the participant(s) can understand?

☐ Yes

☐ No
Compensation for Participation

Previous Version

Compensation for Participation

Compensation *
Will the participants receive payment for participation in this research?
- Participants will be compensated for their time.
- Participants will be reimbursed for their expenses.
- Participants will not be compensated or reimbursed.

Total Compensation
What is the total compensation participants may receive?

Pro-ratiation of Compensation
How will this compensation be pro-rated? (e.g. XX per visit)

Form of Payment
When and how (form of payment) will participants be compensated?

Current Version

Compensation for Participation

Compensation *
Will gifts, payments, compensation, reimbursement or extra credit be provided to the research participants?
- Participants will be compensated for their time.
- Participants will be reimbursed for their expenses.
- Participants will not be compensated or reimbursed.

Total Compensation
Indicate the maximum amount (excluding reimbursement for travel) research participants may receive? If different groups receive different amounts, please explain.

Form of Payment
When and how (form of payment) will participants be compensated?

Pro-ratiation of Compensation
If compensation will be prorated, provide the amount of compensation per visit/procedure:
Drugs and Biologics

Previous Version

**Drugs and Biologics**

Are drugs, biologics or dietary supplements used for research purposes in this study?

- Yes
- No

Current Version

**Drugs and Biologics**

*Information:*

The risks of all drugs specified by the protocol must be described in the consent document. This includes investigational drugs and other drugs required for participation in this research. You must submit a package insert for all drugs required by the protocol with this application.

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.

Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.) From FDA *glossary of terms.*

*Question:*

Are investigational drugs, biologics or dietary supplements being studied in this project? Mark "Yes" only if the research involves a drug that is not FDA-approved or is being used outside of its approved labeling; this is an investigational drug.

- Yes
- No

**Changes**

- Explanatory text added to increase submitter understanding
Full screenshots not included for space considerations. Update limited to addition of *Long-term monitoring* question.
Clinical Trial Phases

Previous Version

Clinical Trial Phase *
Please indicate the phase of this clinical trial:
- Phase I
- Phase I/II
- Phase II
- Phase II/III
- Phase III
- Phase IV
- This is not a clinical trial

Current Version

Clinical Trial Phase *
Please indicate the phase of this clinical trial:
- Phase 0
- Phase I
- Phase I/II
- Phase II
- Phase II/III
- Phase III
- Phase IV
- This is not a clinical trial/Other
Medical Devices

Changes
- Explanatory text has been added to this page.
- Clarification that only medical devices that are:
  - not FDA-approved,
  - not approved for use as described in this research,
  - or are operating under an Investigational Device Exemption (IDE)
require a “Yes” answer.
Medical Device(s) Information

Changes

• This page has been reformatted and extensive explanatory text has been added to facilitate accurate completion.
• Several questions have been removed because the information is captured elsewhere.

Back to the list of substantial changes
International Study

Previous Version

International Study *
Will you conduct or oversee research outside of the US?

☐ Yes
☐ No

Current Version

International Study *
Will you conduct or oversee research outside of the US? Please note, collection of research data using online data collection tools targeting participants outside the US is international research.

☐ Yes
☐ No
Changes

• Question replaced with instructional text

International Study Information

Previous Version

International Study Information *
How will you comply with the requirements for the conduct of research in locations outside of the US? For information: International Studies

Current Version

International Study Information *
For greater than minimal risk research, UC Davis IRB require PIs to obtain approval from local ethics boards (like an IRB) in the country where the study is taking place (or where subjects reside, if conducted online). For information on ethics boards in other countries visit http://www.hhs.gov/ohrp/international/

If a local ethics board is not accessible or does not review your type of research, an approval from a local authority can be accepted. This may be from someone that has local authority to approve such type of research or another research institution in the country who understands this type of research. The authority should comment on whether or not this research is appropriate and meets local standards.

In addition, if this research involves access to or collection of identifiable data from persons within the European Union or the European Economic Area you must comply with GDPR.

If this research is greater than minimal risk, research activities may not begin until approval from a local ethics board or local authority is acknowledged by the UC Davis IRB.
Monitoring for Safety and Compliance

Previous Version

Monitoring for Safety and Compliance
Research that is greater than minimal risk must be monitored for safety and compliance.

Method for Monitoring Safety *
How will this research be monitored for safety?

- Medical Monitor
- Data Safety Monitoring Committee
- Not Applicable/Minimal Risk

Review of Data
Please describe your monitoring plan.

Monitoring of Compliance *
Will this study be monitored for compliance? Please confirm.
- Yes
- No

Current Version

Monitoring for Safety and Compliance
Research that is greater than minimal risk must be monitored for safety and compliance.

Method for Monitoring Safety *
How will this research be monitored for safety?

- Medical Monitor
- Data Safety Monitoring Board or Committee
- Not Applicable/Minimal Risk
- Other

Review of Data
Provide the section of the monitoring plan in the research protocol or describe your monitoring plan.
Number of Participants

**Previous Version**

**Number of Participants**

*Enrolled means: Consented, meets inclusion and exclusion criteria, and are scheduled to participate/or have participated in the research in accordance with protocol. For charts/records that will be reviewed and specimens to be collected/obtained, please provide the total number that will be reviewed.*

**Study-Wide**

Number of anticipated participants enrolled study-wide.

**Locally**

Number of anticipated participants enrolled locally (under UC Davis PI Oversight).

**Current Version**

**Number of Participants**

A subject is enrolled when they have provided consent, met inclusion and exclusion criteria, and is scheduled to participate/or has participated in the research in accordance with protocol.

For secondary analysis research (record review, specimen analysis), enter the projected number of individuals whose information or specimens will be analyzed or studied at this site.

**Local Enrollment Numbers**

How many participants do you plan to enroll in this study at this site?
Vulnerable Participants

Previous Version

Which of the following categories of vulnerable participants will be recruited/enrolled into your study?

- Children
- Pregnant Women/Fetuses
- Neonates
- Prisoners (prisoners in California may not be included in clinical trials or other biomedical studies)
- Cognitively Impaired Adults
- Students of the principal investigator
- Employees of UC Davis
- None of the above

Current Version

For all studies, if the research is limited to only secondary analysis (record review, specimen analysis), no special considerations are required, select “None of the above/NA” for this question.

Will this study be open to enrolment of any of the following categories of participants? These participants may not be enrolled without specific IRB approval.

- Children
- Neonates (infants less than four weeks old)
- Prisoners (prisoners in California may not be included in clinical trials or other biomedical studies)
- Cognitively Impaired Adults
- None of the above/NA

Changes

- Instructions updated to clarify that protections do not apply for research limited to secondary analysis of data or specimens
- Page has been changed to include only subjects who cannot participate in research without specific IRB approval

Back to the list of substantial changes
Changes

- These groups have been moved from previous page
- Participants who belong to the groups listed on this page may participate in research without special IRB approval, but if members of these groups are specifically targeted as part of the research, then the IRB must take this into account during review.

Back to the list of substantial changes
Changes

- Examples of minimal risk and greater than minimal risk procedures added
- Submitters will no longer be asked to determine if signature from one or two legal guardians will be required since this is ultimately determined by the IRB
- Justification for not obtaining children's legal guardian(s) for participation in research has been added to this page
- The *Obtaining Assent from Children* and *Justification For Not Obtaining Assent* sections were edited to focus specifically on whether assent will be obtained and a justification for any cases when assent will not be obtained
These pages were removed.

<table>
<thead>
<tr>
<th>Minimal Risk to Children *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please explain how this research presents no more than minimal risk to the children.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Greater Than Minimal Risk Rationale *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please explain how this research involves greater than minimal risk.</td>
</tr>
</tbody>
</table>
Prospect of Direct Benefit Rationale

Previous Version

Prospect of Direct Benefit Rationale

Please explain how the research presents the prospect of direct benefit to the children.

Current Version

Prospect of Direct Benefit Rationale

Describe the anticipated benefits for children who participate in this research.

Changes

- The instructions for this page have been clarified for increased understanding.
Changes

• The instructions for this page have been clarified for increased understanding.
Relation of Anticipated Benefit to Risk

Changes

- The instructions for this page have been clarified for increased understanding.
No Prospect of Direct Benefit Rationale

Please explain how this research involves a minor increase over minimal risk.
Experiences Presented by Intervention

Previous Version
Experiences Presented by Intervention
Please explain how the intervention presents experiences to the children that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

Current Version
Experiences Presented by Intervention
Explain how participation in this research is equivalent to what participants will experience outside of this research in their actual or expected medical, dental, psychological, social, or educational situations.

Changes
- The instructions for this page have been clarified for increased understanding.
Generalizable Knowledge

Changes

- The instructions for this page have been clarified for increased understanding.
Cognitively Impaired Adults

**Previous Version**

**Cognitively Impaired Adults**

Determining Capacity for Consent

Describe your process for determining whether an adult has capacity to consent.

California Requirements for Surrogate Consent

Will you follow California requirements for surrogate consent?

- Yes
- No

Assent from Cognitively Impaired Adults

Will assent be obtained from all adults who lack capacity to consent and are capable of assenting?

- Yes
- No

Obtaining Consent When and If Subject Regains Capacity

Will you obtain consent from the participant when they regain capacity?

- Yes
- No

**Current Version**

**Cognitively Impaired Adults**

Determining Capacity for Consent

Describe your process for determining whether an adult has capacity to consent.

HRP.013

Review UC Davis Human Research Program Standard Operating Procedure: Legally Authorized Representative, Children, and Guardians (HRP-013), which describes the requirements for identifying an appropriate representative when obtaining consent from a Legally Authorized Representative (LAR).

HRP.090

Review SOP: Informed Consent Process (HRP-090) for information about consent and assent requirements for adults unable to consent.

Assent from Cognitively Impaired Adults

Will assent be obtained from all adults who lack capacity to consent and are capable of assenting?

- Yes
- No

Obtaining Consent When and If Subject Regains Capacity

Will you obtain consent from the participant when they regain capacity?

- Yes
- No
Justification for Inclusion of Students or Direct Reports

**Previous Version**

Justification for Inclusion of Students

If these are your students, please justify their inclusion and describe how you will reduce undue influence and coercion. If these are not your students, please mark N/A in the textbox below.

**Current Version**

Justification for Inclusion of Students or Direct Reports

Justify the inclusion of the PI's students or direct reports and describe how you will reduce undue influence and coercion.
These pages were removed because the information is captured in the HRP-503 Protocol templates.
Data Confidentiality

Previous Version

Data Confidentiality *
I confirm that only authorized persons will be granted access to the identifiers; identifiers stored on computers, electronic notebooks, mobile devices, and/or data-storage devices will be encrypted and password protected; identifiers maintained in paper format will be kept in a locked area with access limited only to research staff who require access to conduct the study.

☐ Yes
☐ No

Current Version

Data Confidentiality

Identifiable Data *
Once data has been collected or received by this PI, how will it be maintained?
The data will be:

☐ Identifiable - Data or specimens will be labeled with identifying information.
☐ Coded with linking key – Data will be stripped of identifiers and assigned a code. The research team will maintain a key that links the identifiers to the data set.
☐ Coded without linking key – Data will be stripped of identifiers and assigned a code. The research team will not have access to a key that links the identifiers to the data set and will not attempt to re-identify the data.
☐ All identifiers will be destroyed. There will be no way to link the data to an individual.

Data Protection *
Only authorized persons should be granted access to participants’ identifiable information. Indicate how you will protect research subjects’ identities and information. For research involving the access, use or disclosure of Protected Health Information, please contact the Biomedical Informatics Department for assistance with data security. Select all that are true:

☐ Identifiable data maintained paper format and/or specimens labeled with identifiers will be kept in a locked area with limited access.
☐ Identifiable electronic data will be maintained on a password protected, encrypted device.
☐ Identifiable electronic data will be maintained on a password protected secured cloud service appropriate for the sensitivity of data collected.
☐ NA - No identifiable data or specimens will be created or stored for this research.

Name of Cloud Service
If you are using a cloud service, provide the name of the cloud service.

Data Transfer Protections
If you will be transferring data between locations, describe your plan to protect the data (for example, using lock boxes or locked cars when conducting field work or transferring data between sites).

Sensitive Data *
If the confidentiality of the research data were compromised, could it reasonably place subjects at risk of criminal or civil liability or otherwise be damaging to the subjects’ financial standing, employability, educational advancement, or reputation?

☐ Yes
☐ No
NOTE: Each study’s list of required documents is based on study details and responses to questions.
Questions?

Contact the IRB Help Desk

Send Email