Human Research Protections (HRP) strives to ensure that people with disabilities have access to all services and content. If you experience any accessibility-related issues with this form or any aspect of the ZOT IRB application process, email OR-Web-Support@uci.edu for assistance.

 INSTRUCTIONS

This information is necessary for the IRB to determine if the UCI should serve as the Reviewing IRB (i.e., single IRB or sIRB) for multi-site research and for cooperative researchin compliance with [45 CFR 46.114](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.114) and considering HRP-833. For more information, visit: [UCI is the Reviewing IRB](https://research.uci.edu/human-research-protections/single-irb-process/uci-is-the-reviewing-irb/).

Answer all questions succinctly using non-technical language as much as possible.

* If a question is a numbered list, respond with a corresponding numbered list.
* If a question is not applicable to the research, state “N/A”.
* If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary “back and forth” for clarification.

**To avoid administrative delays related to establishing sIRB agreements, address the sIRB request after initial approval is granted for the UCI site**. Attach this appendix and other supplemental documentation (see [UCI IRB Submission Requirements](https://research.uci.edu/human-research-protections/single-irb-process/uci-is-the-reviewing-irb/)) in the “Manage Participating Sites” feature. The attachment section will appear in the second step of the process when the status is “Awaiting Site Materials”.

 1. STUDY INFORMATION

**Short Title:** Specify the short study title.

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| Click or tap here to enter text. |

**Reviewing IRB Rationale:** Review [Eligibility: UCI is the Reviewing IRB](https://research.uci.edu/human-research-protections/single-irb-process/uci-is-the-reviewing-irb/) and provide the rationale for UCI to serve as the Reviewing IRB.

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| Click or tap here to enter text. |

 2. RELYING INVESTIGATOR INFORMATION

**Relying Investigator Information:** For each Relying Investigator, use the table below to provide their information and responsibilities on the study. *List only one lead investigator per site, insert additional rows as needed.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Location** | 1. **Investigator’s name, title, and degrees**
2. **Department**
3. **Email and phone number**
 | **Will the investigator’s study team be involved?** | **Does the investigator or their study team have a financial conflict of interest (COI)?** | 1. **List the research activities or procedures to be performed by the investigator or study team.**
2. **Specify the investigator’s relevant qualifications (training, experience) to perform research activities.**
 |
| Click or tap here to enter text. | Click or tap here to enter text. | [ ]  Yes[ ]  N/A | [ ]  Yes*\**[ ]  No | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | [ ]  Yes[ ]  N/A | [ ]  Yes[ ]  No | Click or tap here to enter text. |

*\*Attach the external location’s COI management plan.*

**Communication:** Describe how the Relying Investigators will be provided with a copy of the UCI IRB approved study documentation (i.e. protocol, recruitment, consent, etc.) throughout the duration of the study.

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| Click or tap here to enter text. |

 3. LOCATION INFORMATION

**Location Information:** For each external (not UCI) location, use the table below to provide location information. *List only one relying location per row, insert additional rows as needed.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Location and state** | 1. **Specify if the location participates in SMART IRB v3.0 and if not, explain.**
2. **Specify if the location has an IRB and specify the quality assurance mechanism (e.g. AAHRPP, OHRP, Internal QA, etc.).**
 | **Specify if medical records from the location are accessed, used, or created and if so, specify if the location has a HIPAA Privacy Board.** | **Specify if any ancillary committee approvals (e.g., RSC, IBC) are required at the location and attach their approvals.** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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**Research Outside California:** For each location outside of California, specify if there are any applicable state or local laws, regulations, or policies that are relevant to the research.

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| Click or tap here to enter text. |

**Clinical Research Resources:**

1. Specify the resources available at each external site to treat emergencies resulting from study-related procedures.
2. Describe how will the drugs/agents used in the study be managed at the external location.
	1. Specify the name and title of the pharmacist/responsible person for the drugs/agents at the external location.
	2. Specify how the above individual is provided with a current copy of the protocol.

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| Click or tap here to enter text. |