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](mailto:OR-Web-Support@uci.edu) for assistance.

INSTRUCTIONS

This information is necessary for the IRB to determine if research conducted outside the United States (US) or with participants located outside the US is appropriate. For more information, visit: [International](https://www.hhs.gov/ohrp/international/index.html) and [International Compilation of Human Research Standards](file:////ohrp/international/compilation-human-research-standards/index.html) .

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.

1. STUDY INFORMATION

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

|  |
| --- |
| Click or tap here to enter text. |

2. COUNTRY INFORMATION

**Country:** Specify name of countries and locations where research will be performed.

|  |
| --- |
| Click or tap here to enter text. |

**International Regulations:** Select all that apply and address the required action, as applicable.

|  | **International Regulations** | **Required Action** |
| --- | --- | --- |
|  | [General Data Protection Regulation](https://research.uci.edu/human-research-protections/assessing-risks-and-benefits/privacy-and-confidentiality/european-union-general-data-protection-regulation/): European Union (EU) / European Economic Area (EEA), United Kingdom (UK), Iceland, Liechtenstein, or Norway | Insert the [Consent Language: General Data Protection Regulation (GDPR)](https://research.uci.edu/wp-content/uploads/informed-consent-gdpr.docx) into the consent document. | |
|  | [Personal Information Protection Law](https://research.uci.edu/human-research-protections/assessing-risks-and-benefits/privacy-and-confidentiality/china-personal-information-protection-law/): China | Insert the [Consent Language: China’s Personal Information Protection Law (PIPL)](https://research.uci.edu/wp-content/uploads/informed-consent-pipl.docx) into the consent document. | |
|  | **Office of Foreign Assets Control (OFAC)** [sanctioned countries, individuals and/or entities](https://research.uci.edu/export-controls/international-collaborations/sanctioned-embargoed-countries/) | Research cannot begin until a license is obtained from [Export Controls](https://research.uci.edu/export-controls/). *This process can take several months*. | |
|  | **Other** | **Specify and provide web address of the regulation.** | |

|  |
| --- |
| Click or tap here to enter text. |

**Ethics Committee:** Specify if the international location have an Institutional Review Board (IRB) or an equivalent ethics committee. *Attach to ZOT IRB: IRB/ethics committee approval letter for the research or a letter from them waiving the requirement for their review.*

|  |
| --- |
| Click or tap here to enter text. |

**Cultural Norms:**

1. Explain how the cultural norms differ compared with U.S. culture in respect to research autonomy, consent, recruitment, confidentiality, etc.
2. Include an explanation of the cultural sensitivities that will be required to conduct this study; consider current events (include additional documentation if necessary).

|  |
| --- |
| Click or tap here to enter text. |

**Community Invitation:** Specify UCI researchers been invited into the community and why.

|  |
| --- |
| Click or tap here to enter text. |

3. STUDY TEAM QUALIFICATIONS

**Qualifications of UCI Study Team:**

1. Describe researcher qualifications (e.g., relevant coursework, past experience, training) to conduct human subjects research in an international setting.
2. Specify if researchers speak/read/write the language of the potential participants.
   1. If researchers cannot, explain how recruitment, the informed consent discussion and data collection will take place
3. Explain how the researcher(s) have knowledge of local community attitudes to mitigate the cultural norms and remain in compliance with U.S. regulations for research.

|  |
| --- |
| Click or tap here to enter text. |

**UCI Oversight:** Describe how UCI researchers (including medical faculty, as applicable) will actively oversee the research project, including supervision of the research team (e.g., the Principal Investigator will hold bi-weekly video meetings with the study team to review research data, answer questions, etc.)

|  |
| --- |
| Click or tap here to enter text. |

**Onsite:** Specify who will be physically present at the research site, their role in the research, and how long they intend to be present at the location.

|  |
| --- |
| Click or tap here to enter text. |

4. RESEARCH ACTIVITIES

**Engagement:** Specify whether the international investigator and/or an international site is [engaged](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) in human subjects research activities (e.g., interact with participants; have access to identifiable information) and their level of engagement.

|  |
| --- |
| Click or tap here to enter text. |

**Medical Records:** If the research involves access to participant medical records, explain whether the country has regulations that protect access to medical records for research purposes (i.e. HIPAA in the U.S) and explain how the researchers will adhere to the country’s requirements.

|  |
| --- |
| Click or tap here to enter text. |

**Therapeutic Research:** If the research is therapeutic (i.e. medical, psychological, physical, etc.), describe what provisions have been made to provide continued access to the therapeutic intervention after completion of the study.

|  |
| --- |
| Click or tap here to enter text. |

**Clinical Care:** If the research involves clinical care, please address the following:

1. Describe how the research may address an important scientific question regarding the host community/ country.
   1. If applicable, describe how the proposal is responsive to local health needs of the host community/country.
2. Describe both the standard of care in the US and the available standard of care/alternatives in the host community/country.
3. If UCI medical students/residents are performing clinical procedures, clarify if it within the guides of what they would be allowed to do as a medical student/resident.
4. Describe how any incidental findings will be handled, including who will confirm the findings and how results will be conveyed to the participant.
5. In some countries, the type and level of clinical care provided to participants may not be available to them outside of the research context.
   1. Describe how will the research team minimize the likelihood participants will believe mistakenly that the purpose of the research is solely to provide treatment rather than to contribute to scientific knowledge.
   2. **Clarify whether there has been an effort to secure continued access for all participants to needed experimental interventions that have been proven effective at the conclusion of the project.**
6. Explain whether, if proven effective, the procedures will be available to the country population.
   1. If procedures will be available to the country, describe any pre-negotiations among sponsors, host country officials, and other appropriate parties aimed at making interventions available after the research.
   2. If procedures will not be available to the country, explain why.

|  |
| --- |
| Click or tap here to enter text. |

**Access to Study Data:** Describe any arrangements will be in place for the study data to be available to the participant population at the conclusion of the study.

|  |
| --- |
| Click or tap here to enter text. |