

California State Polytechnic University, Pomona
Institutional Review Board -- Office of Research Compliance
*Federalwide Assurance 00001759 -- IRB principles: respect for persons, beneficence, and justice*

**International Research with Human subjects**

**Use the following checklist as a guide for submitting a cayuse IRB application for international research.**

When conducting international research, Cal Poly Pomona and its researchers must ensure that these activities not only meet the ethical and legal requirements for conducting research at Cal Poly Pomona or other domestic sites, but also respect the cultural norms and research regulations in the host country. Consider the elements listed below when developing research documents, and ensure that all applicable information is included within the IRB submission, citing documents and page number when available.

**Research Oversight**

*Address this in the Cayuse IRB application.*

|  |  |  |
| --- | --- | --- |
| Complete | N/A |  |
|  |  | Provide the name and contact information/website of the IRB, ethics committee, or government entity that is providing review of the study in the host country [Study collaborators **may not** be involved in the review and approval of the study]. *Submit approval letter or provide information about the status of the local review.* *This requirement may also be applicable to Exempt research depending on the regulations in the host country. Please contact the IRB to discuss.* |
|  |  | If there is no formal review body, or if the local research regulations do not require review, provide a letter of support from a local expert or authority, and a description of the local laws/regulations governing research.*This requirement may also be applicable to Exempt research. Please contact the IRB.* |
|  |  | If the study is funded or supported by a US federal agency: Provide the [FWA numbers](http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc) for all international sites engaged in the research. *This requirement does not apply to Exempt research.* |
|  |  | If the study is funded or supported by a US federal agency: Provide the IRB registration numbers for all IRBs providing oversight for this study. *This requirement does not apply to Exempt research.* |
|  |  | If the study will employ or collaborate with individual investigators or institutional investigators at non-assured organizations that do not routinely conduct research, request an Individual Investigator Agreement (IIA) for these individuals. *Provide documentation of COI disclosure and completed educational requirements for each individual investigator.* |
|  |  | Provide the name and contact information of a person not affiliated with the research who has expertise on the local context of the country or community where the research will be conducted. *The IRB may contact this person as a content expert.* |

**Local Context**

*Consider how features of the host country/community may impact conduct of the research. Address this in the Cayuse IRB application.*

|  |  |  |
| --- | --- | --- |
| Complete | N/A |  |
|  |  | Specify the cities, regions, countries where research activities will be conducted. Include the names of specific institutions, if applicable. |
|  |  | Scientific/ethical justification for conducting the research in an international setting |
|  |  | Economic status of the country/community  |
|  |  | Current events or socio-political environment in the country that may impact research conduct or alter the risks or benefits to subjects |
|  |  | Societal and cultural beliefs in the country that may impact the research or alter the risks or benefits to subjects |
|  |  | The role of women and children in the society, including their autonomy and legal capacity to make decisions |
|  |  | Relevance of the research to the area’s health, economic, educational, or other needs |
|  |  | Description of the research team’s knowledge of or experience in the host country |
|  |  | Describe the involvement of organizations, community leaders, or experts in engaging the subject population or conducting the research |
|  |  | Distribution of risks and current and future benefits |
|  |  | Detail any proposed remuneration (payment, gifts, incentives, etc.) for subjects including:1. Specific description of the remuneration (payment, gifts, incentives, etc.)
2. Value both in US and local currency
3. Local household income information (e.g. how much an average household earns in a month or a year in US and local currency)
4. When remuneration will be given during the study (the payment schedule)
5. To whom remuneration will be given
6. Whether the remuneration could pose undue influence on the subject’s decision to participate.
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**Consent Process**

*Consider how features of the host country/community may impact the consent process. Address this in the Cayuse IRB application.*

|  |  |  |
| --- | --- | --- |
| Complete | N/A |  |
|  |  | Submit all information that will be presented to subjects during the course of the study; this material must be reviewed and approved **before** use. This includes, but is not limited to recruitment material, consent documents, educational or instructional material, hand-outs, presentation, or scripts.  |
|  |  | Provide justification for any requests for a waiver of written consent; describe how consent will be documented.  |
|  |  | If minors will be enrolled in research, provide the legal age of majority and describe an appropriate process to obtain parental permission and minor assent consistent with the local context.  |
|  |  | Describe how the research team will address any additional consent processes, if there are expectations of familial or community consent in addition to individual consent.  |
|  |  | If the research intersects with any cultural sensitivities or societal norms, explain how this will be addressed in the consent process, in ICFs and other study documents.  |
|  |  | Ensure that all study documents are written in simple, readable language, while clearly communicating the purpose of the research; take into account the literacy and education levels of the study population. |
|  |  | For non-exempt research, ICFs and study documents must be translated in the language/dialect of the participating subjects. Do not submit translated documents at the time of initial submission. Translations must be based on IRB approved English versions. |
|  |  | The translation of ICFs and study documents should be performed by qualified translators, and credentials must be submitted to the IRB (only 1 research team member may be involved in translation; the other translator(s) must be independent).  |
|  |  | The research team must provide subjects with locally-based and US-based contact information. Select contact information that will ensure subjects have access to individuals who can answer research-related questions, even after the research team has left the host country. |

**Post-Approval Responsibilities**

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| Complete | N/A |  |
|  |  | Describea data and record retention plan consistent with Cal Poly Pomona HS IRB policies, and that makes study documents *accessible* for inspection and copying by authorized representatives of the IRB and/or federal agencies whether the records are maintained in the host country or in the US. |
|  |  | Describe a plan to provide Cal Poly Pomona IRB with reports of serious adverse events and unanticipated problems in accordance with IRB reporting timelines (CPP IRB P&P).  |
| *The PI and research team members must be prepared to meet the following responsibilities once study approval has been granted.*  |
|  | Promptly submit to the IRB: Reports of non-compliance, protocol deviations, subject complaints, study updates, correspondence with the local oversight body, and data/safety monitoring reports. |
|  | Ensure that members of the study team and international collaborators are kept aware of the approval status of the protocol and ensure that they are using current study documents. |
|  | For student projects, there must be a well-defined plan or schedule to ensure communication and oversight between the advisor and student during the conduct of the research. |
|  | The PI must ensure proper conduct of the protocol and compliance with US and international regulations. If Cal Poly Pomona is the primary awardee of a grant for the overall project, the PI is responsible for overseeing the research of any international collaborators. |
|  | Request modifications to the approved protocol from both Cal Poly Pomona IRB and any local oversight bodies **before** initiating any changes in the research.  |