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Cultural Evaluation of International Research for Human Subjects Research Protocol



Instructions and Certifications

Complete this form if the research will take place in at an **international location or setting**, and the circumstances require an evaluation of cultural context.

By signing this Cultural Evaluation of International Research for Human Subjects Research Protocol (Cultural Evaluation), the Principal Investigator (PI) and the Evaluator(s) certify the following:

1. The evaluation(s) provided are the sole work product of the Evaluator(s); the Evaluator(s) is qualified to make the assessment; and
2. Have read and reviewed this Cultural Evaluation; certify the accuracy of its contents; any applicable supporting documentation has been included as an attachment; have signed this Cultural Evaluation electronically.

After completing the foregoing, submit the Cultural Evaluation with supporting documentation via email to the IRB Mailbox:

irb@tamucc.edu

For questions, email:

research.compliance@tamucc.edu

Subject Recruitment; Consent; Risk; Additional Considerations or Recommendations

Evaluate the following areas of the Human Subjects Research Protocol (HSRP) for cultural context. Provide explanation. Include supporting documents as attachments if necessary.

Subject Recruitment

- Is the method of recruitment culturally appropriate?
- Is the setting for recruitment procedures culturally appropriate?
- Are recruitment instruments (e.g., flyer, email) culturally appropriate?
- If offering compensation, is the amount/form of payment coercive to participants?

Evaluation:

Consent

- Is the language and tone used in the consent form or information sheet understandable to the participants?
- Will the format of consent process intimidate or confuse participants?
- Does the setting of the consent process allow for adequate privacy?

Evaluation:

Risk

- Are additional safeguards required to protect the rights and welfare of subjects?
- Could altering some of the procedures lower the risks to participants from a cultural perspective? If so, explain.

Evaluation:

Additional Considerations or Recommendations

Evaluation:

Evaluator Information

Name:

Address:

Email:

Phone:

Signature: