Reed College

Institutional Review Board (IRB)

Appendix B

Research with Non-English-Speaking Participants and/or with Participants outside the U.S.

**SECTION I: RESEARCH INVOLVING NON-ENGLISH-SPEAKING SUBJECTS**

All subjects of your study, regardless of their knowledge of English, need to understand their role and rights as participants. When conducting research involving non-English-speaking subjects, you must plan to manage communications with participants in each stage of your study. In addition to recruitment and consent, this includes study visits, questions, and unexpected issues. You must be prepared to communicate with participants throughout your study.

Communications with non-English-speaking subjects must be translated and/or interpreted by a person who is fluent in both English and the subject’s language. If you do not have this ability yourself, you can engage the services of a qualified translator (for written communication) and/or interpreter (for oral communication).

Communication with non-English-speaking participants, even for studies conducted in the U.S., can also be impacted by cultural differences. Awareness of these differences can help to minimize potential miscommunications.

1. Will you enroll non-English-speaking subjects in your study?

**(If not, please skip to Section II.)**

2. In what language(s) will your research be conducted?

3. Are you fluent in this language? If not, will a translator and/or interpreter be used?

4. If a translator and/or interpreter will be used:

 a. What are their qualifications?

 b. How will they be trained to maintain confidentiality?

 c. Will use of a translator and/or interpreter pose additional risks to

 participants?

 d. How will these risks be minimized?

5. Please indicate how any written communications, including informational materials, consent documents, and research instruments will be translated.

6. Please indicate how any oral communications, including information, oral consent, study visits, follow-up questions, and communication about unexpected issues will be interpreted.

7. Please outline your knowledge of the culture of potential non-English-speaking participants, and how you intend to minimize potential miscommunication resulting from cultural differences.

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**SECTION II: RESEARCH INVOLVING SUBJECTS WHO ARE LOCATED OUTSIDE THE UNITED STATES**

Research involving subjects who are located outside the United States must comply with U.S. and international standards of ethics, as well as with local regulations. Such research also requires knowledge of local culture and context, and awareness of how participants’ national, racial, ethnic, and/or linguistic groups may differ from yours. Depending on the location and nature of your research, your study may require review by an IRB or equivalent ethics committee in the host country or countries.

1. In what countries outside the U.S. will your subjects be located?

2. Will any of your subjects possibly be located in the European Union (EU), European Economic Area (EEA), or United Kingdom (UK)?

 [ ]  Yes [ ]  No

3. Will any of your subjects possibly be located in the People’s Republic of China (PRC)?

 [ ]  Yes [ ]  No

4. Will your subjects’ data be anonymous (or anonymized after collection)?

[ ]  Yes [ ]  No

If your subjects will be located in the PRC **and** their data will not be anonymous or anonymized, please explain how you plan to obtain participant consent to transfer personally identifiable data from the PRC to the U.S.

**If your research involves any of the following methods of data collection, you must fill out questions 5–8. Others may skip these questions.**

1. **in-person research within any country outside the US**
2. **online research in the PRC, in which data is not anonymous or anonymized**
3. **online research in the EU, EEA, or UK, regardless of anonymization**

5. Has your research proposal undergone review by an IRB or equivalent ethics committee in the host country or countries? If so, please submit a copy of this review with your IRB application. If such review is not possible or appropriate, please provide a rationale.

6. Please outline your knowledge of the local context and culture in which you will conduct research.

7. Please identify any additional risks participants might face as a result of the study’s local context and/or within the local culture, and how you intend to minimize these risks.

8. Please specify whether and how research data will be transferred between countries, including any procedures in place to maintain confidentiality.