**Application Supplement D**

D.0 International Research or Research with Non-English-Speaking Subjects

You need to fill out this Supplement if

1. Your research will include non-English-speaking subjects, or
2. Your research will take place outside the United States

D.1 Site and Contact Information

|  |  |
| --- | --- |
| Research Site: | Contact person in country or community where research will be conducted: |
| Agency or institutional affiliation of the contact: | E-mail, phone, and/or other means to reach contact person: |
| If research presents greater than minimal risk, describe how you will be able to maintain contact with the IRB to report adverse events while abroad: | |

**D.2 International Research:** Will you be conducting research outside of the United States?

No. If no, skip to D.3

Yes. If yes, answer the following three questions:

**D. 2.1** Have you and all investigators completed the CITI module “International Studies”:  No. Stop. Do not complete Supp D until you and all investigators on the research team complete the module.

Yes

**D.2.2** Collaboration**:** Will you be collaborating with an institution in the country that will be engaged in the research?

No.

Yes.

**D.2.3** Local Approval: Your project must be approved by an in-country IRB or local equivalent. If approval has already been granted, explain how the approval was obtained. Upload evidence of local approval with your Mentor application. If approval has not been granted, describe your plan to obtain local approval.

|  |
| --- |
|  |

**D.3 Language**: Will any of the subjects be unable to understand English?

No. If no, skip to D.4

Yes. If yes, answer the following three questions:

**D.3.1** What is the primary language(s) of your subjects?

**D.3.2** All recruitment and informed consent materials, as well as all survey instruments, must be translated into a language that is comprehensible to the subjects. The IRB Manual Section 7.6 provides detailed options for complying with translation requirements. After studying the options, describe which method you will follow in detail.

|  |
| --- |
|  |

*English versions of all materials must be uploaded to Mentor. After IRB approval these materials must be translated and translations also uploaded to Mentor.*

**D.3.3** How well do you speak/write this language?

Native speaker  Very fluent  Moderately fluent  Not well or at all

If multiple languages are needed for your project, indicate your fluency level in each relevant language:

**D.3.4** Will you utilize the services of an interpreter?

No. Mark this box only if you are more than “moderately fluent.”

Yes. If yes, answer the following four questions:

**D.3.4.1** How will you utilize the services of an interpreter (e.g., recruitment, consent process, data collection)?

|  |
| --- |
|  |

D.3.4.2 How will you ensure that the interpreter maintains confidentiality?

|  |
| --- |
|  |

D.3.4.3 If you do not speak the language well, how will your subjects be able to reach you if they have questions or concerns during or after participating in the study?

|  |
| --- |
|  |

D.4 Local Research Context: Describe how your research project, especially the informed consent process, takes into account the cultural norms or local laws of the research context with respect to autonomy of individuals, or groups, recruitment techniques, age of majority, if parent consent is required etc. Include an explanation of what cultural sensitivities will be required to conduct this study.

|  |
| --- |
|  |

D.5 Cultural Competence: Describe any prior experience in the local research context. If you have limited experience, how have you educated yourself on the cultural norms and local laws in this context? For example, have you retained a cultural consultant to advise you about the appropriateness of the research for the culture?

|  |
| --- |
|  |

D.6 Access: Have you secured an invitation into the community, and if so, by whom? Provide documentation of the invitation/correspondence by pasting a copy of the information into this text box. If not, how will you gain access to the community?

|  |
| --- |
|  |