

International Research Protocol Addendum

The following information is required by the Einstein IRB in order to obtain information about the cultural and legal context within which the proposed international research will be conducted, and the processes in place to address the unique context.

If information requested in this form is described within the protocol, the relevant protocol page number(s) may be entered instead.

1. **LOCATION AND ADMINISTRATION**
2. Name of the affiliated Principal Investigator:
3. Location in which study is to be conducted:
4. Explain the rationale for including international sites in this research:
5. Describe the experience of affiliated investigators with international research in this location:
6. Describe the collaboration with local partners (e.g. researchers, universities, community leaders):

1. If you are a student or trainee, will your mentor be with you in-country?
2. Describe the division of responsibilities between affiliated and local investigators using the following table:

|  |  |
| --- | --- |
| **Einstein Staff Responsibility** | **Local Site Staff Responsibility** |
| Obtaining Local IRB/Ethics Board Approval  |
|  |  |
| Local Site Staff Selection and Training |
|  |  |
| Local Site Participant Recruitment  |
|  |  |
| Local Site Enrollment and Consenting of Participants |
|  |  |
| Study Interventions at Local Site |
|  |  |
| Data/Specimen Collection and Management  |
|  |  |
| Local Site Monitoring and Reporting  |
|  |  |

1. **Regulatory Information and Local Context**
2. State any local/international laws that impact the proposed study:
3. Will the research be reviewed by a local IRB or ethics committee?
4. Describe the cultural norms and customs as they relate to the research:

Please be sure to include information such as cultural norms around consent (e.g., the importance of communal decision-making), the age at which individuals can provide their own consent to participate in research, the average literacy level and level of education of the study population, or any social, economic, or political concerns regarding the research.

1. For research involving drugs or devices, describe the healthcare system available to the community/study population (i.e. average distance and availability of transport to treatment facilities, hours of operation, availability of health insurance):
2. For research involving drugs or devices, how does treatment of participants on study compare to the local standard of care for this condition/disease?
3. **RECRUITMENT AND CONSENT**
4. Describe the proposed recruitment process.
5. Is the compensation being offered consistent with local wages or local standard of living?
6. Have you received local input on the compensation?
7. Describe the proposed consent process, including local cultural and legal considerations in obtaining informed consent of research volunteers. (e.g. proxy consent by tribe elder, or consent required from husbands, assent in children, thumb print in lieu of signature, etc.).
8. **ADDITIONAL MEDICAL CARE (for research involving drugs or devices)**
9. Describe the medical care that will be available to volunteers in the event of a research-related injury, including who will provide the care, the duration of the care and the cost of this care to the subject.
10. Does the study require a plan for continued health care, medications, and/or referral to the local health care providers after the completion of the study? \_\_\_ Yes \_\_\_ No

If yes, describe the plan.

1. If relevant, do you plan to offer the study drug treatment to placebo-arm subjects after the study is completed? \_\_\_ Yes \_\_\_ No

If yes, describe the plan.