**GUIDE 631: Transnational Research Checklist**

This checklist is intended to help researchers and IRB members to ensure that adequate provisions are in place for research conducted outside of the United States. The following topics should be discussed in the IRB application.

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Local Research Context** | | | |
|  | Yes | No | N/A |
| Foreign research locales |  |  |  |
| Justification for foreign locales |  |  |  |
| The investigator's local knowledge |  |  |  |
| Consultation with local communities |  |  |  |
| Local contact information for persons who can answer research-related questions—including local emergency contact information—if applicable |  |  |  |
| Local contact information for persons who can answer questions about participants’ rights—e.g., local IRB or EC |  |  |  |
| 1. **Consent Process** | | | |
|  | Yes | No | N/A |
| Local customs or culture where the participant may not have autonomy to consent |  |  |  |
| How a person will voluntarily participate in research if the person will not be consenting |  |  |  |
| The literacy level of the population |  |  |  |
| Payment and its relation with the local economy and the participants' income |  |  |  |
| Local languages |  |  |  |
| Whether written consent documentation will be obtained; if applicable, translation of the written documentation or justification for oral consent process |  |  |  |
| 1. **Privacy and Confidentiality** | | | |
|  | Yes | No | N/A |
| Local customs or culture that requires research data to be revealed to someone other than the participant |  |  |  |
| 1. **Local Approval / Oversight** | | | |
|  | Yes | No | N/A |
| Local permissions required to conduct the research |  |  |  |
| Collaborating sites and their roles |  |  |  |
| Collaborators and their institutional affiliations, roles in the research, and scientific qualifications |  |  |  |