WORKSHEET: Additional Criteria International

Research Administration

This worksheet is used to determine whether non-exempt <Human Research> conducted international can be approved.

<table>
<thead>
<tr>
<th>Considerations</th>
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<td>All criteria in 2 must be met</td>
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1. Considerations
   1.1 Is the approval of (a) governmental agencies or officials; (b) a local IRB/ethics committee; or (c) other local officials required to conduct research in this country (or countries)?
   1.2 Is there a local IRB or ethics committee that will review this research?
   1.3 Are there any laws regarding human subject research in the country where the research will be conducted?
   1.4 Are there any laws in the country addressing whether vulnerable populations such as indigenous persons, children, pregnant women, and cognitively impaired individuals can be enrolled in research?
   1.5 Are there any laws or culturally specific norms that we must be aware of with respect to obtaining informed consent?
   1.6 Are there any professional codes (or medical ethics codes if applicable) that govern the conduct of researchers in this country?
   1.7 Are there requirements for compensating subjects who are injured as a result of participating in research?

2. Requirements
   2.1 The IRB has appropriate expertise and knowledge of the country either through membership or consultants
   2.2 The investigators and research staff are qualified to conduct research in the country
   2.3 Communication and coordination with local IRBs is in place when appropriate
   2.4 Procedures for the following are the same as for domestic research:
      • Initial review, continuing review, and review of modifications.
      • Knowledge of local laws.
      • Post-approval monitoring.
      • Handling of complaints, non-compliance, and unanticipated problems involving risk to participants or others.
      • Consent process and other language issues.

3. Notes