

## WORKSHEET: Additional Criteria International

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

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**All criteria in 2 must be met**

### 1. Considerations

1.1	<input type="checkbox"/>	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	<input type="checkbox"/>	Is there a local IRB or ethics committee that will review this research?
1.3	<input type="checkbox"/>	Are there any laws regarding human subject research in the country where the research will be conducted?
1.4	<input type="checkbox"/>	Are there any laws in this country addressing whether vulnerable populations such as indigenous persons, children, pregnant women, and cognitively impaired individuals can be enrolled in research?
1.5	<input type="checkbox"/>	Are there any laws or culturally specific norms that we must be aware of with respect to obtaining informed consent?
1.6	<input type="checkbox"/>	Are there any professional codes (or medical ethics codes if applicable) that govern the conduct of researchers in this country?
1.7	<input type="checkbox"/>	Are there requirements for compensating subjects who are injured as a result of participating in research?

### 2. Requirements

2.1	<input type="checkbox"/>	The IRB has appropriate expertise and knowledge of the country either through membership or consultants
2.2	<input type="checkbox"/>	The investigators and research staff are qualified to conduct research in the country
2.3	<input type="checkbox"/>	Communication and coordination with local IRBs is in place when appropriate
2.4	<input type="checkbox"/>	Procedures for the following are the same as for domestic research: <ul style="list-style-type: none"> <li>• Initial review, continuing review, and review of modifications.</li> <li>• Knowledge of local laws.</li> <li>• Post-approval monitoring.</li> <li>• Handling of complaints, non-compliance, and unanticipated problems involving risk to participants or others.</li> <li>• Consent process and other language issues.</li> </ul>

### 3. Notes