Checklist For Non-Exempt, Minimal Risk Research Conducted in Foreign or Culturally Different Sites

The sections below are additional concerns that relate directly to non-Exempt, Minimal Risk transnational research activities. Investigators and IRB members are to use this checklist as a tool to ensure appropriate review and approval of research at international sites. If you have any questions, please email us at askirb@pitt.edu.

		Yes	No	N/A
1.	The investigator has listed each foreign site where research will be conducted (items CS15.0 and 2.19.1)	☐	☐	☐
2.	If **foreign ethics review is required** under foreign regulation or policy, the investigator has provided an approval letter from the local IRB or ethics committee. (item 2.19.1) **OR** the Pitt IRB approval letter contains standard language indicating research may not begin at the foreign site until a Modification is submitted to and approved by the Pitt IRB to provide documentation of foreign ethics approval.	☐	☐	☐
3.	If **foreign ethics review is not required** under foreign regulation or policy, the investigator provided a Memo of Cultural Appropriateness and a Letter of Acknowledgement of Unregulated Research Activities. (Item 2.19.1)	☐	☐	☐
4.	If the research is being conducted in a non-public setting, within a designated facility or institution (i.e. clinic, hospital, school, church, community center), the investigator has provided a site permission letter/authorization to conduct research at the site (items CS15.0 and 2.19.1).	☐	☐	☐
5.	The investigator has listed the names and qualifications of collaborator(s) at each site. (2.19.1)	☐	☐	☐
6.	The investigator has indicated the anticipated number of subjects to be enrolled at each foreign site. (item 2.19.1)	☐	☐	☐
7.	If Federally funded, the investigator has provided the FWA number assigned to the foreign site (item 2.19.1)	☐	☐	☐
8.	The investigator has described any licenses, permits or other permissions necessary for the procedures to be performed at the foreign site. For example, licensure for clinical procedures or permits for drugs, devices or technology being brought into the foreign country (item 2.19.1)	☐	☐	☐
9.	The investigator has provided a description of the size and adequacy of the foreign site where research procedures will be performed (item 2.19.1).	☐	☐	☐
10.	The investigator has satisfactorily answered question 2.19.1.1 which addresses knowledge of local laws and cultural context in all locations where the research is conducted.	☐	☐	☐

11.	The investigator has described any aspects of the local cultural, political or economic climate that might increase the risks of harm for either local participants or researchers and the steps that will be taken to minimize these risks. (item 2.19.1.2)	☐	☐	☐
12.	If the study involves non-English speaking participants and **does <u>not</u> involve clinical procedures**, all documents research participants will interact with have been translated into foreign languages and a signed translator certification form is included. Translations are <u>not</u> required to be completed by a certified translator. (item 2.19.2.1) **OR** the approval letter contains standard language indicating foreign language documents cannot be used until a Modification is submitted to and approved by the Pitt IRB to provide the translated documents and signed translator certification form.	☐	☐	☐
13.	If the study involves non-English speaking participants and **does involve clinical procedures**, all documents research participants will interact with have been translated into foreign languages, back translated into English and a signed translator certification form is included. Translations are <u>not</u> required to be completed by a certified translator. (item 2.19.2.1) **OR** the approval letter contains standard language indicating foreign language documents cannot be used until a Modification is submitted to and approved by the Pitt IRB to provide the translated documents and signed translator certification form.	☐	☐	☐
14.	Consent process is appropriate (e.g., local collaborators obtaining consent, use of interpreters, alternate methods to document consent). (items 2.19.2 & 4.12)	☐	☐	☐
15.	Consent process respects local custom (permission may obtained from local leader but individual consent must be obtained from participant except if a waiver is approved). (items 2.19.2 & 4.12)	☐	☐	☐
16.	Participants are provided with the appropriate contact information (e.g., local contact person in that country, Pitt Human Subject Advocate number with country code). (information sheet or consent form)	☐	☐	☐
17.	When appropriate, compensation for injury language is included in the consent form. UPMC compensation language should **<u>not</u>** be included. The foreign site may have required language. (information sheet or consent form)	☐	☐	☐
18.	If **foreign ethics review is required** under foreign regulation or policy and the study provides compensation, the OSIRIS application describes the planned amount of compensation in both US and foreign currency and provides information regarding the average daily wage in the foreign country (item 6.2). (Ethics approval from the foreign country implies that compensation is permitted).	☐	☐	☐
19.	If **foreign ethics review is <u>not</u> required** under foreign regulation or policy and the study provides compensation, the OSIRIS application describes the planned amount of compensation in both US and foreign currency and provides information regarding the average daily wage in the foreign country (item 6.2) **<u>and</u>** the Letter of Acknowledgement of Unregulated Research Activities specifically indicates that the laws and regulations of the foreign country permit research participants to receive monetary compensation for their time. (Item 2.19.1)	☐	☐	☐