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| --- | --- | --- | --- | --- |
|  |  | **Yes** | **No** | **N/A** |
|  | The investigator has listed each foreign site(s) where research will be conducted (items CS15.0 and 2.19.1) | [ ]  | [ ]  | [ ]  |
|  | 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 the study team submits documentation of foreign ethics approval to the Pitt IRB via the ‘Send Comments to IRB’ function in OSIRIS and the Pitt IRB responds affirming the study may now begin at the foreign site. | [ ]  | [ ]  | [ ]  |
|  | 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) | [ ]  | [ ]  | [ ]  |
|  | 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). | [ ]  | [ ]  | [ ]  |
|  | The investigator has listed the names and qualifications of collaborator(s) at each site. (2.19.1) | [ ]  | [ ]  | [ ]  |
|  | If Federally funded, the investigator has provided the FWA number assigned to the foreign site (item 2.19.1) | [ ]  | [ ]  | [ ]  |
|  | 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 technology being brought into the foreign country (item 2.19.1) | [ ]  | [ ]  | [ ]  |
|  | 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).  | [ ]  | [ ]  | [ ]  |
|  | 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. | [ ]  | [ ]  | [ ]  |

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|  | **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)** | [ ]  | [ ]  | [ ]  |
|  | If the study involves non-English speaking participants, all documents research participants will interact with have been translated into foreign languages and a signed translator certification form is included. Translations are not 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 the study team submits the translated documents and signed translator certification form to the Pitt IRB via the ‘Send Comments to IRB’ function in OSIRIS and the Pitt IRB responds affirming the documents can now be used. | [ ]  | [ ]  | [ ]  |
|  | Recruitment process is appropriate (e.g., local collaborators explaining the study, use of interpreters). (items 2.19.2 & 4.1) | [ ]  | [ ]  | [ ]  |
|  | Recruitment process respects local custom (permission may obtained from local leader but individuals maintain autonomy in decision to participate). (items 2.19.2 & 4.1) | [ ]  | [ ]  | [ ]  |
|  | Participants are provided with the appropriate contact information (e.g., local contact person in that country, Pitt Human Subject Advocate number with country code). (4.1 Introductory script) | [ ]  | [ ]  | [ ]  |
|  | If 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) **and** 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) | [ ]  | [ ]  | [ ]  |