**Checklist – International/Transnational Research**

PIs conducting research at international sites are expected to provide the same level of subject protections as they would locally. (**Note: Because the culture and customs of other countries may differ from the U.S., be flexible in your consideration of whether the investigator has adequately described his/her plans for providing a high level of participant protections.**)

PI Name:  IRB Number:

Country(ies) where research will be conducted:

Does the PI (or faculty advisor, if applicable) possess the qualifications for conducting research in the country(ies)?  Yes  No

Is the PI (or faculty advisor, if applicable) familiar with local culture/customs/laws?  Yes  No

If “Yes”, explain how:

If “No”, will there be a local collaborator who is familiar with local culture/customs/laws?  Yes  No

Does the PI speak the local language?  Yes  No

If “No”, has the PI adequately identified how communication with participants will be accomplished?  Yes  No

Has there been/will there be a local, regional or national ethics committee (EC) review in the country?  Yes  No

If “No”, does the PI have local, regional or national approval/certification to conduct research (e.g., a letter from appropriate institution or authority)?

Yes  No

If “No”, explain:

Will informed consent/assent/parental permission be obtained?  Yes  No

If “No”, explain why and/or describe local culture/customs for obtaining consent/assent/parental permission:

If “Yes”, will written documentation be obtained?  Yes  No

If “Yes”, does the consent/assent/permission document need to be translated (**Note: Translations may be submitted after the English version is approved as a condition of approval.**)?  Yes  No

If “Yes”, describe how and by whom the form(s) will be translated:

If “No”,is a waiver of the requirement for written documentation appropriate?  Yes  No

If a waiver of documentation is appropriate, has it been requested?  Yes  No

Has the PI adequately described how s/he will assure that participants understand the research procedures, risks, potential benefits, privacy/confidentiality provisions, voluntary nature of participation, etc.?

Yes  No

Are there privacy/confidentiality practices unique to the country’s culture/customs?  Yes  No

If “Yes”, do the practices provide adequate participant protections?  Yes  No

Do you have concerns about the research or researcher(s)?  Yes  No

If “Yes”, describe:

Are protocol or consent process revisions required (Include the requirement for submission of translated consent/assent/permission forms after revision of the English version(s), if applicable)?  Yes  No

If “Yes”, describe: