**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: