Additional information to be included in protocols conducted in another country

For all studies being conducted in a foreign nation, the following information must be included in the protocol, or provided as a written supplement to the protocol or as separate documentation.

Required Information about the site in the foreign nation at which the research will be conducted:

- Site name and location
- Name of PI/Lead site investigator, if collaborating with a foreign institution/local investigators.
- Site PIs employer or institutional affiliation.
- Federalwide Assurance number for the entity conducting the research, if collaborating with a foreign institution/local investigators.

Required information on local IRB/Ethics Committee (EC) review

- Name of IRB/EC conducting review in the foreign nation
- IRB registration and IRB Organization (IORG) number
- Documentation of approval from the in-country IRB/EC. This is required before the NIH IRB can issue a final approval for the research.
- If no in-country IRB/EC, then written assessment of the research for its consistency with foreign country laws and regulations, or local customs and culture, by an individual with appropriate expertise in the foreign country's culture, who is independent of the research team

Required local context information (if not already described in the protocol)

- Rationale and plan for conducting research in the foreign country
- Information about the foreign study population and what is required to enroll them in research, (e.g., legal age at which subjects can provide consent to participate in research, capacity to consent standards, legally authorized representative standards, local processes for obtaining research informed consent, local languages or dialects, and vulnerable populations)
- A description of the foreign country's laws and regulations or local customs that impact the conduct of the proposed research
- Whether the protocol will require, in addition to any necessary local IRB/EC approval, local review and approval by any other in-country entities (e.g., institutions, offices, government departments, Scientific Committees, drug and/or device oversight agencies).

For FDA regulated studies in which any drugs or devices will be shipped by the NIH Investigator from the US to the foreign site:

- Written documentation provided to the NIH IRB confirming that all necessary approvals for use of a test article under local laws have been obtained. Consult with the Office of Research Support and Compliance (ORSC) for questions related to shipping drug products overseas.