JEFFERSON—Office of Human Research

**CHECKLIST FOR INTERNATIONAL RESEARCH**

**Version Date – FOR OHR USE: 5/22/20**

PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Control # (if available):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Instructions:** Please include this checklist in your IRB application to provide information about your international research and to certify that the research adheres to OHR Policy SC 509 pertaining to international research.

Please certify the following:

1. Is the study federally funded? YES\* NO

\* If YES, the regulations of the sponsoring agency apply and the required protections must be provided.

1. Is the study investigating a test article regulated by the FDA? YES\*\* NO

\*\* If YES, study must adhere to FDA regulations pertaining to use, storage, and tracking of the test article.

1. Regardless of whether the research is subject to U.S. federal regulations, the Principal Investigator, and the local Ethics Committee (if serving as the designated IRB), will be guided by at least one of the following statements of ethical principles (must check at least one):

**The Belmont Report**: Ethical Principles and Guidelines for the Protection of Human Subjects or Research of the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Note: The Belmont Report is the foundation of 45 CFR 46, the Common Rule)

**Nuremburg Code**

The World Medical Association’s **Declaration of Helsinki** (as adopted in 2001)

Other appropriate international ethical standards recognized by U.S. Federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule. Please describe:

1. The PI must (check all that apply):

Obtain Jefferson IRB approval.

Establish a reliance agreement with the local Ethics Committee that will assume oversight for the research in the host country.

If an Ethics Committee or other similar review committee does not exist in the host country, obtain a letter of support from a community leader, liaison or official from the institution where the research will take place.

Obtain any other approvals required to conduct research in the country (e.g., national, regional, local).

1. Please describe pertinent issues of local context that may intersect with the research. The IRB will use this information to confirm that the research is culturally appropriate and to determine whether any modifications need be made to make the research more culturally appropriate.

This should include, where pertinent:

* Gender relations
* Age of consent and who serves as legally authorized representative
* Norm of providing consent (written vs. other methods)
* Individual vs. community identity
* Medical taboos
* Economic status of populations to be enrolled
* Other cultural issues pertinent to the research

1. By checking each box below, you confirm that you understand the following:

You will abide by the tenets of Good Clinical Practice as promulgated by the International Congress of Harmonization.

If the facility where the research will be conducted is not under the jurisdiction of the local Ethics Committee, a letter of permission must be obtained from the appropriate individual to conduct research at the facility.

If the research receives federal funding from the U.S., any international institution involved with the research will be required to have a Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) prior to initiation of the research in that country.

Cultural competency and appropriateness. Investigators are required to be knowledgeable about and comply with local laws while conducting their research. They also must take into account local customs and cultural context, which may require them to modify certain aspects of the research. Consultation with researchers or other individuals familiar with the culture in which the research will take place is advised.

Consent forms, scripts or statements must be translated into the native language. These translations should be certified to be accurate and reflect appropriate cultural nuances, and letters of certification in English must be provided to Jefferson IRB.

All documents from the country in question must be translated into English before being provided to Jefferson IRB for the purposes of verification and auditing.

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PI Signature Date