

# MCW Office of Research Standard Operating Procedure

## INTERNATIONAL RESEARCH

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Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

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### PURPOSE:

The MCW IRB reviews international research using the same approval criteria, policies and procedures that are applied to research conducted the domestic U.S.. When the research is sponsored by a U.S. federal agency, the regulations of that agency will also apply.

International research refers to human subject research conducted outside the United States using participants from the local in country community. Such research requires investigators to be aware of the additional requirements that accompany the research, including those of the country in which the research is to be conducted.

Investigators are responsible for ensuring that research performed in other countries meets equivalent levels of protection that would be required in the Investigator's principal location, taking into account local laws and cultural context.

### DEFINITIONS:

**Assurance:** An assurance of compliance is a written document submitted by an institution (not an Institutional Review Board) that is engaged in non-exempt human subjects research conducted or supported by HHS. Through the assurance of compliance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46.

**FWA:** The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by a US federal department or agency. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.

### PROCEDURE:

1. For new projects, investigators will complete the eBridge PRO SmartForm in accordance with the IRB SOP: Submitting New Projects.
  - a. For approved projects which will add an international location where research will be conducted, Investigators must submit an amendment in eBridge along with the identified documents noted below.
2. Regulations, policies and procedures that are applied to research conducted domestically will be applied to research conducted in other countries, as appropriate.
3. While local review that considers how the project may impact the country is required, it does not replace review and approval by the MCW IRB.
4. Investigators must include in the eBridge PRO SmartForm:



2. A copy of the most recent approval by the local in country IRB or Ethics Committee.

Amendments:

Prior to implementing any change to a project, Investigators must submit an amendment in accordance with IRB SOP: Amendments. In addition, Investigators must provide a copy of approval by the local IRB or Ethics Committee for this change along with the revised approved documents.

REFERENCES:

45 CFR 46