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**IRB Supplement Form M**

**Transnational Research**

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| **PI Name:** | **Date:** |
| Protocol Title: | WMed IRB #: |

1. **International Setting**
   1. **Where is the research to be conducted?**

* 1. **Describe the cultural norms in this setting with respect to research, individual autonomy, consent, age of majority, etc. in this setting:**

1. **Consent**
   1. **Describe how consent will be obtained from subjects:**

**Note #1:** If children will be included in the study, please complete *Supplement A.*

**Note #2:** Any request for a waiver of the requirements for informed consent must include completion of *Supplement E.*

* 1. **Describe how the investigators will ensure that subjects understand the nature of the research:**

* 1. **Describe the steps that will be taken to ensure that potential subjects understand that participation is voluntary:**

* 1. **If consent forms are to be used with persons not fluent in written English, how will translations be obtained?**

**Note:** All translated consent forms, assent forms, recruitment materials must be submitted to the IRB. Any request for a waiver of the requirements for documentation of informed consent must include completion of *Supplement E.*

1. **Language**
   1. **What is the primary language(s) in the region(s) where the research will be conducted?**

* 1. **Are the investigators who will be interacting with subjects fluent in the primary language of the subjects?**

Yes

No

If no, describe the steps that will be taken to ensure that subjects and investigators are able to communicate with each other:

1. **Expertise and Consultation**
   1. **What are the investigator’s qualifications to conduct research in this setting?**

* 1. **Will the investigator be collaborating with local persons (e.g., researchers, universities, community leaders, etc.)?**

Yes

No

If yes, describe:

* 1. **Will this research be reviewed by a local IRB or ethics committee?**

Yes

No

If yes, describe:

**Please provide the contact information for the local IRB or ethics committee:**

1. **Export Control**
   1. **Will this research be conducted in a country under embargo or sanctions with regard to export control?**

Yes

No

**If yes, consult with Associate Dean for Administration, Finance, Research Contract Specialist, Director of Sponsored Programs Administration, and the Information Technology Director to ensure that the data collection tools (e.g. laptops, iPads, and the technology they contain) and other study materials are permitted to bring into that country.**