**UMB Local Context Questionnaire for International Research Sites**

# The International LCQ is the tool for describing and demonstrating the investigator and study team’s knowledge of the laws, regulations, and customs where research will be conducted.

# **General Information**

1. Name of Study:

Click or tap here to enter text.

1. UMB Principal Investigator:

Click or tap here to enter text.

1. International Relying Site Name and Location (Country/Region/Territory):

Click or tap here to enter text.

1. Name of the Ethics Review Committee (ERC), Institutional or Government Entity Responsible for Local Study Review:

Click or tap here to enter text.

# **Regulatory & Training Information**

1. Confirm that the UMB researcher and the research team will comply with the country's laws, regulations, and guidelines governing research involving human participants, including their privacy laws. ([https.//www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html))

[ ]  **Yes** [ ]  **No**

1. Describe how the researchers will monitor compliance at the international site with applicable regulatory requirements for protecting the study participant's data.

Click or tap here to enter text.

1. International study staff has completed appropriate human subjects research training as required by the study and the international location policies.

[ ]  **Yes** [ ]  **No**

1. For NIH-funded trials, confirm that investigators and clinical trial site staff responsible for the study's conduct, management, and oversight completed the Good Clinical Practices (GCP) training.

[ ]  **Yes** [ ]  **No** [ ] Not an NIH-funded trial

# **Local Context Information**

# If not applicable, indicate “N/A”

1. Describe the relevance of the research to the area's health, economic, educational, or other needs.

Click or tap here to enter text.

1. Describe the research team's knowledge of, or experience, in the host country.

Click or tap here to enter text.

1. Describe the involvement of organizations, community leaders, or experts in engaging the subject population or conducting the research.

Click or tap here to enter text.

1. Describe the country's current events, political or economic climate, and religious or cultural beliefs that could impact the research conduct or alter the risks or benefits to subjects and research staff. Describe the steps the research will implement to minimize these risks.

Click or tap here to enter text.

1. Describe the role of women and children in their social environment, including their autonomy and legal capacity to make decisions that may impact the conduct of the research or alter the risks or benefits to subjects.

Click or tap here to enter text.

1. Identify additional considerations not mentioned above specific to the targeted community or study population at the international site, such as emergency procedures.

Click or tap here to enter text.

1. Provide the emergency telephone number of the country (e.g., 911 in North America).

Click or tap here to enter text.

1. Languages and dialects of the targeted study population.

Click or tap here to enter text.

1. Confirm that someone on the research team can communicate the consent process and answer any research-related questions in a language understandable to the research subject.

Yes No

# **Consent Process**

# Skip this section if there is no interaction or intervention with human subjects

1. Describe how the informed consent process will occur while complying with the country or community laws and customs. How will researchers address cultural or societal norms during the consent process?

Click or tap here to enter text.

1. How will the consent be documented? Will there be a translated Consent Form? Will the study require a waiver of documentation?

Click or tap here to enter text.

1. Indicate the legal age of majority of the targeted study population and not any exceptions for emancipated minors, as applicable.

Click or tap here to enter text.

1. Describe the consent process for obtaining permission when individuals are unable to provide legal consent, such as an individual that is cognitively impaired, including how their legally authorized representative will be identified.

Click or tap here to enter text.