UMass | Dartmouth

Institutional Review Board (IRB)

IRB International Research Checklist

Instructions: Complete for all studies proposing to include international participants in research, as applicable.

Part A - General Information:

International Sites/Regions: *Physical or Virtual* City and Country:	Ethics Oversight Entity:

Personnel and Affiliation:	Role and Qualifications:	Domestic (*D*) or International (*I*)

Part B – Background Information:

1. **Justification for conducting study at listed site(s).** *Clarify if and how research is relevant to area's health, economic, educational, or other needs.*

2. **Clarify the local site's oversight.** *Is local governmental or community permission to conduct research required at any of the sites? If so, explain how permission will be obtained. Attach ethics oversight approval and/or letter of cultural appropriateness.*

3. **Identify international organizations, community leaders, or experts involved with the target population.**

4. **Describe the research team's knowledge of or experience in the host country.** *Clarify if the UMassD researcher has conducted research at the site or with the population previously and elaborate on the circumstances, topics, and duration.*

5. **Are there local collaborators (interviewers, interpreters, translators, guides, etc.)?** *If so, identify collaborator, role, and expected involvement in the research. Clarify if local ethics committee approval is required for their role on the study?*

Part C – Population Information:

1. **Who is the target population to be recruited?** *If multiple groups, identify each and the number of participants to be enrolled in each.*

2. **What are the languages and dialects of the target population?** *Clarify if languages are written or oral. Attach study instruments (recruitment flyers/emails, consents, surveys, questionnaires, interviews, etc.) in English and certified translations.*

3. **What is the literacy rate of the target population?** *If necessary, detail a comprehension assessment plan to confirm participant understanding.*

4. **Is anyone, in addition to the participant, responsible for providing consent?** *If yes, address any extra protections to ensure voluntary participation. If necessary, address concerns about female autonomy and legal capacity to make decisions. In tribal populations, clarify if a tribal council or community leader must/can provide consent for an entire group.*

5. **Are there are laws/standards regarding the enrollment of minors?** *If appliable, clarify cultural considerations for parental permission. Address: What the age of majority is? Who is the appropriate person to provide permission for a minor? What is an acceptable and effective parental permission process and child assent process? Clarify if there are laws pertaining to orphans in that country.*

Part D – Procedure Information:

1. **Clarify culturally specific norms for recruitment and the informed consent process.** *If there are anticipated cultural sensitivities (culture, traditions, and religious norms), identify potential barriers and their resolutions, and the culturally acceptable process for both.*

2. **Clarify how participants will be introduced to research.** *If participants are known to the researcher, explain the circumstances. If the researcher will introduce themself to a group or a community, clarify circumstances. For anthropological or ethnographic research involving smaller tribal communities, identify the local contact and explain how the researcher will be invited into the community.*

3. **Will written documentation of informed consent be obtained?** *If not, clarify if there any local cultural norms against signing consent.*

4. **Does research involve a long-term or multi-stage project?** *If yes, address how consent will be continually obtained from participants, identify opportunities for people to withdraw conversations, interactions, recordings, or entirely from study data.*

5. **Do procedures involve population observation or recording?** *If yes, clarify what will be observed and/or recorded (individual behaviors, community practices, societal norms, etc.), how participants will be selected for observation/recording (demographics), and the number of participants necessary to consider data collection complete. If procedures involve observation/recording of a group interaction in a public setting, clarify process for people to decline to participation and ensure only people who agree to participation are included in the recording/field notes.*

Part E – Risks/Benefit Assessment:

1. **Compensation Details.**
   a. **Is there compensation (payment, gifts, incentives, etc.)?** *If yes, include the value of compensation in U.S. and local currency.*
   b. **What is the local average monthly household income?** *Clarify if compensation can influence decision to participate.*
   c. **When and who compensation be given to**? *Clarify if compensation is prorated.*

2. **Can the economic status of the region, current events, or socio-political environment impact the participant risks?** *If yes, elaborate. If politically volatile regions are involved, clarify the potential risks to participants, and detail a plan to protect them. If there are different risks of harm for different groups of participants, describe the risks for each group.*

3. **Will recruitment, enrollment, and data collection occur in a public or private setting?** *If entirely public, address if lack of privacy at any stage introduces additional risks to participants.*

4. **What are the potential risks of participation?** *Risk Examples include:*
   - Physical Risks– if asked to engage in a physical activity, such as exercise or a walking tour.
   - Psychological Risks – if asked to discuss thoughts, experience, or topics which induce stress, discomfort, embarrassment, guilt, etc.
   - Social Risks– if participation results in stigma or condemnation by their peers or accrues a social risk to the entire community or group.
   - Economic Risks – if participation results in economic harm due to conflicts with participation in a profitable activity.

5. **Will sensitive information be collected?** *If yes, clarify if population will be vulnerable due to the topic. Identify potential risks in the event of a breach of confidentiality. Describe steps to minimize the risks of harm and ensure participant privacy. [Sensitive information relates to: An individual's: psychological mental health; sexual behavior, abuse, violence, attitudes, preferences, or practices; illegal or incriminating behavior, or the use of alcohol, drugs, or substances; medical history which could lead to discrimination stigmatization of disclosed, places the individual at risk of criminal or civil liability, or damages the individual's financial standing, employability, or reputation;]*

6. **Are the any benefits to participation?** *Clarify if the anticipated benefits are for the participant, community, field, or for society in general.*

7. **Are any resources, community activities, or referrals provided to participants?** *Clarify if there any concerns with distribution locally.*

Part F – Attribution:

1. **Will participants consult on the accuracy and representation of publications?** *If yes, clarify if and how input will impact research.*

2. **Will participants be attributed in publications?** *Note, even with pseudonyms, it may be possible to reidentify participants based on contextual factors due to the location or characteristics of the group. Note, the consent should disclose the researcher's intent for attribution.*

Part G – Confidentiality:

1. **Where will data be stored and kept secure while in the host country, while returning to the U.S., and once in the U.S.?**

2. **Will identifiers be recorded that could be linked to private research material?** ☐ **Yes** ☐ **No** *If yes, address the following*:
   a. **What identifiers will be kept?**

   b. **How long will identifiers be kept?**

   c. **How confidentiality will be maintained during the retention period?**

   d. **Who will have access to the data?** *In each case, identify who (sponsors, advisors, agencies, etc.), explain the access to study data as with identifiers or only to coded data with no access to the identifying study code. If identifiers will be maintained indefinitely, explain why (e.g. recontact participants or communicate with them over a long period of time, the data is identifiable by nature, etc.)*

   e. **How data will be protected from a breach of confidentiality?**

   f. **Could retained data place participants at risk for criminal or civil liability or be damaging to their financial standing, employability, or reputation?** *Note, it may be advisable to obtain a federal Certificate of Confidentiality in this case.*

Part H – Reporting Requirements:

1. **Outline the process for reporting adverse events, unanticipated problems, protocol noncompliance, or any activity which poses risk to participants (or to others) or fails to meet compliance requirements.**

2. **Provide process for handling participant complaints locally.** *If there is local point of contact, identify by name and email/phone.*

3. **Are there are any local mandatory reporting requirements for specific data collected?** *If yes, clarify reporting structure/plan.*