UWI Research Ethics Application Form

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| **Title** |
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| **Expected Start Date for data collection** |
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| **Expected End Date for data collection** |
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| 1. **Abstract(?)** *to retitle to Lay Summary* |
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| 1. **Background and Rationale for the study (300 words)** |
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| 1. **Aims, Objectives and Research Questions (300 words)** |
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| 1. **Hypotheses (If Applicable)** |
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| 1. **Methodological Design** |
| * 1. **Overall Study Design (including Theoretical Framework, where applicable)** |
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| * 1. **Location and Time Frame of the study** |
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| * 1. **Justification for Participants or Subjects (not applicable for Waiver applications)** |
| * + - 1. **Inclusion Criteria** |
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| * + - 1. **Exclusion Criteria is required** |
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| * + 1. **Special/Vulnerable Populations and Justification** |
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| * + 1. **Research Related Justification for Sample Size is required** |
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| * + 1. **Recruitment of Subjects** |
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| * 1. **Data Collection/Research Intervention Procedures** |
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| * 1. **Data Collection Instruments [FILE UPLOAD SECTION]** |
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| * 1. **Methods of Data Analysis** |
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| 1. **Confidentiality** |
| * 1. **Methods for storing and securing study/biological data** |
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| * 1. **Methods for protecting participants' confidentiality (not applicable for Waiver Application)** |
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| 1. **Risk/Benefit (provide more details on risk and types of risk)**    1. **Indicate what is the level of risk associated with this research is required** |
| * **Minimal Risk** * **Greater than Minimal Risk** * **Significantly Greater than Minimal Risk** |
| * 1. **Please describe risk, discomfort (physical/psychological), inconvenience, side effects, and financial costs to participants (include measures to mitigate these risks/discomforts)** |
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| * 1. **Indicate direct benefits to participants (not applicable for Waiver Applications)** |
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| * 1. **Impacts of the study on human groups/social environment that are not participants in the study (positive/negative, where applicable)** |
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| * 1. **Impacts of the study on the environment (positive/negative, where applicable)** |
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| 1. **Compensation for participants: including payments or payments in kind** |
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| 1. **Informed Consent (written/verbal)** |
| * 1. **Describe process for informed consent. Indicate if waiver of written consent is requested with justification or waiver of consent all together with justification. is required** |
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| **10. Funding** |
| * 1. **State sources of Funding. Indicate any potential for conflict of interests between researcher and funder.**   **10.2.1 What is the budget for the study (enter details below)**  **10.2.2. Or upload a file containing the budget details** |
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| 1. **Expected outcomes and impact of the study** |
| * 1. **How the results will be disseminated?** |
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| * 1. **How the results will be acted upon for both the participants and the community?** |
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| * 1. **Limitations** |
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| 1. **References** |
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| 1. **Documents to be attached:** |
| * Research Proposal * SPIRIT/WHO guidelines checklist for clinical trials * Recruitment Materials * Letters to institutions for permission to access research sites and approvals as required * Consent Forms * Other Documents |