**[DOWNLOAD FORM AND USE MS WORD FOR FILLING. Do not use Google Docs]**

**Submit this Application form along with all applicable supplements and documents.**

**IRD-IRB Administration Use Only** IRD-IRB # assigned:

Primary Reviewer       Secondary Reviewer

Review Date       Review Decision: Approval date:       Expiry date:

Comments:

Re-open study application:

|  |  |
| --- | --- |
| **INVESTIGATOR (PI) INFORMATION** | |
| Principal Investigator: | Name: |
| Institution/Organization: |
| Dept/Division:       Designation: |
| Phone:       **Official** E-mail: |
| Co-Investigator(s) | Name:       E-mail:       Dept/Division:  Name:       E-mail:       Dept/Division:  Name:       E-mail:       Dept/Division: |
| *For non IRD applications, is there an IRD Collaborator/Site PI?*    ( *not applicable*) | Name:       Phone:       E-mail: |
| Dept/Division:       Designation:  Has the IRD site-PI reviewed this application? (Yes/No)  Has a Research Agreement or MOU been signed with IRD? (Yes/In progress/No) |

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| **Name of Person filling form (if not PI**):       **Role in project:** |
| **Study Title:** | |
| **Short study title/Acronym:** | |
| **Study Design:** | |

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| **FUNDING SOURCES** | |
|  | **Is it a sponsored study?** (Yes/No)    **If yes, please specify the source of funding:** |
|  | Pakistani Industry Sponsor / private for-profit funding (Specify): |
|  | International Funding (Specify): |
|  | Pakistani non-profit foundation/ non-industrial sponsor (Specify): |
|  | Other (Specify): |

|  |  |  |  |  |
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| **MANDATORY DOCUMENTS (check and attach all that apply)** | | | | |
| Included | | N/A | |  |
|  | |  | | 02. English Informed Consent **OR** Verbal Consent Script with contact info |
|  | |  | | 03. Translated Informed Consent in Urdu or local language **OR** translated Verbal Consent Script with contact info |
|  | |  | | 04. Description of Study |
|  | |  | | 05. Study Protocol (Must include appropriate sections such as Introduction, Study Rationale, Aims and Objectives, Methods, Analysis Plan, Confidentiality) |
|  | |  | | 06. Surveys/Questionnaires/Data Extraction Sheet/Focus Group Discussion Script |
|  | |  | | 07. Translated Survey/Questionnaire/Script in Urdu or local language to be administered in (required if language of interview is other than English) |
|  | |  | | 08. International Research/multi-center collaboration – provide written evidence of IRB approval, or pending approval document (if applicable) |
|  | |  | | 09. Study Personnel Roster |
|  | |  | | 10. Data Collection Instrument List (recommended if multiple questionnaires) |
|  | |  | | 11. CITI or NIH Training Certificates of PI and key study team members |
|  | |  | | 12. IRB Review Fee Form |
|  | |  | | 13. Good Clinical Practice certification (for investigational device or drug studies) |
|  | |  | | 14. PI and Co-PI Current Bio sketch (required only if non-IRD person) |
|  | |  | | 15. Other, specify: |
| **UNDERTAKING & SIGNATURES** (For electronic submission, typed name is acceptable; but please check relevant box to constitute a written signature) | | | | |
| **As the PI for this study, I assure that the following consent process will be followed by anyone taking consent in my study:** (Please read and check the following indicating your agreement) | | | | |
|  |  | | Only a consent form that has the IRB stamp on it will be used | |
|  |  | | Data collection forms being used are the correct version | |
| ***As the PI, I will ensure that all data collecting persons will be trained on consent process as follows:*** | | | | |
|  |  | | Research consent will be taken in such a way that the participant understands what they are agreeing to participate in | |
|  |  | | Participant will be explained what happens when the study is over or what will happen if a follow-up is required | |
|  |  | | Person taking informed consent will ask and ensure that the subject wants to continue participation and knows s/he may refuse to participate | |
|  |  | | The rights and welfare of research participants will be respected | |
|  |  | |  | |
| Principal Investigator | | | | |
| \*\*A check in this box will constitute a written signature  Date | | | | |

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| Person Submitting on behalf of PI:        N/A |
| \*\*A check in this box will constitute a written signature  Date |