**[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:

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| **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       |