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| **SJREB FORM 1**  **APPLICATION FOR SJREB INITIAL REVIEW**  *To be filled up by the Coordinating Investigator* |

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|  |  | SJREB Protocol Number *(to be filled-up by secretariat staff)*: |  |
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| Sponsor Protocol Number: |  | Submission Date: |  |

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| Protocol Title: |  |

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| Type of Research: |  | Clinical Research |  | Clinical Trial |  | Laboratory Research |
|  | Genetic Research |  | Socio-behavioral |  | Public health |
|  | Others (*specify)*: ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |  |  |

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| Study Duration: |  |

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| Sponsor: |  |

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| Coordinating Investigator: |  |

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| Sites and Site Principal Investigators |  |

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| --- | --- | --- | --- |
| Telephone number: |  | Fax: |  |

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| E-mail: |  | Preferred  means of contact |  | Phone |  | Fax |  | Email |
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| Institution: |  |

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| Declaration of Conflict of Interest (COI) | | | | |
| Are you an employee of the sponsor/s? |  | Yes |  | No |
| Did you do consultancy or part time work for the sponsor/s? |  | Yes |  | No |
| In the past year, did you receive P500,000 or more from the sponsor/s? |  | Yes |  | No |
| Other ties with the sponsor: | | | | |
| **Ethical Responsibility and COI Statement**  I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Coordinating Investigator (CI). | | | | |

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| CI Signature: |  |

**Documents submitted:**

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| Basic documents: | |
|  | Application Form [SJREB FORM 1 – APPLICATION FORM] |
|  | Protocol Summary Sheet [SJREB Form 1.2 – Protocol Summary Sheet] |
|  | Informed Consent Forms (in English and in local language) |
|  | Recruitment and Advertisement Materials |
|  | Data Collection Forms |
|  | CVs of PIs |
|  | Study Budget |
|  | Study Protocol |
|  | Technical Clearance |
|  | Proof of parallel submission to at least three (3) study sites |

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| Study-specific Documents (submit as needed): | |
|  | FDA Approval/Clearance (for clinical trials) |
|  | Patient Information Sheet (for clinical trials) |
|  | Investigator Brochure (for clinical trials) |
|  | GCP Certificates of PIs (for clinical trials) |
|  | Other protocol-related documents (please specify): |

Received by:

*(SJREB Secretariat)*

Date: