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| 1. **Protocol Information** | | |
| SPUP REC Protocol Code | | Submission Date |
| Protocol Title | | Study Site |
| Name of Principal Investigator | Sponsor/Contract Research Organization/Institution | |

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| 1. **Guide Questions for Assessment** | | |
|  |  | COMMENTS |
| 1. Does the Informed Consent document state that the procedures are primarily intended for research? | Yes  No  Unable to assess |  |
| 1. Are procedures for obtaining Informed Consent appropriate? | Yes  No  Unable to assess |  |
| 1. Does the Informed Consent document contain comprehensive and relevant information? | Yes  No  Unable to assess |  |
| 1. Is the information provided in the protocol consistent with those in the consent form? | Yes  No  Unable to assess |  |
| 1. Are study related risks mentioned in the consent form? | Yes  No  Unable to assess |  |
| 1. Is the language in the Informed Consent document understandable? | Yes  No  Unable to assess |  |
| 1. Is the Informed Consent translated into the local language/dialect? | Yes  No  Unable to assess |  |
| 1. Is there adequate protection of vulnerable participants? | Yes  No  Unable to assess |  |
| 1. Are the different types of consent forms (assent, legally acceptable representative) appropriate for the types of study participants? | Yes  No  Unable to assess |  |
| 1. Are names and contact numbers from the research team and the SPUP REC in the informed consent? | Yes  No  Unable to assess |  |
| 1. Does the ICF mention privacy & confidentiality protection? | Yes  No  Unable to assess |  |
| 1. Is there any inducement for participation? | Yes  No  Unable to assess |  |
| 1. Is there provision for medical / psychosocial support? | Yes  No  Unable to assess |  |
| 1. Is there provision for treatment of study-related injuries? | Yes  No  Unable to assess |  |
| 1. Is there provision for compensation? | Yes  No  Unable to assess |  |
| 1. Does the ICF clearly describe the responsibilities of the participants? | Yes  No  Unable to assess |  |
| 1. Does the ICF describe the benefits of participating in the research? | Yes  No  Unable to assess |  |

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| **Recommendation** | **Justification for the Recommendation** |
| Approved  Minor Modifications Required  Major Modifications Required  Disapproved |  |

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