

## STUDY PROTOCOL ASSESSMENT FORM FOR STUDY

|                                                                                                                                                                                                                                                                          |            |            |                                                                        |                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|------------|------------------------------------------------------------------------|----------------------------|
| <b>Study Protocol Title:</b>                                                                                                                                                                                                                                             |            |            |                                                                        |                            |
| <b>Principal Investigator:</b>                                                                                                                                                                                                                                           |            |            |                                                                        |                            |
| <b>Study Protocol Submission Date:</b>                                                                                                                                                                                                                                   |            |            |                                                                        |                            |
| <b>Indicate if the study protocol contains the specified assessment point</b>                                                                                                                                                                                            |            |            | Page and paragraph where element is found (TO BE FILLED BY RESEARCHER) | <b>REVIEWER'S COMMENTS</b> |
|                                                                                                                                                                                                                                                                          | <b>YES</b> | <b>N/A</b> |                                                                        |                            |
| <b>Justification for study and literature review</b><br><i>Summarize the available knowledge and important knowledge gap to justify the scientific merit of the study proposed</i>                                                                                       |            |            |                                                                        |                            |
| <b>Objectives</b><br><i>General and specific objectives</i>                                                                                                                                                                                                              |            |            |                                                                        |                            |
| <b>Research design</b>                                                                                                                                                                                                                                                   |            |            |                                                                        |                            |
| <b>Sample size estimation</b>                                                                                                                                                                                                                                            |            |            |                                                                        |                            |
| <b>Sampling method</b>                                                                                                                                                                                                                                                   |            |            |                                                                        |                            |
| <b>Inclusion and exclusion criteria</b>                                                                                                                                                                                                                                  |            |            |                                                                        |                            |
| <b>Recruitment of subject/participant &amp; informed consent seeking</b><br><i>Method of inviting participants eg: Advertisement</i>                                                                                                                                     |            |            |                                                                        |                            |
| <b>Assent form requirement</b><br><i>Under 7 years old: No assent. Complete Parental Consent.</i><br><i>7-under 12 years old: Verbal Assent</i><br><i>12-under 15 years old: Assent Form</i><br><i>15-under 18 years old: Co-sign informed consent form with parents</i> |            |            |                                                                        |                            |
| <b>Study location</b>                                                                                                                                                                                                                                                    |            |            |                                                                        |                            |
| <b>Research instrument</b>                                                                                                                                                                                                                                               |            |            |                                                                        |                            |
| <b>Data collection method</b>                                                                                                                                                                                                                                            |            |            |                                                                        |                            |
| <b>Duration of participant</b>                                                                                                                                                                                                                                           |            |            |                                                                        |                            |

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|--------------------------------------------------------------------------------|--|--|--|--|
| <b>involvement</b>                                                             |  |  |  |  |
| <b>Proposed data analysis</b>                                                  |  |  |  |  |
| <b>Declaration of conflict of interest</b>                                     |  |  |  |  |
| <b>Collaborative study terms of reference e.g. Intellectual property, etc.</b> |  |  |  |  |

|                         |            |
|-------------------------|------------|
| <b>REVIEWER</b>         | Signature  |
| Date:                   | Name _____ |
| <b>SECRETARY</b>        | Signature  |
| Received Feedback Date: | Name _____ |