**Study Protocol Assessment Form**

STUDY PROTOCOL INFORMATION

**IRB Protocol No:**

**Date:**

**Study Protocol Title**:

**Study Protocol Number**:

**Principal Investigator**:

**Sub**-**Investigator/s:**

**Total # of Participants:**

**No. of study sites:**

**Sponsor:**

**Duration of the Study:**

**Status: \_\_\_\_New \_\_\_\_\_Amended**

 **Reviewer:**

 **Review Status: \_\_\_\_\_\_Full Board \_\_\_\_\_\_Expedited**

INSTRUCTIONS

**PRINCIPAL INVESTIGATOR:** Please put a check in the space provided below if the evaluation point is addressed by the study protocol. Please specify the page and paragraph where the information can be found to facilitate the assessment.

**REVIEWER:** Please assess how the evaluation points have been properly addressed by the study protocol by placing your comments in the space provided below. Finalize your review by ticking one of the boxes under “Suggested Action” and signing in space provided for the reviewer.

|  |  |  |
| --- | --- | --- |
|  | **To be filled out by the PI** |  |
| **ASSESSMENT POINTS** | Indicate if the study protocol contains the specified assessment point | Page and paragraph where it is found | **REVIEWER COMMENTS** |
| 1. **SCIENTIFIC DESIGN**
 | **YES** | **N/A** |  |  |
| * 1. **Objectives**

*Review of viability of expected output* |  |  |  |  |
| * 1. **Literature review**

*Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials* |  |  |  |  |
| * 1. **Research design**

*Review of appropriateness of design in view of objectives* |  |  |  |  |
| * 1. **Sampling design**

*Review of appropriateness of sampling methods and techniques* |  |  |  |  |
| * 1. **Sample size**

*Review of justification of sample size* |  |  |  |  |
| * 1. **Statistical analysis plan (SAP)**

*Review of appropriateness of statistical methods to be used and how participant data will be summarized* |  |  |  |  |
| * 1. **Data analysis plan**

*Review of appropriateness of statistical and non-statistical methods of data analysis*  |  |  |  |  |

**SUGGESTED ACTION**

[ ]  APPROVAL

[ ]  MINOR REVISIONS

[ ]  MAJOR REVISIONS

[ ]  DISAPPROVAL

[ ]  PENDING, MAJOR CLARIFICATIONS REQUIRED BEFORE DECISIONS CAN BE MADE

**JUSTIFICATION FOR RECOMMENDED ACTION**

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REVIEWER: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_