**Pre-Ethics IRRB Dataset and Description**

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| --- | --- |
| **ECTR Field** | **Description** |
| Public title of study |  |
| Scientific title of study |  |
| Principal Investigator’s name and address |  |
| Investigator’s name and address Contact person (Scientific Querry) |  |
| Site/s of study |  |
| Health condition/problem studied |  |
| Study type |  |
| Intervention and comparator agentFor each intervention, describe other intervention details as applicable (dose, duration,mode of administration, etc. ) |  |
| Inclusion criteria |  |
| Exclusion criteria |  |
| Method of generating randomization sequence |  |
| Method of allocation concealment |  |
| Blinding / masking |  |
| Primary outcome/s |  |
| Secondary outcome/s |  |
| Target sample size  |  |
| Phase of trail  |  |
| Date of first enrolment |  |
| Estimated duration of trail |  |
| Brief summary Short description of the primary purpose of the protocol, including the brief statement of the study hypothesis. Include publication details. (link/reference), if any |  |

**UNDERTAKING:**

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ hereby give an undertaking that,

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| --- |
| My project involves drug intervention in human subjects |
| The reference (s) of the Drug(s) as given in Ayurvedic texts are cited,( photocopies of original refrences are attached) |

 **Investigator Co-Investigator Principal Investigator/Supervisor**