

Pre-Ethics IRRB Dataset and Description

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 Query)	
Site/s of study	
Health condition/problem studied	
Study type	
Intervention and comparator agent For 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,

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