Research Ethics Committee

Bandaranaike Memorial Ayurveda Research Institute

Proposal Evaluation Form – Human Study

For official use	*REC No:*Enter text.	*PI name:*Enter text.	*Date received:*dd/mm/yyyy

		Sufficient?			
		Yes	**No**	**NA**	**Comment**
Scientific validity and Ethical Conduct					
1	Justification				
	(1) The scientific importance of the study in relation to improving health care and/or knowledge on the subject	☐	☐	☐	Enter text.
	(2) The justification for a replication study, if this is a replication study.	☐	☐	☐	Enter text.
2	Scientific validity				
	1) Justification for conducting the study in this population	☐	☐	☐	Enter text.
	2)Study design	☐	☐	☐	Enter text.
	3)Objectives: General and specific	☐	☐	☐	Enter text.
	4)The inclusion and exclusion criteria	☐	☐	☐	Enter text.
	5)How the sample size was calculated	☐	☐	☐	Enter text.
	6) Plan for selection of the sample	☐	☐	☐	Enter text.
	7)Details of data collection tools, methods, investigations, etc	☐	☐	☐	Enter text.
3	Consent				
	1)The procedure for approaching the relevant community and initial contact of with the participants	☐	☐	☐	Enter text.
	2)The procedure for obtaining informed consent	☐	☐	☐	Enter text.
	3)The information (written/oral) provided to participants	☐	☐	☐	Enter text.
	4) The procedure for ensuring that subjects have understood the information provided.	☐	☐	☐	Enter text.
	5)The procedure for obtaining proxy consent	☐	☐	☐	Enter text.

	6) The procedure for consenting if vulnerable groups / children under 18 years of age are being recruited.	☐	☐	☐	Enter text.
	7)The procedure for withdrawing consent and withdraw from the research	☐	☐	☐	Enter text.
	8) The procedure for re-consenting	☐	☐	☐	Enter text.
	9) The procedure for re-consenting if data or specimens that have been collected are to be used for other research projects that may be in the same (Extended Consent) or a different (Unspecified Consent) field of study	☐	☐	☐	Enter text.
	10)Incentives/rewards/compensation/reimbursement provided or not provided to participants and their accompanied persons	☐	☐	☐	Enter text.
	11) The procedure for re-consenting if the research protocol changes during the course of research	☐	☐	☐	Enter text.
4	Confidentiality				
	1)How the data and samples was obtained	☐	☐	☐	Enter text.
	2)How long data and samples was kept	☐	☐	☐	Enter text.
	3)Justification for collection of personal identification data	☐	☐	☐	Enter text.
	4)Who had access to the personal data of the research participants	☐	☐	☐	Enter text.
	5) confidentiality of participants be ensured	☐	☐	☐	Enter text.
	6)The procedure for data and sample storage	☐	☐	☐	Enter text.
	7)The procedure for data and sample disposal	☐	☐	☐	Enter text.
5	Vulnerability and Inducement				
	1)Justification for including vulnerable populations	☐	☐	☐	Enter text.
	2) Compensation provided to participants.	☐	☐	☐	Enter text.
6	Collaborative partnership				
	1) The collaborations have established with institutions where the study is to be conducted	☐	☐	☐	Enter text.
	2)The collaborations have established with the community where the study is to be conducted	☐	☐	☐	Enter text.
	3) Benefit due to this collaboration to individual, institution, society, etc.	☐	☐	☐	Enter text.
	4) Patient and public engagement and involvement (PPEI) in research	☐	☐	☐	Enter text.
7	Social Value				

	1) The beneficiaries of the research and the benefit to them	☐	☐	☐	Enter text.
	2) The plan for dissemination of study findings	☐	☐	☐	Enter text.
8	Rights of the participants				
	1) Procedure for subjects to ask questions and register complaints	☐	☐	☐	Enter text.
	2) The contact person for research participants	☐	☐	☐	Enter text.
	3)Provisions for participants to be informed of results	☐	☐	☐	Enter text.
	4) Procedure for subjects to withdraw from the research at the time	☐	☐	☐	Enter text.
	5) Provision to make the study product available to the study participants after research	☐	☐	☐	Enter text.
9	Assessment of Risks/Benefits				
	1) The risks to research participants (physical, psychological, etc.)	☐	☐	☐	Enter text.
	2) Benefits to research participants	☐	☐	☐	Enter text.
	3) Steps taken to minimize risks	☐	☐	☐	Enter text.
	4) Support provided to the research participants (medical, psychological and other)	☐	☐	☐	Enter text.
	5) Justification of the potential benefits against the risks	☐	☐	☐	Enter text.
	6) Risk-benefit analysis/discussion	☐	☐	☐	Enter text.
10	Responsibilities of the researcher				
	1) The provision of medical services to research participants	☐	☐	☐	Enter text.
	2) The provisions for continuation of care after the research is completed	☐	☐	☐	Enter text.
	3) Declaration of conflicts of interests and how the investigators plan to manage the conflicts	☐	☐	☐	Enter text.
	4) The ethical/legal/social and financial issues relevant to the study	☐	☐	☐	Enter text.
11	Fair participants selection				
	1) Justifications for the selection of the study population	☐	☐	☐	Enter text.
	2) The inclusion and exclusion criteria	☐	☐	☐	Enter text.
12	Research funded by foreign agencies/companies				
	1) Justification for conducting the study in Sri Lanka	☐	☐	☐	Enter text.
	2) Relevance of the study to Sri Lanka	☐	☐	☐	Enter text.

	3) Post research benefits to Sri Lanka	☐	☐	☐	Enter text.
	4) The steps taken to take into account cultural and social customs, practices, and taboos in Sri Lanka	☐	☐	☐	Enter text.
	5) The sharing of rights to intellectual property	☐	☐	☐	Enter text.
	6) The fate of data and biological samples including whether they will be transferred abroad and what will happen to them after the conclusion of the study	☐	☐	☐	Enter text.
	7) How the results of research will be conveyed to relevant authorities in Sri Lanka	☐	☐	☐	Enter text.
	8) The agreement between the sponsor/funding agency and the investigator	☐	☐	☐	Enter text.
	9) The material transfer agreement if biological material is to be transferred abroad	☐	☐	☐	Enter text.
13	Community base research				
	1) The impact and relevance of the research on the community in which it is to be carried out	☐	☐	☐	Enter text.
	2) The steps taken to consult with the concerned community during the design the research	☐	☐	☐	Enter text.
	3) The procedure used to obtain community consent	☐	☐	☐	Enter text.
	4) The contribution to capacity building of the community	☐	☐	☐	Enter text.
	5) The procedure for making available results of research to the community	☐	☐	☐	Enter text.
14	Clinical trials				
	1) Justification for withdrawing any therapy from participants to prepare them for the trial	☐	☐	☐	Enter text.
	2) Justification for withholding any therapy from participants (eg. control group)	☐	☐	☐	Enter text.
	3) Justification for proving care which is not the standards of care	☐	☐	☐	Enter text.
	4) Procedure for dealing with adverse events	☐	☐	☐	Enter text.
	5) Procedure for reporting adverse events	☐	☐	☐	Enter text.
	6) Provisions for safety monitoring	☐	☐	☐	Enter text.
	7) Provisions/criteria for termination of the trial	☐	☐	☐	Enter text.

	8) Provisions for making the trial drug available to participants after the trial if found to be effective	☐	☐	☐	Enter text.
Information Sheet (IFS)/Informed Consent Form (ICF) Check List					
1	Purpose of the study	☐	☐	☐	Enter text.
2	Voluntary participation	☐	☐	☐	Enter text.
3	Duration, procedures of the study and participant's responsibilities	☐	☐	☐	Enter text.
4	Potential benefits	☐	☐	☐	Enter text.
5	Risks, hazards and discomforts	☐	☐	☐	Enter text.
6	Collection and fate of biological samples	☐	☐	☐	Enter text.
7	Reimbursements	☐	☐	☐	Enter text.
8	Confidentiality	☐	☐	☐	Enter text.
9	Termination of study participation	☐	☐	☐	Enter text.
Is all the documentation provided?		☐	☐	☐	Enter text.

Participant Information Sheet	**Need Further Modifications/ Adequate**
Informed Consent Form	**Need Further Modifications/ Adequate**
Recommendation	**Approved /Minor corrections / Major corrections/ Rejected**

Additional comments:

Enter text.

Name of the reviewer: Enter text.

Signature:

Date:dd/mm/yyyy