FORMAT FOR SUBMISSION OF PROTOCOL INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY INSTITUTE ETHICS COMMITTEE OF AIIA FOR MD / MS AND Ph.D. STUDENTS (FOR THESIS OR DISSERTATION)

Submit one copy (If meeting is conducted offline, then another two copies may also be asked for reference purpose IEC members) of the all documents along with Covering letter to the Member Secretary, Institute Ethics Committee for Post Graduate Research at Room No. 621, 6th Floor, Block C. The documents should also be sent in PDF format containing all below documents and one word file of synopsis to iec-membersecretary@aiia.gov.in

PDF (Signed copies):

1. Covering letter (through the Head of Department)
2. First or signed page/s of the Format
3. Dated Undertaking that the work has not started and that the work will be done as per
   a. AYUSH/ICMR/WHO guidelines
4. Dated Undertaking that the scales/questionnaires/scores to be used are not copyrighted or permission to be obtained
5. Dated undertaking that the research design and the analysis part has been finalized after consulting the research advisor AIIA with due sign of research advisor.
6. Bio-safety where applicable.
7. Any other signed document/s
8. Duly filled format of Ethics Committee For Post Graduate Research except signed first page/s
9. All relevant Participant Information Sheets in **English and Hindi**
10. All relevant Participant Informed Consent Forms in **English and Hindi**
11. Copy of Thesis Protocol and Case Record Form
12. Budget (if applicable)
13. Any other relevant annexure

Word file:

1. Synopsis copy in Microsoft word format – for review and comment by the IEC members before PPT presentation in IEC meeting.

The Scholar must submit protocol through **Chief Guide** and **Head of Department** who ensures that the project has been wetted both from the scientific and ethical point of view.

Note: No thesis work shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the ethics committee.

अखिल भारतीय आयुर्वेद संस्थान

ALL INDIA INSTITUTE OF AYURVEDA (AIIA)

(आयुष मंत्रालय, भारत सरकार के अंतर्गत स्वायत्त संस्थान)

(An autonomous organization under the ministry of AYUSH, Govt. of India)

PROFORMA TO BE SUBMITTED TO ETHICS COMMITTEE

1. Full Title of Study	**********
2.1 Name & signatures of the candidate	2.1 Name Signature_____
2.2 Department	2.2 **********
2.3 Degree	2.3 **MD/MS**
2.4 Batch of admission to course	2.4 Batch of 2016 -2019
2.5 Month & year of submission of thesis	2.5 June/November _____(year)
2.6 Email ID of the Candidate	2.6.1
Chief Guide	2.6.2
Co-Guide	
Co-Guide	
3. Name of Faculty & Department (Guide/Co-guide)	Signatures of the chief guide and co-guides
3.0 Chief guide:	3.0 _____
********** Co-guides:	
3.1 **********	3.1_____
3.2 **********	3.2 _____

3.3 ********** 3.4.	3.3 _____ 3.4 _____
4. Objectives of the study	4.1 4.2 4.3
5. Why is this study required? Please provide brief justification.	
6. Methodology	6.1. Number of Patients: 6.2. Inclusion criteria a) Age : b) Gender: c) Willing to participate in the study d) e) 6.3. Exclusion criteria a) b) Not willing to participate in the study c)

	d) 6.4. Control(s) 6.5. Study design (Pl provide with a graphical tree as ANNEXURE – 1) 6.6. Dosages of drug 6.7. Duration of treatment 6.8. Investigation specifically related to projects 6.9 Permission to use copyrighted Questionnaire/proforma 6.10 Brief Methodology 6.11. Timeline of activity schedule ANNEXURE - 2 6.12 Others
7. Drug - collection, standardization (mention the source/certification)	
8. a) Safety measures for proposed interventions b) Results of relevant laboratory tests c) Result of studies in human laboratory tests (as applicable)	a) ********** b) The standard methods of ********** will be followed. c) The routine clinical data will be recorded
9. Plans to withdraw standard therapy in research	**********
10. Plan for provision of coverage for medical risk	No plan for medical coverage is required.

	If there will arise any emergency, the study subjects will be referred to the casualty or to be treated under the supervision of the chief guide and co-guides as per the AIIA guidelines.
11. How you will maintain confidentiality of subject?	The confidentiality of the subjects will be maintained by assigning the code number of the subjects.
12.0 Cost involved in Rs 12.1 Investigations 12.2 Disposables 12.3 Drug 12.4 Therapies	
13.Who will bear the costs of the requirements mark?	
14. Participant Information Sheet	Pl provide ANNEXURE - 3
15. Participant Informed Consent Form	Pl provide ANNEXURE - 4
16. Standardized Case Record Form/questionnaire	Pl provide ANNEXURE - 5
17. Whether any work on this project has started or not?	No
18.Attached documents in addition to ANNEXURE – 1 to ANNEXURE – 5.	18.1 Covering letter, through proper channel. 18.2 Copy of the detailed protocol is mandatory 18.3 Undertaking that the study shall be done in accordance with AYUSH/WHO/ICMR guidelines

	18.4 In case of multi centric study, IEC clearance of other centers must be provided 18.5 Definite undertaking as to who will bear the expenditure of injury related to the project. 18.6 In case of Clinical trials, proof of registration of Clinical trial with ICMR needs to be updated to IEC after registration 18.7 Investigator should provide undertaking what they will do with the left-over blood sample – if applicable 18.8 Others:

Annexure 3

PARTICIPANT INFORMATION SHEET) PIS (

The project must be accompanied by the Participant information sheet addressed to the patient or participant or parent/ guardian, in case of minor. While formulating the participant information sheet, the investigator must provide the subjects with the following information in English and Hindi, in a simple layman's language which can be understood by them, in a narrative form, directed to the participant/ LAR, covering all the points:

1. Study Title
2. Aims and methods of the research study
3. Expected duration of participation
4. The benefits to be expected from the research to the participant or to others
5. Any risk or discomfort to the participant associated with the study
6. Maintenance of confidentiality of records
7. Provision of free treatment for research related injury
8. Compensation of subjects for disability or death resulting from such injury
9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise
10. Amount of blood sample) quantity in tea spoon full (to be taken
11. Costs and source of investigations, disposables, implants and drugs/ contrast media
12. Telephone number/ contact number of Principle investigator and Co-Investigator at the top of each page
13. In case of a drug trial:
    a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned
    b. Initial bioequivalence study of the drug/ references should be provided
14. Self-certification should be given that the translation to vernacular language is correct

Annexure 4

PARTICPANT INFORMED CONSENT FORM (PICF)

Protocol Study number : _____

Patient identification number for this study : _____

Title of the project :

_____

_____

Name of Principal investigator : _____Tel . No) s (. _____

The contents of the information sheet dated_____ that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents . I confirm that I have had the opportunity to ask questions .

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail . I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my medical care or legal right being affected .

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIA . I give permission for these individuals to have access to my records .

I agree to take part in the above study .

---------- Date :

) Signatures / Left Thumb Impression (Place :

Name of Participant : _____Son / Daughter / spouse of : _____

Complete postal address : _____ This is to certify that the above consent has been obtained in my presence .

---------- Date :

Signatures of the Principal Investigator Place :

1) Witness – 1

Signature

Address :

2) Witness – 2

Signature

Address :

NB : Three copies should be made, one each for) 1 (Patient) 2 (Researcher) 3 (Institution) Investigators are advised to prepare the translation in simple understandable Hindi on their own (

सहभागी सुचित सहमति प्रपत्र

इस जाचं के लिए सहभागी पहचान नमबर_____

अनुसन्धान शीर्षक_____ ___

मुख्य अन्वेषक का नाम _____ फोन नंबर: _____

मैंने दिनांक_____ के सूचना पत्र में दिये गए सभी तथ्यो को पड़ लिया हैं| मुझे समझ आने वालीं भाषा मैं विस्तारपूर्वक बत्ता दिया है और मैनें तथ्यो को भली भांति समझ लिया है| मैं पुष्टि करता हूँ कि मुझे प्रशन पुछने का अवसर दिया गया है|

मुझे अध्ययन की प्रकृति, उद्देश्य और इसके सम्भावित लाभ/जोखिमों और अध्ययन की सम्भावित अवधि अन्य प्रासंगिक जानकारी के बारे में विस्तार पुर्वक समझा दिया गया है | मैं समझाता हूँ कि इस अध्ययन में मेरी भागिधारी स्वेछिक है और इस अध्ययन से किसी भी समय बिना कोई कारण बताए, बिना मेरी चिकित्सा देखभाल या कानूनी अधिकारों के प्रभावित हए अपना नाम वापिस ले सकता/सकती हैं |

मैं समझता हूँ कि इस अनुसन्धान में मेरी सहभागिता से मेरे बारे में एकत्र जानकारी और चिकित्सीय नोटों को एम्स अस्पताल के जिम्मेदार लोगो द्वारा देखा जायेगा| मैं इन व्यक्तियों को अपने रिकोर्ड देखने कि अनुमति प्रदान करता/करती हूँ |

मैं उपयुक्त अध्यन में भाग लेने के लिए अपनी सहमति प्रदान करता /करती हूँ |

सहभागी के हस्ताक्षर / बाएं अंगूठे का निशान दिनांक स्थान

सहभागी का नाम

पिता/पति का नाम

पूरा पता

यह प्रमाणित किया जाता हे कि उपयुक्त सहमति मेरी उपस्थति में ली गई हैं |

मुख्य अन्वेषक के हस्ताक्षर दिनाक: स्थान:

१) गवाह के हस्ताक्षर

नाम

पता

२) गवाह के हस्ताक्षर

नाम

पता