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)

INSTITUTIONAL ETHICS COMMITTEE

APPLICATION FORM – RESEARCH PROJECT

Proposal Title:

	Name, Designation, Department & Qualifications	Address Tel & Fax Nos. Email ID	No of projects already with Investigator	Signature
PI				
Co-PI / Collaborators 1.				
2.				
	Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

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Tick appropriately

Sponsor Information :

1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐
   b) Private ☐
2. International Government ☐ Private ☐ UN agencies ☐
3. Industry National ☐ Multinational ☐

Contact Address of Sponsor:

Total Budget :

Who will bear the cost of investigation / implants drugs / contrasts? 1. ☐ Patient 2. ☐ Project 3. ☐ Exempted 4. ☐ Other Agencies

1.Type of Study : Cross sectional ☐ case control ☐ cohort ☐ Clinical Trial ☐ Review ☐

Participating Centre : Single center ☐ Multi-centric ☐ Others (Specify) ☐

2. Status of Review: New ☐ Revised ☐

3. Clinical Trials:
Drug /Vaccines/Device/Herbal Remedies :

i. Does the study involve use of:
Drug ☐ Devices ☐ V ☐
Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ a ☐

ii. Is it approved and marketed
In India ☐ UK & Europe ☐ USA ☐
Other countries, specify ☐

iii. Does it involve a change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No

d). Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐

e). Are you aware if this study/similar study is being done elswhere ? **If Yes**, attach details	Yes	No

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i. Number of Subjects :

ii. Duration of study :

iii.	Will subjects from both sexes be recruited	Yes	No
iv.	Inclusion / exclusion criteria given	Yes	No

v. Type of subjects Volunteers ☐ Patients ☐

vi. Vulnerable subjects Yes ☐ No ☐
(Tick the appropriate boxes)

pregnant women	☐	children	☐	elderly	☐
fetus	☐	illiterate	☐	handicapped	☐
terminally ill	☐	seriously ill	☐		☐
	☐		☐	me ntal	

vii. Special group subjects Yes ☐ No ☐
(Tick the appropriate boxes)

captives	☐	institutionalized	☐	employees	☐
students	☐	nurses/dependent	☐	armed	☐
any other	☐	staff	☐	forces	

6. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymised/ ☐

ii.	Confidential handling of data by staff	Yes	No

7. Use of biological/ hazardous materials		Yes	No
i.	Use of fetal tissue or abortus		
ii.	Use of organs or body fluids	Yes	No
iii.	Use of recombinant/gene therapy	Yes	No
	If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iv.	Use of pre-existing/stored/left over samples	Yes	No
v.	Collection for banking/future research	Yes	No

vi. Use of ionizing radiation/radioisotopes If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes Yes	No No
vii.Use of Infectious/bio hazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad? If Yes, justify with details of collaborators	Yes	No
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriatee box):

- ☐ Facility not available in India
- ☐ Facility in India inaccessible
- ☐ Facility available but not being accessed. If so, reasons...

8. Consent : ☐ Written ☐ Oral ☐ Audio-visual

i. Consent form : (tick the included elements)

Understandable language ☐

participation Statement that study involves ☐

Records Sponsor of study ☐

Purpose and procedures ☐

Risks & Discomforts Benefits ☐

Material Compensation for participation ☐

Alternatives to research ☐

Confidentiality of Contact information ☐

Statement that consent voluntary ☐

Right to withdraw Consent for future use of biological Benefits if any on ☐

Commercialization Compensation for study related injury eg. genetic basis for drug development ☐

*If written consent is not obtained, give reasons:

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ii. Who will obtain consent?

PI/Co-PI ☐ Research staff ☐

Nurse/Counsellor ☐ Any ot her ☐

9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy) - Yes / No

10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? If Yes,Minimal or no risk More than minimum risk High risk	Yes	No

Iii.Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b) Benefit to society ☐		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long ?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No
Conflict of interest for any other investigator(s) (if yes, please explain in brief	1_____Yes No 2_____Yes No	
15. Participant Information Sheet *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ Certified that Hindi version is a true translation of	
16. **Participant Informed Consent Form** *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ Certified that Hindi version is a true translation of	
17. Whether any work on this project has started or not?	☐ *(mark √ if yes, X if no) (Please enclose a separate certificate to this effect).*	
18. In case of clinical trials CTRI status		

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Checklist for attached documents:

Covering letter, through proper channel	☐
Project proposal – 06 Copies	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Patient information sheet	☐
Informed Consent form	☐
Investigator's brochure	☐
Copy of advertisements/Information brochures	☐
Copy of clinical trial protocol and/or questionnaire	☐
AYUSH /DCGI/DBT/BARC clearance if required	☐
Undertaking that the study shall be done in accordance with AYUSH /ICMR / GCP ☐ guidelines	
In case of multi-centric study, IEC clearance of other centres must be provided ☐	
Definite undertaking as to who will bear the expenditure of injury related to the project ☐	
If an insurance cover is intended, Insurance certificate must be provided (as per ICMR ☐ guidelines)	
Permission to use copyrighted Questionnaire/proforma	☐
Investigator should provide undertaking what they will do with the leftover sample ☐ tissue	
Certificate/undertaking as mentioned in column 17	☐
Others	☐