Annexure 4A

Project Submission Application Form for Initial Review for Drug Trials and Other Regulatory Studies (Industry and Government sponsored studies)

- Please fill in the details in legible hand writing
- Tick √ in the box for the appropriate answer
- Tick/ Write NA if question is not applicable

Title of the protocol

IEC Protocol No.

	Name	**Designation**	**Department & Institution**	**Signature**
Principal Investigator				
Co- Investigator				
Co- Investigator				
Co- Investigator				
Co- Investigator				
Co- Investigator				
Coordinator				
Coordinator				

(If additional collaborators attach details and letter of Consent by the collaborator(s) on a separat page.)

Please attach brief curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator) Attached

Is the study funded? Or non-funded (investigator initiated)

1.**Sponsor Information** :

1. Indian a) Government Central ☐ State ☐

b) Private

2. International Government Private UN agencies

3. Industry National ☐ Multinational ☐

Contact Address of Sponsor:

If sponsor is not from India, contact address in India:

2.Total Budget : Rs.

_____

Allocation of budget heads: ☐

Type of Study : Epidemiological Basic Sciences Animal studies Any Other

Please specify_____

Clinical: Single center_____ Multi-centric _____(Attach list of centers)

If multicentric, how many centres : India_____and Globally :_____(attach list of countries)

3. Clinical Trials:

Medicines/Vaccines/Device/Herbal Remedies : (Tick the appropriate boxes)

i. What does the study involve use of? Medicine
Devices Vaccines
Indian Systems of Medicine Any other NA

If others, specify_____

ii. Where is it approved and marketed?
In India UK & Europe USA NA Other countries, specify _____

iii. Is it an Investigational New Drug (IND)? If yes, IND No:			
a) Investigator's Brochure submitted			
b) *In vitro* studies data			
c) Preclinical Studies done			

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

e) To submit package insert in case test drug is already marketed in India Attached

(Tick the appropriate box/option)	Yes	No	NA
iv. Does it involve a change in use, dosage, route of Administration of an already marketed drug? If yes, whether DCGI permission is obtained? If yes, date of permission :----------			

v.	Are you aware if this study/similar study is being done elsewhere? If Yes, Specify details ----------	Yes ☐	No ☐
vi.	Whether DCGI's permission for testing IND obtained? If yes, date of permission :----------	Yes ☐	No ☐ NA ☐
vii.	Whether DCGI's permission for testing IND is applied for?	☐	
viii.	For Ayurvedic or herbal formulations, is a copy of the marketing/ manufacturing license issued by the FDA to	☐	☐

the company submitted?			

4. **Protocol 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 (Submit as attachment)

5. Research participants Sample Size :

i. Number of research participants at this centre : Number of research participants at other sites in India :
Total number of research participants at all sites (globally):

ii. Duration of study: No. of visits :

iii. Will research participants from both genders be recruited	Yes	No	NA
iv. Inclusion / exclusion criteria given	Y	No	

v. Type of research participants: Volunteers Patients NA

vi. Vulnerable research participants Yes No NA

pregnant women	elderly	mentally challenged
fetus	illiterate	handicapped
children	captives	terminally ill ☐
elderly	seriously ill	economically or socially backward
dependent staff	institutionalized ☐	students ☐
	employees ☐	
HIV ☐	Any other ☐	

To specify_____

6. Privacy and confidentiality

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

ii. Confidential handling of data by	Yes ☐	No ☐

7. **Use of biological/ hazardous materials** i. Us of fetal tissue abort us ☐	Yes	No ☐	NA ☐
ii. Use of organs or body fluids			

iii. Use of recombinant/gene therapy If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?			
iv. Use of pre-existing/stored/left over samples			
v. Collection for banking/future research			
vi. Use of ionizing radiation/radioisotopes			
If yes, has Bhabha Atomic Research Centre (BARC) approval for radioactive isotopes been obtained?	☐		
vii. Use of Infectious/ bio hazardous specimens	Yes	No	NA
viii. Proper disposal of material	Yes	No	NA

8. **Will any sample collected from the patients be sent abroad?** Yes No NA If yes

a) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐ Facility in India inaccessible ☐

Facility available but not being accessed ☐

If so, reasons……..

Lab. Address:_____

If no,

b) test on samples be carried out: In institution ☐

Outside institution ☐

If outside institution, Address: _____ If Yes**,** specify with details of collaborators ☐

☐

9. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) /ICMR for international collaboration? (as applicable in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution) ☐

Yes ☐ No ☐ NA ☐

10. In case of studies involving collaborations with other Indian or foreign Laboratory/ Clinic/Institution has administrative sanction from the Dean obtained/ applied for?

Yes ☐ No ☐ NA ☐

Memorandum of Understanding: Yes ☐ No ☐ NA (If applicable) ☐

Material Transfer Agreement : Yes ☐ No ☐ NA (If applicable) ☐

11. **Consent** :	Oral	Audio-visual	NA	☐

i. Consent form : (tick the included elements)

Simple language that study involves research of study
Purpose and procedures
Discomforts
Benefits
Compensation for participation
Benefits, if any, on future commercialization for future use of biological material
Alternatives to participation Statement
Confidentiality of records Sponsor Contact information
Statement that consent is voluntary Risks & Right to withdraw
Compensation for study related inju
NA Consent
NA

*If written consent will not be obtained, give reasons: _____

Whether applied for waiver of Consent: _____

ii. Who will obtain consent? PI/Co-PI Nurse/Counselor Research staff Any other, specify

12. Will any advertising be done for recruitment of research participants? (posters, flyers, brochure, websites – please attach a copy)	Yes	No	NA
13. **Risks & Benefits**: i. Is the risk reasonable compared to the anticipated benefits to research participants / community / country?	Yes	No	NA
ii. Is there physical / social / psychological risk / discomfort? If Yes, Minimal or no risk More than minimum risk High risk	Yes	No	NA
iv. Is there a benefit (a) To the research participants? Direct Indirect (b) Benefit to society			
14. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No	NA
ii. Is there a plan for interim analysis of data?	Yes	No	NA ☐
vi. Are there plans for storage and maintenance of all trial database? If Yes, for how long? ----------	Yes	No ☐	
15. Is there compensation for participation If Yes, Monetary In kind Specify amount and type: ------	Yes ☐	No	NA ☐
16. Is there provision for compensation for study related injury? If Yes, by Sponsor by Investigator by insurance by any other	Yes	No	NA ☐
17. Do you have any **conflict of interest** in the present study? (financial/non financial) If Yes, specify :---------- ----------	Yes ☐	No ☐	

18. Number of protocols handled by the PI at present including current Status of ongoing studies approved by IEC and carried out by the Principal Investigator. (Information to be given: whether study is initiated, no. of approved research participants, no. of research participants enrolled, no. of active research participants, no. of research participants who have completed the study and total duration of the study. Describe briefly in a separate sheet, if required)			_____ _____
19**. Current Brief Curriculum Vitae** (signed and dated copy) of the study team members- principal investigator, co-investigator and study coordinator (Information required: age, designation and department, educational qualification, previous research experience in last five years)			(To be enclosed along with the form)
20. GCP training certificates of principal investigator and coordinators			(To be enclosed along with the form)
21. Is the trial registered with Clinical Trial Registry? (mandatory only for drug trials) Clinical Trial Registry of India(CTRI)/ any other WHO platform registry _____ Registration number: _____ If not registered, state the reason _____	Yes	No	NA

Statement of Compliance:

We hereby declare that the information given above is true and that we will comply with the guidelines mentioned in the Schedule Y [Drugs and Cosmetic Act 1940; amendment 20th January 2005, 30th January 2013, 8th February 2013 and any other recent notification/s from CDSCO (updated as applicable)], Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2006), Indian GCP Guidelines (2001) and the International Conference on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (1996) while conducting the research study.

Signature of Principal Investigator with date: _____

Signature/s of Co-investigators with date: 1._____

2._____3._____4._____5._____

Signature of coordinator: 1._____2._____

Forwarded by Heads of Department(s)
Signature/s with date of Heads of
Department(s):

_____, _____, _____, _____

_____, _____, _____,_____

Stamp/Seal of the Department(s)

Annexure 4B

SHAHEED HASAN KHAN MEWATI GOVT. MEDICAL COLLEGE, NALHAR MEWAT

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)

IEC Protocol No.

(For attachment to each copy of the proposal)

Project Submission Application Form for Initial Review for Academic (non-regulatory) Studies

Please fill in the details in legible hand writing

Tick √ in the box for the appropriate answer/ Write NA if question is not applicable

Title of the project

	Name	Designation	Department and Institution
Principal Investigator			
Co-Investigator			
Co-Investigator			
Co-Investigator			
Co-Investigator			
If additional collaborators attach details and letter of consent by the collaborator (s) on a separate page.			
Non-sponsored study		Sponsored study	

If Non-Sponsored Study:

Type of study: Thesis/dissertation ICMR Other Academic

Duration of study_____ Approx. Completion date (MM/YY)

If sponsored, Total Budget : Rs.

_____

From where is the study being funded_____

Research fund is being utilized from in-house funding authority _____

any other If any other,

please give details _____ Allocation of budget heads (Please attach separate sheet if needed)

1.Type of Study : Prospective Retrospective Cross-sectional

Is the study Observational/ Interventional? _____

If interventional, does the study involve testing of a new drug or any deviation from

2. Does the study involve use of : Drug / Vaccine Device Alternative Medicine

New Technique (surgical/PT/OT/Pshychotherapy etc) Diagnostic Kit/ Investigations

If other, please specify _____

i) Is the test drug / device marketed in India Yes No

Please attach copy of package insert/product insert.

ii) Does the test drug involve a change in use, dosage, route of administration? Yes No

If yes, please attach copy of DCGI permission

3. Subject selection:

i) Number of subjects at this centre if multicentric, total number of subjects

ii) Vulnerable subjects Yes No (If yes, tick the appropriate boxes)

pregnant women illiterate seriously/terminally ill

children neonates mentally challenged

elderly handicapped economically/socially backward

institutional employees / students any oth

If other, please specify_

4. Does the study involve use of i) fetal tissue or abortus	Yes	No
ii) organs or body fluids	Yes	No
iii) Gene therapy If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission.	Yes	No
iv) ionizing radiation/radioisotopes, If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) Permission.	Yes	No
v) infectious / biohazardous specimens	Yes	No
vi) Will pre-existing/stored/left over samples be used?	Yes	No
vii) Will samples be collected for banking/future research	Yes	No
viii) Will any sample collected from patient be sent abroad? If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission.	Yes	No
ix) Is there any collaboration with any foreign lab., clinic or hospital ? If yes, please submit a copy of Health Ministry Screening Committee (HMSC)/ ICMR approval (as applicable for foreign collaborations).	Yes	No
5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) If yes, please attach a copy for IEC review.	Yes	No
6. Is there compensation for participation (travelling allowance)? If Yes, Monetary In kind Specify amount / type:	Yes	No
7. Are there any arrangements for compensation / treatment of trial related injury? If yes , by sponsor by investigator By insurance company by others Please submit a copy of the insurance policy if it is available.	Yes	No

8. Do you have any conflict of interest in the present study?
(financial / non – financial/ any other) If yes, specify:
……

9. Is any other department involved in participant recruitment/investigation, but not co-investigators or collaborators? Yes No If yes, specify …….

Name and signature of concerned Head of Department……

We hereby declare the information given above is true. A copy of the study report will be submitted at the end of the study.

Signature of Principal Investigator:

Signatures of Co- investigators: 1. 2.

3. 4.

Forwarded by Heads of Department(s)

Stamp/Seal of the Department(s)

Please fill the form in legible handwriting or type the information. Write 'Not Applicable' (NA) wherever necessary. Incompletely filled form will not be accepted.

Check List of Documents for Protocol Submission to the Institutional Ethics *Committee to be*

filled in by the study team

Protocol submission for initial review (Tick accordingly; compulsory documents have to be submitted by ticking in the box marked as 'Yes') * Compulsory documents for initial review.

Sr. No.	Document	Yes	No	Date by which it will be submitted, if	NA
1	*Project submission application form duly filled				
a.	. Covering Letter				
b.	Project proposal – 3 hard copies				
c.	Project proposal – soft copy sent by e-mail / CD-ROM				
d.	CV of all investigators (including guide)				
e.	Fee for review				
2	Approval of Departmental Review Board (DRB)(for thesis/dissertations proposals)				
3	*Letter to Member Secretary/ Chairperson				
4	*Summary of protocol (in not more than 500 words)				
5	*Protocol				
6	*Informed consent document in English				
7.	*Informed consent documents in Regional languages (Total No:-)				
8.	Back translation of Informed Consent Documents (if available)				
9	Translation and Back translation certificates (if available)				
10	*Case Record Form				
11	*Research participants recruitment procedures: advertisement, notices (If applicable)				
12	*Patient instruction card, identity card, diary etc.				
13.a	*Research Participants Questionnaire/s (If applicable)				
13.b	Research participants confidentiality statement				
14	*Investigator Brochure				
15	*Insurance certificate and policy				
16	*Investigator's undertaking to DCG(I)				
17	DCG(I) approval [if DCGI approval is awaited, the same is mentioned in the covering letter to the IEC]				

18	*Clinical Trial Agreement for drug trial / Memorandum Of Understanding / Copy of clinical trial protocol Material Transfer Agreement (MTA), as applicable, for collaborator & Govt sponsored trials (draft if final not ready)				
19	FDA marketing/manufacturing license for herbal formulations/ nutraceutics				
20	Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations				
21	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy				
22	a) Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy) Or Memorandum of Understanding (as applicable)				
	b) Administrative sanction from the Head of the Institution for the samples to be sent to outside institution (one copy) Or Material Transfer Agreement (as applicable)				
23	*Budget Sheet for the Proposed Study (Format for budget sheet stated below)@				
24	*Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study co- ordinator) (one copy only)				
25	*Ethics Committee clearance of other centres (Total No_____)				
26	*Log of delegation of responsibility of the study team members - Sample Format Enclosed) (*AX*				
27	*Document Receipt Form (one copy only)				
28	*Current Status of Ongoing Studies approved by IEC and IEC conducted by principal investigator (information may be submitted separately)				
29	Documentation of clinical trial registration (in Clinical Trial Registry of India) / any other WHO platform registry (whenever applicable)				
30	*GCP training certificates of principal investigator, co investigator/s, study co- ordinator/s for interventional clinical trial sponsored by pharmaceuticals companies of training taken in last				

31	Any other Documents submitted				

1. **@Budget Sheet for the Proposed Study**

1	Title of the Project:	
2	Name of Principal Investigator (PI)	
3	Designation and address of the PI	
4	Names of Co-investigators with department/ institution:	
5	Source of funding	
	Government:	Central [ ], State [ ], Local [ ]
	In-house	
	Private Foundation:	Indian [ ], Foreign [ ]
	Non profit agency/trust funded	
	Pharma./ industry sponsored	
	Other:	
	No funding required	
	Address, phone, fax. E-mail of sponsor with the name of the contact person	
6	Total Budget for the entire project in Rs.	
7	Duration of the Project in months	
8	Proposed date of starting the project	
9	Direct payments to investigators, if any	
10	Any other benefits to the investigators/department/institution	
11	Conflict of Interests, if any	
Name of PI:		**Signature & Date:**

Delegation of Responsibilities of Study team

Study title: _____

Name	**Role**	**No**
	Principal Investigator	1
	Co-Investigator	2
	Co-Investigator	3
	Co-investigator	4
	Co-Investigator	5
	Co-investigator	6

	Study co-ordinator *	7
	Study co-ordinator *	7
	Laboratory Technician	8

* Study coordinator may preferably be a person specifically appointed for coordinating the clinical trial; other than the staff member (assistant / associate professor)

(Please place tick marks against assigned duties for each member in the following table)

Code	**TASKS**	**Role Played by Each Study Team Member**									
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
A	All relevant documents pertaining to protect blinding										
B	Research participants selection/ Screening										
C	Obtain informed consent										
D	Evaluate inclusion/ exclusion criteria										
E	Conduct the visit assessments										
F	Physical examination										
G	Complete the source documents										
H	Complete Case Record Form										
I	Final review and sign Case Record Form										
J	Collect laboratory safety test samples										
K	Processing of blood samples										
L	Preparing aliquots & keeping a track of the samples sent										
M	Review & sign of the lab reports										
N	Receive the study drug**, ,** document drug dispensing, storage & accountability										
O	Person to whom research participants should contact in case of adverse event										
P	Report all serious adverse events										

Q	Follow up of Serious Adverse Event										
R	Maintaining study site master file										
S	In-charge of inventory & supplies										
T	Archiving of study documents										
U	Resolution of queries										
V	Overall coordination and supervision										