Application Form for Ethical Clearance of Research Involving Human Participants

Section I. ADMINISTRATION DETAILS

Date of Submission:		
Researcher's Name		
Department		
Supervisor/ Head of Department:		
Protocol Number:		
Title of Study:		
Type of research	☐ UG/ PG Academic Study	☐ Exempt Academic Study*
	☐ Staff Academic Study	☐ Regulatory Clinical Trial

*Studies that do not require CDSCO approval

For MNR-MC IEC Use:			
Reference Number		Date received:	
Review Date:		Outcome: ☐	Approval
Applicant Informed ☐ Yes ☐ No		☐	Conditional Approval
Date:		☐	Deferral
		☐	Approval Declines

Please complete form and select YES/NO options as appropriate.
An application will only be accepted for review by MNR-MC IEC if it is completed fully and the relevant enclosures are received. Complete the checklist on the next page before submitting the form. Where you have received permission to do this, please provide evidence of permission with this application.

Please ensure that all copies of the same document are collated together in sets:

- Application form
- Study Protocol
- Participant Consent Document
- CRF
- Questionnaire(s), if any
- Investigator Brochure.

Address to send application: The IEC Chair, MNR-MC Institutional Ethics Committee.

Section II. SUBMISSION CHECKLIST

Please complete the ethics application form below and provide additional information as attachments.

Application includes the following documentation:	**# Copies**	**eCopy Yes**	**pCopy Yes**	**No**	**NA**
• Review Application Form					
• Research Study Protocol					
• Recruitment advertisement					
• Participant Information Sheet					
• Participant Informed Consent Form					
• Questionnaire/Survey					
• Interview/Focus Group Questions					
• Case Report Form					
• Investigator Brochure					
• CVs of PI and Team Members					
• Insurance & Indemnity					
• Annex 1					
• Annex 2					
• Annex 3					

Section III. DETAILS OF DRUG/ DEVICE				**Yes**	**No**
1) Is it an Investigational New Drug/ Device (IND)?				☐	☐
2) Is it approved and marketed in					
a) India				☐	☐
b) USA/ UK/ EU/ Japan/ Australia/ Canada				☐	☐
c) Other countries:				☐	☐
3) Is a Test License obtained?				☐	☐
Generic name (TEST)					
Trade name					
Strength		Dose			
Frequency		Route			
Generic name (Ref 1)					
Trade name					

Strength		Dose	
Frequency		Route	
Generic name (Ref 2)			
Trade name			
Strength		Dose	
Frequency		Route	

1) Who will administer the drug or fit the medical device?

2) If a medical device, has the device been through acceptance and safety testing?

3) Who is supplying the drug(s)/medical device? (If imported, name country)

4) Who will dispense the drug(s)/medical device?

Section IV. RESEARCH SPONSOR

1) Is the Sponsor? ☐ Government ☐ Commercial ☐ Non-Commercial

2) Name and Address of Sponsor:

3) Name and Address of Indian representative, if Sponsor is outside India

4) Name and Address of Funding Agency

5) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for international collaboration? (Required in case of academic studies involving collaborations with foreign institution)	☐ Yes ☐ No ☐ NA

Section V. STUDY DESCRIPTORS

☐ Healthy volunteers	☐ Randomised	☐ Radioactive
☐ Patient	☐ Non-randomised	☐ Biological
☐ Adult	☐ Open label	☐ Pharmaceutical
☐ Neonate	☐ Controlled	☐ Cosmetics
☐ Infant	☐ Cross-over	☐ Vaccine
☐ Children 0-12	☐ Case-study	☐ Medical device
☐ Children 13-18	☐ Placebo	☐ In vitro diagnostic kit
☐ Intervention	☐ Single-blind	☐ Ayurveda
☐ Observational	☐ Double-blind	☐ Dentistry
☐ Interview	☐ Prospective	☐ Biological tissue

☐ Questionnaire	☐ Retrospective	☐ Biological Sample
☐ Record-based	☐ Surgical	☐

Section VI. APPLICANT'S DETAILS

1) Title of Project

2) Principal Investigator (All correspondence will be sent to this address unless indicated otherwise.)

First Name:	Last Name:
Contact address:	
Mobile:	Extension:
Email id	
Present appointment:	
Qualification of PI:	

3) Sub-Investigator 1

First Name:	Last Name:
Contact address:	
Mobile:	Extension:
Email id	
Present appointment:	
Qualification of PI:	

4) Sub-Investigator 2

First Name:	Last Name:
Contact address:	
Mobile:	Extension:
Email id	
Present appointment:	
Qualification of PI:	

5) Clinical Research Coordinator

First Name:	Last Name:
Contact address:	MNR-FRI Clinical Trials Unit
Mobile:	Extension:
Email id	
Present appointment:	Clinical Research Coordinator
Qualification of PI:	

	Yes	**No**
6) Do you have any conflict of interest in the present study?	☐	☐
7) Are the team up-to-date on GCP and Regulations	☐	☐
8) Is the trial registered with CTRI	☐	☐
9) Number of protocols handled by the PI at present		

Section VII. STUDY DETAILS

Please outline, in terms that any non-expert would understand, what your research project is about, including what participants will be required to do.

10) Subject selection:	Yes	No	NA
a) Will subjects from both genders be recruited?	☐	☐	☐
b) Number of subjects to be recruited globally			
c) Number of subjects to be recruited in India			
d) Number of subjects to be recruited at MNR-MC			

11) Aim and Objectives of Study (i.e. what is the intention of the study, key research questions?)

12) Specify the primary research question/objective

13) Specify the secondary research questions/objectives

14) Scientific justification for the clinical trial?

15) What are the inclusion criteria?

16) What are the exclusion criteria?

17) What criteria exist for withdrawing research participants prematurely?

18) Scientific justification for the clinical trial?

19) Brief Study Procedure & Investigations (paste Study Flow Chart table)

20) Anticipated risks to participants (what, when, how often). Such risks could include physical stress, emotional distress, perceived coercion e.g. lecturer interviewing own students. Detail the measures and considerations you have put in place to minimize these risks.

21) Will treatment be withheld from research participants as a result of taking part in the clinical trial?	☐ Yes	☐ No

If Yes, please give details

22) What procedures are in place to monitor the health of the research participants during the trial or when they are no longer involved in the trial?

23) What are the potential benefits for research participants?

24) Proposed start date and duration of study

Proposed start date:
Estimated close date:
Duration (months):

25) Research location and in what setting?

26) Forms of obtaining consent

☐ Audio only	☐ Paper only	☐ Assent
☐ Audio & Video	☐ AV & Paper	☐

27) Clinical phase of study

☐ Pilot investigation	☐ Phase 1	☐ Post-marketing surveillance

☐	Pivotal investigation	☐	Phase 2	☐	BA-BE
☐	Pilot performance (IVD)	☐	Phase 3	☐	Single center
☐	Pivotal performance (IVD)	☐	Phase 4	☐	Multi center

28) Does the study involve investigations and/or interventions	**Yes**	**No**
a) Self completion questionnaire	☐	☐
b) Audio/video tape recording	☐	☐
c) Physical examination	☐	☐
d) Venepuncture	☐	☐
e) Arterial puncture	☐	☐
f) Biopsy	☐	☐
g) Hospitalization	☐	☐
h) Local anesthesia	☐	☐
i) General anesthesia	☐	☐
j) Use of pre-existing/ stored/ left over biological samples		
k) Use of fetal tissue or abortus		
l) Use of organs or body fluids		
m) Use of recombinant/ gene therapy		
n) Collection for banking/ future use		
o) Use of ionizing radiation / radioisotopes		
p) Use of infectious / biohazard specimens		
q) Export of biological samples		

29) Please indicate and justify where standard of care is withheld as a result of taking part in the study

30) Data & Safety Monitoring	Yes	No	NA
a) Is a DSMB constituted by the Sponsor	☐	☐	☐
b) Is there a plan for interim analysis of data?	☐	☐	☐

Section VIII. PARTICIPANT DETAILS

31) Study population (include number overall and per site expectation)

Participants overall:
Participants from MNR-MC:

32) Will the participants be from any of the following groups? (tick as appropriate)

☐	Children under 16	☐	Adults with learning disabilities
☐	Adults who are unconscious	☐	Adults who have a terminal illness
☐	Adults in emergency situations	☐	Adults with mental illness
☐	Pregnant women / women of child bearing age	☐	Prisoners
☐	Adults suffering from dementia	☐	Healthy volunteers
☐	Those who could be considered to be vulnerable or have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students.		

Justification for selecting a specific gender, age, or any other group, if any

33) Will participants receive any payment or other incentives to participate, and how much?

☐ Yes	Amount to be received per visit
☐ No	

Section IX. INFORMED CONSENT	Yes	No	NA
34) Is written consent for participation to be obtained?	☐	☐	☐
35) Does the study include participants for whom English is not a first language?	☐	☐	☐
36) Will you inform the participants that their participation is voluntary and may be withdrawn at any point?	☐	☐	☐
37) Will you tell participants that their data will be treated with	☐	☐	☐

full confidentiality and that, if published, it will not be identifiable as theirs?			
38) Will the data be anonymous?	☐	☐	☐
39) Are women of childbearing potential included in this study?	☐	☐	☐
40) A copy of the written participant information sheet is attached	☐	☐	☐
41) Will the participant's family physician be notified of his or her participation in the trial?	☐	☐	☐
42) How long will the subject have to decide whether to take part in the study?			

43) If you are recruiting from a vulnerable group, please specify and justify:

Section X. RISKS AND ETHICAL ISSUES	**Yes**	**No**	**NA**
44) Are there are any potential risks to participants?	☐	☐	☐
a. Less than minimal risk	☐	☐	☐
b. Minimal risk	☐	☐	☐
c. More than minimal risk	☐	☐	☐
d. High risk	☐	☐	☐
45) Is this study likely to cause any discomfort or distress, either physical or mental?	☐	☐	☐
46) Is the risk reasonable compared to the anticipated benefits to subject/ community/ country?	☐	☐	☐
47) Will treatments provided during the study be available if needed at the end of the study?	☐	☐	☐

48) What particular ethical problems or issues do you consider to be important or difficult with the proposed study?

49) What arrangements have been made for research participants who might not adequately understand verbal or written information?

Section XI. FINANCIAL ARRANGEMENTS

50) What arrangements have been made to provide indemnification and/or compensation in the event of a claim by, or on behalf of, a participant for negligent harm? Please submit a copy of insurance.

51) Does any of the Investigator(s) in the team have any direct/indirect involvement in the outcome of the clinical trial that could in anyway be regarded as a possible conflict of interest?	☐ Yes	☐ No
52) Has funding for the clinical trial been secured?	☐ Yes	☐ No
If Yes, give details of funding organisation(s) and amount secured and duration:		
Organisation:		
Address:		
Amount:		
If No, what arrangements have been made to cover the cost of the research?		

53) The Investigator fees received, will be deposited with:

☐ Principal Investigator	☐ PI & Institution	☐ Organisation
☐ MNR-MC	☐ Department	☐ MNR-FRI

Section XII. CONFIDENTIALITY	**Yes**	**No**
54) Will the study data be held on computer?	☐	☐

Section XII. CONFIDENTIALITY	Yes	No
55) Will paper records linking study participant ID with identifying features be stored confidentially?	☐	☐
56) Will the study team in the study examine the participants' medical records?	☐	☐
57) Will external people (auditors, monitors and inspectors) be allowed to examine medical or other personal records?	☐	☐
58) Does the proposed clinical trial involve the retention of biological material (tissue, bodily fluids) or data derived from them?	☐	☐

Section XIII. DECLARATION OF PRINCIPAL INVESTIGATOR

This declaration must be signed and sent to MNR-MC IEC together with the requisite fee before the application will be considered as valid.

- I certify that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I undertake to abide by the ethical principles outlined in the Declaration of Helsinki, and my obligations as set out in CDSCO Good Clinical Practice Guidelines and Schedule Y of the Drugs & Cosmetics Act.
- If the clinical trial is approved, I undertake to adhere to the study protocol and to comply with any conditions set out in the letter of approval sent by MNR-MC IEC.
- I am aware of my responsibility to be up to date and comply with the requirements of the law relating to security and confidentiality of patient or other personal data.

Researcher	**Supervisor/Head of Department**
Signature	Signature
Name	Name
Date:	Date: