# MAGANBHAI ADENWALA MAHAGUJARAT UNIVERSITY
## Institutional Ethics Committee for Human Research
**J. S. Ayurveda College Campus, College Road, Nadiad – 387001**
Phone: (0268) 2520724, 2527055, 2520646 Email: office@mamuni.edu.in Web: www.mamuni.edu.in.


**(Annexure 1)**

# APPLICATION FORM FOR EXPEDITED REVIEW

**EC Ref. No.*** ***(For office use):***

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Choose reasons why expedited review from EC is requested[12] ?
   - i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
   - ii. Involves clinical documentation materials that are non-identifiable (data, documents, records). ☐
   - iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐
   - iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal. ☐
   - v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
   - vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
   - vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre. ☐
   - viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
   - ix. Any other (please specify) .....
2. Is waiver of consent being requested? Yes ☐ No ☐
3. Does the research involve vulnerable persons[13] ? Yes ☐ No ☐

If Yes give details: .....

.....

.....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[12] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*
[13] *For details, refer to application for initial review, Section-C, 5(b)*
* *In case this is first submission, leave it blank*

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**(Annexure 2)**

# APPLICATION FORM FOR EXEMPTION FROM REVIEW

**EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Choose reasons why exemption from ethics review is requested[14]?
   - i. Research on data in the public domain/ systematic reviews or meta-analyses ☐
   - ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person ☐
   - iii. Quality control and quality assurance audits in the institution ☐
   - iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
   - v. Consumer acceptance studies related to taste and food quality ☐
   - vi. Public health programmes by government agencies[15] ☐
   - vii. Any other (please specify in 100 words): .....

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[14]*Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

[15]*Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)*

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**(Annexure 3)**

# CONTINUING REVIEW / ANNUAL REPORT FORMAT

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC Approval: dd mm yy Validity of approval: dd mm yy
2. Date of Start of study: dd mm yy Proposed date of Completion: dd mm yy

   Period of Continuing Report: dd mm yy ---- to ------ dd mm yy
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected..... Number Screened: ..... Number Enrolled: .....

   Number Completed:..... Number on followup:.....

   (b) Enrolment status – ongoing / completed/ stopped

   (c) Report of DSMB[16] Yes ☐ No ☐ NA☐

   (d) Any other remark.....

   .....

   (e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA☐

   If yes, total number withdrawn and reasons: .....

   .....

   .....
4. Is the study likely to extend beyond the stated period ?[17] Yes ☐ No ☐

   If yes, please provide reasons for the extension. .....

   .....

   .....
5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

   If No, skip to item no. 6 Yes ☐ No ☐

   (a) If yes, date of approval for protocol and ICD : dd mm yy

   (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐

   No☐ If yes, when / how:

   .....

   .....

   .....

[16] *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*

[17] *Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

6. Is any new information available that changes the benefit – risk analysis of human participants involved in this study? Yes ☐ No ☐

If yes, discuss in detail: .....

.....

.....

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐

If yes, give details:.....

.....

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

Describe in brief: .....

.....

.....

(b) Have any SAE's occurred since last review? Yes ☐ No ☐

If yes, number of SAE's :..... Type of SAE's: .....

.....

.....

(c) Is the SAE related to the study? Yes ☐ No ☐

Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

.....

.....

9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations .....

Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

.....

.....

10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

.....

.....

Any other comments:.....

.....

Signature of PI: ..... dd mm yy

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**(Annexure 4)**

# APPLICATION/NOTIFICATION FORM FOR AMENDMENTS

**EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study dd mm yy

2. Details of amendment(s)

| S.No | Existing Provision | Proposed Amendment | Reason | Location in the protocol/ICD [18] |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

3. Impact on benefit-risk analysis Yes ☐ No ☐

If yes, describe in brief: .....

.....

4. Is any reconsent necessary? Yes ☐ No ☐

If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants) ☐

Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure/ICD: .....

Signature of PI: ..... dd mm yy

[18] *Location implies page number in the ICD/protocol where the amendment is proposed.*

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**(Annexure 5)**

## PROTOCOL VIOLATION/DEVIATION REPORTING FORM (REPORTING BY CASE)

**EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval dd mm yy Date of start of study dd mm yy
2. Participant ID: ..... Date of occurrence dd mm yy
3. Total number of deviations /violations reported till date in the study: .....
4. Deviation/Violation identified by: Principal Investigator/study team ☐ Sponsor/Monitor ☐
   SAE Sub Committee/EC ☐
5. Is the deviation related to (Tick the appropriate box) :

| | | | |
|---|---|---|---|
| Consenting | ☐ | Source documentation | ☐ |
| Enrollment | ☐ | Staff | ☐ |
| Laboratory assessment | ☐ | Participant non-compliance | ☐ |
| Investigational Product | ☐ | Others *(specify)* | ☐ |
| Safety Reporting | ☐ | | |

6. Provide details of Deviation/Violation: .....

.....

.....

.....

7. Corrective action taken by PI/Co-I: .....

.....

.....

.....

8. Impact on (if any): Study participant ☐ Quality of data ☐
9. Are any changes to the study/protocol required? Yes ☐ No ☐

   If yes, give details.....

.....

Signature of PI: ..... dd mm yy

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**(Annexure 6)**

# SERIOUS ADVERSE EVENT REPORTING FORMAT

**EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Participant details :

| Initials and ID | Age at the time of event | Gender | Weight: ..... (Kgs) |
|---|---|---|---|
| ..... | ..... | Male ☐ Female ☐ | Height: ..... (cms) |
| ..... | ..... | | |

2. Suspected SAE diagnosis:.....

3. Date of onset of SAE: dd mm yy

Date of reporting SAE: dd mm yy

Describe the event [19]:

.....

.....

.....

.....

.....

.....

.....

4. Details of suspected intervention causing SAE [20]

.....

.....

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.....

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.....

5. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

6. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....

.....

.....

[19] *Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious*

[20] *Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

7. In case of a multi-centric study, have any of the other study sites reported similar SAEs ?

(Please list number of cases with details if available)

.....

.....

8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)

A. Expected event ☐ Unexpected event ☐

B.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Hospitalization | ☐ | Increased Hospital Stay | ☐ | Death | ☐ | Congenital anoma- ly/birth defect | ☐ |
| Persistent or signifi- cant disability/inca- pacity | ☐ | Event requiring inter- vention (surgical or medical) to prevent SAE | ☐ | Event which poses threat to life | ☐ | Others | ☐ |

.....

In case of death, state probable cause of death.....

C. No permanent/significant functional/cosmetic impairment ☐

Permanent/significant functional/cosmetic impairment ☐

Not Applicable ☐

9. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include infor- mation on who paid, how much was paid and to whom).

.....

.....

10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom).....

.....

11. Outcome of SAE

| | | | |
|---|---|---|---|
| Fatal | ☐ | Recovered | ☐ |
| Continuing | ☐ | Unknown | ☐ |
| Recovering | ☐ | Other *(specify)* | ☐ |

.....

12. Provide any other relevant information that can facilitate assessment of the case such as medical history

.....

.....

.....

13. Provide details about PI's final assessment of SAE relatedness to research.

.....

.....

.....

Signature of PI: ..... dd mm yy

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**(Annexure 7)**

## PREMATURE TERMINATION/SUSPENSION/ DISCONTINUATION REPORT FORMAT

**EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study: dd mm yy
2. Date of last progress report submitted to EC: dd mm yy
3. Date of termination/suspension/discontinuation: dd mm yy
4. Tick the appropriate

   Premature Termination ☐ Suspension ☐ Discontinuation ☐

   Reason for Termination/Suspension/Discontinuation: .....

   .....

   .....

   .....

   Action taken post Termination/ Suspension/Discontinuation (if any): .....

   .....

   .....

   .....
5. Plans for post study follow up/withdrawal[21] (if any): .....

   .....

   .....
6. Details of study participants:

   Total participants to be recruited: ..... Screened: ..... Screen failures:.....

   Enrolled:..... Consent Withdrawn:..... Reason (Give details): .....

   .....

   .....

   Withdrawn by PI:..... Reason(Give details): .....

   .....

[21] *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.*

Active on treatment: …… Completed treatment : …… Participants on follow-up: ……

Participants lost to follow up: …… Any other: …… Number of drop outs:……

Reasons for each drop-out: ……

……

……

……

7. Total number of SAEs reported till date in the study: ……

Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes ☐ No☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No☐

If yes, provide details:……

……

9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No☐

If yes, have you implemented that suggestion? Yes ☐ No☐

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes ☐ No☐

(e.g., making arrangements for medical care of research participants): If Yes, provide details

……

……

Summary of results (if any): ……

……

……

……

……

……

Signature of PI: …… dd mm yy

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**(Annexure 8)**

## APPLICATION FORM FOR CLINICAL TRIALS

**EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Type of clinical trial Regulatory trial ☐ Academic trial ☐

   CTRI registration number: ..... NABH accreditation number:..... EC registration number:.....

2. If regulatory trial, provide status of CDSCO permission letter

   Approved and letter attached ☐ Applied, under process ☐

   Not applied (State reason) ☐.....

3. Tick all categories that apply to your trial

| | | | |
|---|---|---|---|
| Phase – I | ☐ | Phase II | ☐ |
| Phase III | ☐ | Phase IV or Post Marketing Surveillance | ☐ |
| Investigational medicinal products | ☐ | Investigational New drug | ☐ |
| Medical devices | ☐ | New innovative procedure | ☐ |
| Drug/device combination | ☐ | Bioavailability/Bioequivalence studies | ☐ |
| Non-drug intervention | ☐ | Repurposing an existing intervention | ☐ |
| Indian system of medicine (AYUSH) | ☐ | Stem cells | ☐ |
| Phytopharmaceutical drug | ☐ | Approved drug for any new indication | |
| Others (specify) | ☐ | or new route of administration | ☐ |

.....

4. Trial design of the study

| | | | |
|---|---|---|---|
| I. Randomized | ☐ | Factorial | ☐ |
| Non randomized | ☐ | Stratified | ☐ |
| Parallel | ☐ | Adaptive | ☐ |
| Cross-over | ☐ | Comparison trial | ☐ |
| Cluster | ☐ | Superiority trial | ☐ |
| Matched-pair | ☐ | Non-inferiority trial | ☐ |
| Others *(specify)* | ☐ | Equivalence trial | ☐ |

.....

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

.....

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III. Describe the method of allocation concealment (blinding / masking), if applicable.

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5. List the primary / secondary outcomes of the trial.

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6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation/human resource? Yes ☐ No ☐

If yes, Name and Contact details: .....

.....

.....

State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

| | | | |
|---|---|---|---|
| Project management | ☐ | Clinical and medical monitoring | ☐ |
| Regulatory affairs | ☐ | Data management | ☐ |
| Statistical support | ☐ | Medical writing | ☐ |
| Site management | ☐ | Audits, quality control, quality assurance | ☐ |
| Finance management | ☐ | Recruitment and training | ☐ |
| Administrative support | ☐ | Others *(specify)* | ☐ |

.....

7. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; if yes, provide regulatory approval details. Yes ☐ No ☐ NA ☐

.....

.....

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details. Yes ☐ No ☐ NA ☐

.....

.....

III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.

.....

.....

IV. Provide details of patent of the drug/s, device/s and biologics.

.....

.....

8. Describe in brief any preparatory work or site preparedness for the protocol? Yes ☐ No ☐ NA ☐

If yes, provide details (100words).....

.....

.....

.....

.....

9. Is there an initial screening/ use of existing database for participant selection? Yes ☐ No ☐ NA ☐

If Yes, provide details[22].....

.....

.....

.....

10. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention?

If yes, provide details of arrangements made to address them. Yes ☐ No ☐ NA ☐

.....

.....

.....

11. Does the study use a placebo?

If yes, justify the use of the placebo and risks entailed to participants. Yes ☐ No ☐ NA ☐

.....

.....

.....

12. Will current standard of care be provided to the control arm in the study? Yes ☐ No ☐ NA ☐

If no, please justify.

.....

.....

.....

13. Are there any plans to withdraw standard therapy during the study? If yes, please justify. Yes ☐ No ☐ NA ☐

.....

.....

.....

14. Are there any rules to stop the protocol in case of any adverse events? If yes, please specify. Yes ☐ No ☐ NA ☐

.....

.....

.....

.....

15. Does the study have a Data and Safety Monitoring Plan? If no, please justify. Yes ☐ No ☐

.....

.....

.....

[22] *In order to select participants for your protcol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same*

16. Participant Information Sheet(PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐
(certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)

Other*(Specify)* ☐

.....

List the languages in which translations were done .....

Justify if translation not done.....

.....

17. Involvement/consultation of statistician in the study design Yes ☐ No ☐ NA ☐

18. Is there any insurance coverage of the trial? If yes, provide details. Yes ☐ No ☐

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.....

I. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration?

Please provide details. Yes ☐ No ☐

.....

.....

II. Is the PI trained in GCP in last 3 years? If yes, Please enclose certificate Yes ☐ No ☐

Signature of PI: ..... dd mm yy

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**(Annexure 9)**

## SERIOUS ADVERSE EVENT REPORTING FORMAT (CLINICAL TRIALS)

**EC Ref. No.** ***(For office use):***

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Participant details :

Initials and Case No./ Subject ID .....

Age at the time of event .....

Gender Male ☐ Female ☐

Weight: .....(Kgs)

Height: .....(cms)

2. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

What was the assessment of relatedness to the trial in the initial report?

By PI – Related ☐ Unrelated ☐ By Sponsor – Related ☐ Unrelated ☐ By EC – Related ☐ Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:.....

.....

.....

4. Date of onset of SAE: dd mm yy Date of reporting: dd mm yy

5. Onset lag time after administration of intervention: ..... Location of SAE (Clinic/Ward/Home/Other) .....

6. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: .....

.....

II. Indication(s) for which suspect study drug was prescribed or tested: .....

.....

III. Route(s) of administration, daily dose and regimen, dosage form and strength : .....

.....

IV. Therapy start date: dd mm yy Stop date: dd mm yy

7. Was study intervention discontinued due to event? Yes ☐ No ☐

8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes ☐ No ☐

   If yes, provide details about the reduced dose.....

9. Did the reaction reappear after reintroducing the study drug / procedure? Yes ☐ No ☐ NA ☐

   If yes, provide details about the dose.....

10. Concomitant drugs history and lab investigations:

   I. Concomitant drug (s) and date of administration: dd mm yy

   .....

   .....

   II. Relevant test/laboratory data with dates: dd mm yy

   .....

   .....

   III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc).....

   .....

   .....

11. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

   .....

   .....

12. Seriousness of the SAE:

| | | | |
|---|---|---|---|
| Death | ☐ | Congenitial anomaly | ☐ |
| Life threatening | ☐ | Required intervention to prevent | |
| Hospitalization-initial or prolonged | ☐ | permanent impairment / damage | ☐ |
| Disability | ☐ | Others *(specify)* | ☐ |

   .....

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include infor- mation on who paid, how much was paid and to whom).

   .....

   .....

14. Outcome of SAE:

| | | | |
|---|---|---|---|
| Fatal | ☐ | Recovered | ☐ |
| Continuing | ☐ | Unknown | ☐ |
| Recovering | ☐ | Other *(specify)* | ☐ |

   .....

15. Was the research participant continued on the trial? Yes ☐ No ☐ NA ☐

16. Provide details about PI's final assessment of SAE relatedness to trial.

   .....

   .....

17. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes ☐ No ☐

   Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol? Yes ☐ No ☐

19. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom).....

   .....

Signature of PI: ..... dd mm yy

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(Annexure 10)

## APPLICATION FORM FOR HUMAN GENETICS TESTING RESEARCH

**EC Ref. No.** ***(For office use):***

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Describe the nature of genetic testing research being conducted.
   (e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)
   .....
   .....
   .....
2. Does the study involve pretest and post-test counselling? If yes, please describe. Yes ☐ No ☐ NA ☐
   .....
   .....
3. Explain the additional safeguards provided to maintain confidentiality of data generated.
   .....
   .....
   .....
4. If there is a need to share the participants' information/investigations with family/community, is it addressed in the informed consent? Yes ☐ No ☐ NA ☐
   If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)
   .....
   .....
   .....
5. Is there involvement of secondary participants? Yes ☐ No ☐ NA ☐
   If yes, will informed consent be obtained? State reasons if not. Yes ☐ No ☐ NA ☐
   .....
   .....
6. What measures are taken to minimize/mitigate/eliminate conflict of interest?
   .....
   .....
   .....
7. Is there a plan for future use of stored samples for research? Yes ☐ No ☐
   If yes, has this been addressed in the informed consent ? Yes ☐ No ☐

Signature of PI: ..... dd mm yy

# MAGANBHAI ADENWALA MAHAGUJARAT UNIVERSITY
## Institutional Ethics Committee for Human Research
**J. S. Ayurveda College Campus, College Road, Nadiad – 387001**
Phone: (0268) 2520724, 2527055, 2520646 Email: office@mamuni.edu.in Web: www.mamuni.edu.in.


**(Annexure 11)**

## APPLICATION FORM FOR SOCIO-BEHAVIOURAL AND PUBLIC HEALTH RESEARCH

**EC Ref. No.** ***(For office use):***

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Data collection method used in the study

| | | | | | |
|---|---|---|---|---|---|
| Focus group | ☐ | Questionnaire/Survey | ☐ | Observation | ☐ |
| Interviews | ☐ | Documents and records | ☐ | Ethnographies/Oral history/Case studies | ☐ |
| Others *(Specify)* | ☐ | | | | |

.....

If it is an interview, will there be audio-video recording of participants' interview? If yes, justify the reasons and storage strategies. Yes ☐ No ☐

.....

.....

.....

2. Type of informed consent used in the study.

| | | | | | |
|---|---|---|---|---|---|
| Individual consent | ☐ | Gate-keeper consent | ☐ | Community consent | ☐ |
| Others | ☐ | *(specify)*..... | | | |

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.

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.....

4. Describe strategies to manage if any patterns of behaviour of self-harm or harm to the society are identified.(e.g.: Suicide or infanticide) Yes ☐ No ☐ NA ☐

.....

.....

.....

5. Are cultural norms/Social considerations/Sensitivities taken into account while designing the study and participant recruitment? Yes ☐ No ☐

6. Is there a use of an interpreter? If yes, describe the selection process. Yes ☐ No ☐ NA ☐

.....

.....

.....

7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐

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8. I. Type of risk related to procedures involved in the study

Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

Describe the risk minimization strategies.

.....

.....

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.....

II. Justify reasons if individual harm is overriding societal benefit. Yes ☐ No ☐ NA ☐

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III. Describe how do societal benefits outweigh individual harm.

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9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception. Yes ☐ No ☐

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10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

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.....

.....

Signature of PI: ..... dd mm yy

# MAGANBHAI ADENWALA MAHAGUJARAT UNIVERSITY
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**(Annexure 12)**

# Study completion/Final report format

**EC Ref. No.** ***(For office use):***

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Date of EC approval: dd mm yy
2. Date of start of study: dd mm yy Date of study completion: dd mm yy
3. Provide details of:

   a) Total number of study participants approved by the EC for recruitment: .....

   b) Total number of study participants recruited: .....

   c) Total number of participants withdrawn from the study (if any): .....

   Provide the reasons for withdrawal of participants[23] : .....

   .....

   .....
4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) .....

   .....

   .....
5. Describe the main ethical issues encountered in the study (if any) .....

   .....

   .....

   .....

   .....
6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

   Deviations: ..... Violation: ..... Amendments: .....
7. Describe in brief plans for archival of records / record retention:.....

   .....

   .....

   .....

   .....

[23] *Explanation for the withdrawal of participants whether by self or by the PI*

8. Is there a plan for post study follow-up? Yes ☐ No ☐

If yes, describe in brief: .....

.....

.....

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9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes ☐ No ☐

If yes, describe in brief: .....

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10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No ☐

If yes, describe in brief: .....

.....

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11. Describe results (summary) with Conclusion [24] : .....

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.....

12. Number of SAEs that occurred in the study: .....

13. Have all SAEs been intimated to the EC ? Yes ☐ No ☐

14. Is medical management or compensation for SAE provided to the participants? Yes ☐ No ☐

If yes, provide details.....

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.....

Signature of PI: ..... dd mm yy

[24] *For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.*

# MAGANBHAI ADENWALA MAHAGUJARAT UNIVERSITY
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**(Annexure 13)**

# FORMAT FOR CURRICULUM VITAE FOR INVESTIGATORS

**EC Ref. No.** ***(For office use):***

| |
|---|
| Name: |
| Present affiliation *(Job title, department, and organisation)*: |
| Address (Full work address): |
| Telephone number: Email address: |
| Qualifications: |
| Professional registration *(Name of body, registration number and date of registration):* |
| Previous and other affiliations *(Include previous affiliations in the last 5 years and other current affiliations):* |
| Projects undertaken in the last 5 years: |

| Relevant research training/experience in the area [25] : |
| --- |
| |
| Relevant publications *(Give references to all relevant publications in the last five years):* |
| |

| Signature | Date: |
| --- | --- |
| | |

[25] *Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*