**FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE (FMIEC)**

**APPLICATION FORM FOR INITIAL REVIEW OF RESEARCH PROPOSALS (FORMS 1,2,3,4)**

* **Please Note That :**

**I. There are Separate Application forms for :**

1. ACADEMIC STUDIES OF STAFF WITH RESEARCH GRANTS (FMRC & EXTERNAL) & CLINICAL TRIALS : FORM-1

2. Academic Studies of Students (UG.PG) and academic studies of staff which do not involve research grant : FORM-2

3. Case Reports : FORM-3

4. Resubmission of revised /additional documents –FORM-4

**II. The Researchers are requested to use the appropriate application form only .**

**III. Other Documents to be Submitted Along with Application form are made available in a Separate File ( FORMATS OF FMIEC ).**

**Please Submit these documents as applicable to the Type of Study**

IV. For all studies, **prior approval of the FMIEC is mandatory before initiating the Study.**

Once you complete the approved study and go for publication, submit completion report and obtain approval for publication/presentation is not required.

FMIEC will not give approval to those studies which are completed or initiated without its approval.

V. **For case reports,** approval of FMIEC has to be obtained after studying the case, for presentation /publication.

VI. **Meeting :** FMIEC meets on second Saturday of every month. However, additional meetings may be held depending on the number of proposals awaiting approval. The proposals should reach FMIEC at least 10 days before the scheduled date of meeting.

VII. **Scientific Committee**  : **All research proposals should be first submitted to Father Muller Institutional Scientific Committee for FMRC. After approval from this committee , the application will be considered by Ethics Committee (FMIEC) . One soft copy as PDF to be submitted for initial review.**

VIII. Clinical trial applications and research proposals form external institutions should be submitted directly to FMIEC.

IX. **Forms are also made available for** : Request for renewal of IEC approval, resubmission, protocol amendment report, protocol deviations report, SAE reporting, progress report and study completion report.(REFER TO ADDITIONAL FORMS OF FMIEC)

* **E mail ID of Scientific Committee :** [scfmrc@fathermuller.in](mailto:scfmrc@fathermuller.in).
* **E mail ID of Ethics Committee :** [**fmiethicscommittee@fathermuller.in**](mailto:fmiethicscommittee@fathermuller.in)

**FORM-1 : APPLICATION FOR INITIAL REVIEW OF RESEARCH PROPOSALS**

**(FOR STAFF RESEARCH WITH GRANTS – FMRC /EXTERNAL & CLINICAL TRIALS )**

**FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE (FMIEC)**

**For Office Use Only : FMIEC**

1. Application received by FMIEC on :
2. Protocol No. :
3. Categorized for : Full Review/Expedited Review/Exempted from Review
4. Proposal approved on :
5. Signature of Member Secretary , FMIEC with Date :

General Instructions : a) Tick one or more options as applicable. Mark NA if not applicable

b) Attach additional sheets if required

# SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization: ………………………………………………………………………………………………..........................……………………..........

(b) Name of Principal Investigator: ………………………………………………………………………………….........................………………..……………

(c) Department/Division: (d) Date of submission:

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

(e) Title of the study: ………………….........................……………………………………………………………………………………………………………………

……………………………………………………………………………………………………………………………………................................………………………..

…………………………………………………………………………………………………………………………………................................…………………………..

(f) Protocol number (If any): ……………………………………………………… Version number: ……………………………….......…...………

**(g)Details of Investigators:**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Designation and Qualification | Department and Institution | Address for communication (address, phone number, e mail ID) |
| **Principal Investigator** | | | |
|  |  |  |  |
| **Co-investigators** | | | |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |

1. Number of studies where applicant is a:
   1. Principal Investigator at time of submission ii) Co-Investigator at time of submission:

………………………………………………………...............………. ……………………...........………………….………………...............………..... (j) Duration of the study: …………………………………………………………………………………………………………..…………...........................………

1. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: …………………………………………………………………………………………………….......................……………

At site…………………………….................... In India…………………………...…………… Globally ………………........…...................................

(b) Self-funding  Institutional funding  Funding agency *(Specify)* 

..........………....………….....................................................…………………............................................................................................................

SECTION B - RESEARCH RELATED INFORMATION

1. OVERVIEW OF RESEARCH

(a) Lay summary -*3Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*

(within 300 words): ……………………..................................…………………………………………….....………………………...

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

..................................……………………………………………………………………………………………………………………………………………………………

(b) Type of study (tick whichever is applicable)

|  |  |  |
| --- | --- | --- |
| Basic Sciences  Clinical |  Cross Sectional |  |
| Retrospective  Epidemiological/ |  Case Control |  |
| Prospective  Public Health | Cohort |  |
| Qualitative  Socio-behavioural |  Systematic Review |  |
| Quantitative  Biological samples/ Data |  |  |
| Mixed Method  Any others *(Specify)* |  |  |

..........................................................................................................................................................………............…………………................

1. METHODOLOGY
   1. Sample size/ number of participants *(as applicable)*

At site…………………………….................... In India…………………………...…………… Globally ………………........…...................................

Control group………………………………………………………………… Study group ……………………………….…......….........................………

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation ...................………………………………………………………………………………………………………………………………….........................

...............…………………………………………………………………………………………...………………………………………………….....................….......…

………..................................…………………………………………………………….....……………….…………………………………………………………………

………..................................…………………………………………………………….....………………….………………………………………………………………

………..................................…………………………………………………………….....…………….…………………………………………………………...………

………..................................…………………………………………………………….....…………….…………………………………………………………...………

* 1. Is there an external laboratory/outsourcing involved for investigations?4 Yes  No  NA 

If Yes, provide the details.

1. RECRUITMENT AND RESEARCH PARTICIPANTS
   1. Type of participants in the study:

Healthy volunteers  Patients  Vulnerable persons/ Special groups 

Others  *(Specify)* .................................................................................................…........…………...........................

Who will do the recruitment? ……………………………………………………………………………………………………………………......................

* 1. Participant recruitment methods used(Tick whichever is applicable)

Posters/ leaflets/Letters /

TV/Radio ads/

Social media/ Institution website/

Patients / Family/ Friends/

visiting hospitals/

Others  *(Specify)* ……………………………………...................................................................................................……

* 1. i. Will there be vulnerable persons / special groups involved ? Yes  No  NA 

ii. If yes, type of vulnerable persons / special groups

Children under 18 yrs  Pregnant or lactating women  Differently abled (Mental/Physical)  Employees/Students/Nurses/Staff  Elderly  Institutionalized  Economically and socially disadvantaged  Refugees/Migrants/Homeless  Terminally ill (stigmatized or rare diseases) 

Any other *(Specify)*:  ……………………......................................................................................

iii. Provide justification for inclusion/exclusion …………………………………………………………………………..................………………..

…………………………………………………………………………………………………………………………………………………………….…....…………………

…………………………………………………………………………………………………………………………………………………………….…....………………… iv. Are there any additional safeguards to protect research participants?..........................................................................

…………………………………………………………………………………………………………………………………………………………….…....…………………

…………………………………………………………………………………………………………………………………………………………….…....…………………

* 1. Is there any reimbursement to the participants? Yes  No 

If yes, Monetary  Non-monetary  *Provide details*

………………………………………………………………………………………………………………………………….……………………….………………………………

……………………………………………………………………………………………….....………………………………….……………………….………………….........

* 1. Are there any incentives to the participants? Yes  No 

If yes, Monetary  Non-monetary  *Provide details*

……………………………………………………………………………………………………………………………………………………………………………..……………

…………………………………………………………………………………………………………………………....................................................................….

* 1. Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?

If yes, Monetary  Non-monetary  *Provide details* Yes  No 

……………………………………………………………………….….………………………………………………………………………………………………………………

…………………………………………………………………………...……………………………………………………….……………………….……………….…….......

1. BENEFITS AND RISKS
   1. i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes  No 

If yes, categorize the level of risk :

Less than Minimal risk  Minimal risk 

Minor increase over minimal risk or low risk  More than minimal risk or high risk 

ii. Describe the risk management strategy: …………………………………………………………………………………....................................

..…………………………………………………..…………….….……………………………………………………………………………………………….....………....

..…………………………………………………..…………….….……………………………………………………………………………………………….....………....

* 1. What are the potential benefits from the study? For the participant

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Yes | No | If yes, | Direct | Indirect |
|      |      |  |      |      |

For the society/community For improvement in science

Please describe how the benefits justify the risks …………………………………………………………………………………………..……………

………………………………………………………………………….….…………………………………………………………………………………………….………………

………………………………………………………………………….….……………………………………………………………………………………………….……………

………………………………………………………………………….….……………………………………………………………………………………………….……………

* 1. Are adverse events expected in the study ? Yes  No  NA  Are reporting procedures and management strategies described in the study? Yes  No  If Yes, Specify …………………………………………………………………................................……………………………………………………………………

…………………......……………………………………………………….….……………………………………………………………………………………………………….

..................................................................................................................................................................................................................

1. INFORMED CONSENT
   1. Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 8 Yes  No 

.....................………………………………………………………………………………………………………………………….…………….....…………..………………

.....................………………………………………………………………………………………………………………………….…………....………………………………

* 1. Version number and date of Participant Information Sheet (PIS):…………………………………......................………………………

Version number and date of Informed Consent Form (ICF):………………………………………………….......................………………

* 1. Type of consent planned for :

Signed consent  Verbal/Oral consent  Witnessed consent 

Audio-Video (AV) 

consent

Consent from LAR 

(If so, specify from whom)

.....................................................

Other 

For children<7 yrs 

parental/LAR consent

Verbal assent from  minor (7-12 yrs) along with parental consent

Written assent from  minor (13-18 yrs) along with parental consent

*(specify)* ..............................................................................................................................................................................................

* 1. Who will obtain the informed consent?

PI/Co-I  Nurse/Counselor  Research Staff  Other  (*Specify)* ………….............................……...

Any tools to be used ……………………………………………………………………………………………………………............................……………....

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

English  Local language  Other  *(Specify)*………………………........................................……...

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

If translation has not been done, please justify …………………………………………………………….....................….….………………......

………………………………………………………………………………………………………………………………………………………………...............................

* 1. Provide details of consent requirements for previously stored samples if used in the study7

....................………………………………………………………………………………………………………………………….…………….....…………..………………

....................………………………………………………………………………………………………………………………….…………....………………………………

* 1. Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language 

Risks and discomforts  Alternatives to participation  Right to withdraw 

Benefits 

Purpose and procedure 

Others(Specify) 

Data/ Sample sharing 

Need to recontact 

Confidentiality 

Storage of samples  Return of research results  Payment for participation 

Compensation for study related injury  Statement that consent is voluntary  Commercialization/ Benefit sharing  Statement that study involves research  Use of photographs/ Identifying data  Contact information of PI and Member  Secretary of EC

.........................………………………………………………………………………………………………………………………….…………....………………………………

1. PAYMENT/COMPENSATION
   1. Who will bear the costs related to participation and procedures ?

PI  Institution  Sponsor  Other agencies  *(specify)*

………………………………….......................................................................................................................................................................…

* 1. Is there a provision for free treatment of research related injuries? Yes  No  N/A 

If yes, then who will provide the treatment? …………………………………………………………………………………………..........................

* 1. Is there a provision for compensation of research related SAE? If yes, specify. Yes  No  N/A 

Sponsor  Institutional/Corpus fund  Project grant  Insurance 

* 1. Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes  No  N/A 

.........................………………………………………………………………………………………………………………………….…………………………………………

* 1. Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify.

Yes  No  N/A 

1. STORAGE AND CONFIDENTIALITY
   1. Identifying Information: Study Involves samples/data. *If Yes, specify* Yes  No  NA  Anonymous/Unidentified  Anonymized: Reversibly coded  Irreversibly coded  Identifiable  If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) …………………………………………………….

....…………………………………………………………………………………………………………………………..……………...............................…………………

....…………………………………………………………………………………………………………………………..……………...............................…………………

....…………………………………………………………………………………………………………………………..……………...............................…………………

....…………………………………………………………………………………………………………………………..……………...............................………………… (b) Who will be maintaining the data pertaining to the study? …………..……….......................………………………………………………. (c) Where will the data be analyzed and by whom? ……………………….……………………..............................……………………………..

(d) For how long will the data be stored? ………………………………………...………………………........................…………………………………

(e) Do you propose to use stored samples/data in future studies? Yes  No  Maybe 

If yes, explain how you might use stored material/data in the future?...................................................................................

....…………………………………………………………………………………………………………………………..……………...............................…………………

....…………………………………………………………………………………………………………………………..……………...............................…………………

....…………………………………………………………………………………………………………………………..……………...............................…………………

SECTION D: OTHER ISSUES

1. PUBLICATION, BENEFIT SHARING AND IPR ISSUES
   1. Will the results of the study be reported and disseminated? If yes, specify. Yes  No  NA 

.…………......……………………………………………………….….………………………………………………………………………………………………………………

.…………......……………………………………………………….….………………………………………………………………………………………………………………

* 1. Will you inform participants about the results of the study? Yes  No  NA 
  2. Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes  No  NA 

.…………......……………………………………………………….….………………………………………………………………………………………………………………

.…………......……………………………………………………….….………………………………………………………………………………………………………………

* 1. Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes  No  NA 

.…………......……………………………………………………….….………………………………………………………………………………………………………………

.…………......……………………………………………………….….………………………………………………………………………………………………………………

* 1. Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes  No  NA 

.…………......……………………………………………………….….………………………………………………………………………………………………………………

* 1. Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes  No 

.…………......……………………………………………………….….………………………………………………………………………………………………………………

.…………......……………………………………………………….….………………………………………………………………………………………………………………

.…………......……………………………………………………….….………………………………………………………………………………………………………………

.…………......……………………………………………………….….………………………………………………………………………………………………………………

**For clinical trials provide following additional information :**

1. Please attach detailed curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years)
2. **Details about the clinical trial protocol :**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Category of Trial (Tick all categories which are Applicable to Your Trial ) | * Phase –I  * Phase-II  * Phase-III  * Phase –IV or Post-marketing Surveillance  * Investigational Medicinal Plants  * Investigational New Drug  * Medical Devices  * Stem Cells  * Phytopharmaceutical Drug    Others : (Please Specify)  | | * New Innovative Procedures  * Bioavailability or Bioequivalance Studies  * Drug/Device Combination  * New Drug –Intervention  * Indian System of Medicine (AYUSH)  * Repurposing an Existing Intervention  * Approved for Drug for any new indication or new route of administration **** |
| 1. Trial Design (Tick all the applicable) | * Randomized  * Nonrandomized  * Parallel  * Cross –Over  * Cluster  * Matched Pair  * Others (Specify) | | Factorial   Stratified   Adaptive   Comparison Trial   Superiority Trial   Non Inferiority Trial   Equivalence Trial  |
| 1. 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) | * Finance Management  * Administrative Support  * Site Management  * Statistical Support  * Regulatory Affairs  * Project Management  * Others (Specify) : | | * Clinical and Medical Monitoring  * Data Management  * Medical Writing  * Audits, Quality Assurance  * Recruitment and Training  |
| 1. Please provide the following details about the intervention being used in the protocol | 1. Drug/s, device/s and/or biologics :   Yes  No  NA   If Yes, provide regulatory approval details (Mention here and give reference to the relevant document)   1. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. Yes  No  NA    If Yes, Mention and give reference to the relevant document | | |
| 1. Does the study use a placebo? | Yes  No  NA   If Yes, justify the use of placebo | | |
| 1. Will current standard of care be provided to the control arm in the study? | Yes  No  NA   If no, please justify | | |
| 1. Are there any plans to withdraw standard therapy during the study? If yes, please justify. | Yes  No  NA   If Yes, Please justify | | |

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

SECTION E: DECLARATION AND CHECKLIST

|  |  |
| --- | --- |
| 11. DECLARATION (Please tick as applicable) | |
|  | I/We certify that the information provided in this application is complete and correct. |
|  | I/We confirm that all investigators have approved the submitted version of proposal/related documents. |
|  | I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guide- lines. |
|  | I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines. |
|  | I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted. |
|  | I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol. |
|  | I/We declare that the expenditure in case of injury related to the study will be taken care of. |
|  | I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable. |
|  | I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed. |
|  | I/We confirm that we will maintain accurate and complete records of all aspects of the study. |
|  | I/We will protect the privacy of participants and assure confidentiality of data and biological samples. |
|  | I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study. |
|  | I/We have the following conflict of interest (PI/Co-I):  1. .....................................................................................................................................................................................................  .....................................................................................................................................................................................................  2. ....................................................................................................................................................................................................  ...................................................................................................................................................................................................... |
|  | I/We declare/confirm that all necessary government approvals will be obtained as per requirements  wherever applicable. |
| Name of PI: ………………....................................................................................................................................……………......................  Signature: ........................……………………………….............................................................................................  Name of Co-PI: ..................................................................................................................................…………………………….................  Signature: ........................……………………………….............................................................................................  Name of Guide: ..................................................................................................................................…………………………….................  Signature: ........................……………………………….............................................................................................  Name of HOD: ..................................................................................................................................…………………………….................  Signature: ........................………………………………............................................................................................. | |

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |
| --- | --- | --- |
| dd | mm | yy |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 12. CHECKLIST | | | | | | | | | | | | | |
| S. No | Items | | | | | | | | Yes | No | NA | Enclosure No | EC Remarks (If applicable) |
| ADMINISTRATIVE REQUIREMENTS | | | | | | | | | | | | | |
| 1 | Cover letter | | | | | | | |  |  |  |  |  |
| 2 | Brief CV of all Investigators | | | | | | | |  |  |  |  |  |
| 3 | Good Clinical Practice (GCP) training of investigators in last 3 years | | | | | | | |  |  |  |  |  |
| 4 | Approval of scientific committee | | | | | | | |  |  |  |  |  |
| 5 | EC clearance of other centers\* | | | | | | | |  |  |  |  |  |
| 6 | Agreement between collaborating partners\* | | | | | | | |  |  |  |  |  |
| 7 | MTA between collaborating partners\* | | | | | | | |  |  |  |  |  |
| 8 | Insurance policy/certificate | | | | | | | |  |  |  |  |  |
| 9 | Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification | | | | | | | |  |  |  |  |  |
| 10 | Copy of contract or agreement signed with the sponsor or donor agency | | | | | | | |  |  |  |  |  |
| 11 | Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol | | | | | | | |  |  |  |  |  |
| PROPOSAL RELATED | | | | | | | | | | | | | |
| 12 | Copy of the detailed protocol | | | | | | | |  |  |  |  |  |
| 13 | Investigators Brochure (If applicable for drug/biologicals/device trials) | | | | | | | |  |  |  |  |  |
| 14 | Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated) | | | | | | | |  |  |  |  |  |
| 15 | Assent form for minors (12-18 years) (English and Translated) | | | | | | | |  |  |  |  |  |
| 16 | Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated) | | | | | | | |  |  |  |  |  |
| 17 | Advertisement/material to recruit participants (fliers, posters etc) | | | | | | | |  |  |  |  |  |
| PERMISSION FROM GOVERNING AUTHORITIES | | | | | | | | | | | | | |
|  | **Other permissions** | **Required** | | **Not required** | | **Received** | | **Applied dd/ mm/yy** | **EC Remarks** | | | | |
| 18 | CTRI |  | |  | |  | |  |  | | | | |
| 19 | DCGI |  | |  | |  | |  |  | | | | |
| 20 | HMSC |  | |  | |  | |  |  | | | | |
| 21 | NAC-SCRT |  | |  | |  | |  |  | | | | |
| 22 | ICSCR |  | |  | |  | |  |  | | | | |
| 23 | RCGM |  | |  | |  | |  |  | | | | |
| 24 | GEAC |  | |  | |  | |  |  | | | | |
| 25 | BARC |  | |  | |  | |  |  | | | | |
| 26 | Tribal Board |  | |  | |  | |  |  | | | | |
| 27 | Others (Specify) |  | |  | |  | |  |  | | | | |
| ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY | | | | | | | | | | | | | |
|  | **Item** | | **YES** | | **NO** | **NA** | **Enclosure no.** | | **EC remarks** | | | | |
| 28 |  | |  | |  |  |  | |  | | | | |
| 29 |  | |  | |  |  |  | |  | | | | |

*\* For multicentre research.*

*MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry’s Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Com- mittee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre*

**FORM-2 : APPLICATION FOR INITIAL REVIEW OF RESEARCH PROPOSALS**

**(FOR STAFF PROPOSALS WITHOUT RESEARCH GRANTS AND ALL STUDENT PROPOSALS FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE (FMIEC)**

**For Office Use Only : FMIEC**

1. Application received by FMIEC on :
2. Protocol No. :
3. Categorized for : Full Review/Expedited Review/Exempted from Review
4. Proposal approved on :
5. Signature of Member Secretary , FMIEC with Date :

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **I** | **INVESTIGATOR INFORMATION (UG/PG/STAFF)** | | | |
|  | 1. NAME OF THE PRINCIPAL INVESTIGATOR (PI)   (in block letters) | | |  |
|  | 1. ADDRESS FOR COMMUNICATIOIN OF PI | | |  |
|  | 1. DEPARTMENT (of the PI or in case of UG the department of the guide ) | | |  |
|  | 1. MOBILE NUMBER OF PI | | |  |
|  | 1. EMAIL ID ( only institution ID for staff ) of PI | | |  |
|  | 1. COURSE AND SUBJECT( only for PG student projects) | | |  |
|  | 1. NAME OF GUIDE WITH DEPARTMENT (FOR PhD,UG and PG STUDENTS) | | |  |
|  | 1. NAME OF CO INVESTIGATORS /   CO GUIDE WITH DEPARTMENT | | | 1.  2.  3. |
| **II** | **PROTOCOL INFORMATION** | | | |
|  | 1. TITLE OF THE RESEARCH PROJECT |  | | |
|  | 2. NATURE OF SUBMISSION | | | |
|  | 1. UNDERGRADUATE | | External Grant /FMRC Grant | |
|  | B. POSTGRADUATE / PhD | | Thesis / Original Research for Paper Presentation/ Original Research for Publication/Any Other (please specify) | |
|  | C. STAFF | | Original Study : Funded/Not Funded  Any Other Study Type (Please Specify) : | |
| **III** | **PROTOCOL CHECKLIST (Tick the relevant boxes)** | | | |
|  | 1. TITLE | |  | |
|  | 1. INTRODUCTION AND NEED FOR   STUDY | |  | |
|  | 1. REVIEW OF LITERATURE | |  | |
|  | D. AIMS AND OBJECTIVES | |  | |
|  | E. MATERIALS AND METHODS – study  design, sample size, methodology | |  | |
|  | F. STATISTICAL ANALYSIS | |  | |
|  | G. IMPLICATIONS OF THE STUDY | |  | |
|  | H. REFERENCES IN VANCOUVER  STYLE | |  | |
|  | I. PROFORMA | |  | |
|  | J. INFORMED CONSENT FORM  (in English and Kannada ) | |  | |
|  | K. INFORMED CONSENT DOCUMENTS AS APPLICABLE  Tick whatever is applicable and submitted | | 1) Participant Information Sheet and Informed Consent Form : English /Kannada  2) Child Assent Form and Parental Consent Form : : English /Kannada  3) Request for Waiver of Consent | |
|  | L. BUDGET FOR THE PROJECT  (Filled budget estimation form) | |  | |
|  | M. Who will bear the cost of the project ? (Source of Funding) | | Self Funding : Full /Partly  FMRC Grant : Full /Partly  Any Other Source of Funding (Please Specify) : | |
| **IV** | **OTHER INFORMATION** | | | |
|  | 1. DATE OF PRESENTATION IN THE DEPARTMENT( applicable only to UG and PG student projects) | |  | |
|  | 1. DATE OF SUBMISSION TO THE SCIENTIFIC COMMITTEE | |  | |
|  | 1. PERMISSION LETTER FROM THE HOD OF ANOTHER DEPT( where non routine/special investigations/procedures are being done for the study) | |  | |
|  | 1. PERMISSION LETTER FROM THE DEAN/PRINCIPAL/ MEDICAL SUPERINTENDENT/   ADMINISTRATOR ( only in relevant cases as applicable ) | |  | |
|  | 1. DATE OF E MAIL SUBMISSION OF THE PROPOSAL | |  | |

**Declaration by The Investigators :**

Please tick as Appropriate

|  |  |
| --- | --- |
| Tick Box | Declaration |
|  | I/We certify that the information provided in this application is complete and correct. |
|  | I/We confirm that all investigators have approved the submitted version of proposal/related documents. |
|  | I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guide­lines. |
|  | I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted. |
|  | I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol. |
|  | I/we confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report to FMIEC and also participate in any audit of the study if needed. |
|  | I/We confirm that we will maintain accurate and complete records of all aspects of the study. |
|  | I/We will protect the privacy of participants and assure confidentiality of data and biological samples. |

NAME AND **SIGNATURE OF THE PRINCIPAL INVESTIGATOR**

**NAME AND SIGNATURE OF COGUIDE/COINVESTIGATORS**

**NAME AND SIGNATURE OF GUIDE WITH SEAL**

**NAME AND SIGNATURE OF THE HOD WITH SEAL**

**FORM-3 : APPLICATION FOR REVIEW OF CASE REPORTS**

**FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE (FMIEC)**

|  |  |  |  |
| --- | --- | --- | --- |
| **I** | **AUTHOR INFORMATION (UG/PG/STAFF)** | | |
|  | 1. NAME OF THE CORRESPONDING/PRESENTING AUTHOR (in block letters) | |  |
|  | 2. ADDRESS FOR COMMUNICATIOIN | |  |
|  | 3. DEPARTMENT (of the PI or in case of UG the department of the guide ) | |  |
|  | 4. MOBILE NUMBER | |  |
|  | 5. EMAIL ID ( only institution ID for staff ) | |  |
|  | 6. COURSE AND SUBJECT( only for PG student projects) | |  |
|  | 7. NAME OF GUIDE WITH DEPARTMENT (FOR PhD, UG and PG STUDENTS) | |  |
|  | 8. NAME OF CO AUTHORS  WITH DEPARTMENT | | 1.  2.  3. |
| **II** | **PROTOCOL INFORMATION** | | |
|  | 1. TITLE OF THE CASE REPORT |  | |
|  | 2. NATURE OF SUBMISSION | | |
|  | 1. UNDERGRADUATE | | For Presentation /Publication |
|  | B. POSTGRADUATE / PhD | | For Presentation/ Publication |
|  | C. STAFF | | For Presentation /Publication |
| **III** | **CHECKLIST (Tick the relevant boxes)** | | |
|  | A. CASE REPORT | |  |
|  | B. INFORMATION ABOUT ANY PHOTOGRAPHS OF THE PATIENT TO BE USED FOR PRESENTATION/PUBLICATION | |  |
|  | C. INFORMED CONSENT FORM SIGNED BY THE PATIENT /LAR OF THE PATIENT (CHILD ASSENT FORM AND PARENTAL CONSENT FORM FOR CHILDREN) | |  |
|  | 1. D. If informed consent is not obtained, request for waiver of consent, with a explanation why informed consent was not obtained . | |  |

**Declaration by The Authors :**

Please tick as Appropriate

|  |  |
| --- | --- |
| Tick Box | Declaration |
|  | I/We certify that the information provided in this application is complete and correct. |
|  | I/We confirm that all authors have approved the submitted version of case report/related documents. |
|  | I/We confirm that the informed consent was obtained from the patient for recording and using the case for presentation /publication purpose |
|  | I/We confirm that we will maintain accurate and complete records of all aspects of the study. |
|  | I/We will protect the privacy of participants and assure confidentiality of data and biological samples. |

**Name and Signature of Corresponding /Presenting Author:**

**Name and Signature of Co Authors :**

**Date :**

**FORM- 4 : Resubmission Form For Investigators (to be used for resubmission of revised protocols /submission of additional documents**

1. FMIEC - Protocol No.:
2. Date of Ethical Clearance (if approved already)
3. Title :
4. Name of Principal Investigator :
5. Purpose of this submission :
6. Submission details :

|  |  |  |  |
| --- | --- | --- | --- |
| Sl. No. | Revision/Corrections Suggested by IEC | Corrections done : Yes/ No | What correction is done ? Mention. |
|  |  |  |  |
|  |  |  |  |

7 .List of documents submitted during resubmission:

1)

2)

3)

Date :

Signature of Principal Investigator :

Department and Designation :

Note : Please submit this form along with a covering letter to member secretary, Father Muller Medical College Institutional Ethics Committee, and one soft+one hard copy of the revised proposal, and other documents.

---------------------------------------------------------------------------------------------------------------