* **THIS DOCUMENT HAS :** Guidelines for Conducting Research in FMCI, Guidelines for Submission of documents to FMIEC, Application form for clinical trials, Application form for Studies other than clinical trials, Budget form, Informed consent documents , waiver of consent request form and Resubmission form.
* FMIEC does not give approval for already completed / On going studies.
* Approval of IEC is mandatory before you start the study.
* Post-study approval is given only for case reports.

**Guidelines for Conducting Clinical Research in FMCI :**

1. Follow the guidelines of ICMR 2017 for carrying out the biomedical research.
2. All clinical studies should be reviewed and approved by the IEC before initiation of the study
3. No retrospective approvals will be granted
4. Studies may be considered for full board or expedited review or may be granted exemption from review depending on the risk involved.
5. It is mandatory to register interventional studies in the Clinical Trials Registry of India (ctri.nic.in).
6. The investigator team should be trained in GCP or ethics in clinical research ( certificates – valid for 5 years as per FMIEC policy). For randomized controlled trials, guidelines of Consolidated Standards of Reporting Trials (CONSORT) .
7. Studies involving AYUSH, should follow GCP guidelines of Ministry of AYUSH.
8. If a clinical study is planned on an “alternative system of medicine” (Ayurveda, Homeopathy, Siddha, Unani etc.),by a clinician of modern medicine, a Co-Investigator/ Collaborator from that system should be included in the study team. The co-investigator appointed should be appropriately qualified and registered with the relevant Council and he/she should not have a conflict of interest with the study, investigator or sponsor. This is in accordance with the ICMR 2017 guidelines. If a principal investigator from AYUSH wants to do a study comparing the alternate system of medicine with modern medicine, then a co investigator from modern medicine should be included.
9. The research study protocol should be scientific and complete with respect to the following sections:

A. Introduction with relevant literature,

B. Objectives,

C. Justification for a clinical study (demonstrate clinical equipoise) and its implications for future,

D. Detailed methodology describing

 i. Settings of the study,

 ii. Duration of entire study and duration for participation for each individual,

 iii. Eligibility criteria (inclusion and exclusion criteria),

 iv. Sample size (number of participants that may need screening, number that is required to be completed for analysis)

 v. Sampling method

 vi. Ethical aspect : A statement saying that the study will be conducted in adherence to relevant national/international laws; Placebo justification if applicable; Risk benefit assessment; Compensation for participation if applicable; Compensation for research related injury; Informed consent process, Choice of participants; If vulnerable population what protections are in place; Policy regarding autonomy (voluntariness, right to withdraw); Confidentiality - Statement of Participant confidentiality; including ownership of data and coding procedures; Policy regarding dissemination of data, presentation of data, publication.

vii. Description of variables, inpatient/outpatient, number of outpatient visits•

 viii. Statistics: Sample size determination, Power estimates / level of significance, Tests for comparison/ any other descriptive statistical analysis.

1. Informed consent documents should be made in English and Kannada and other relevant regional languages

**Guidelines for Submission of Documents for Review to FMIEC :**

1. The committee meets on fourth Saturday once in two months, at 3 PM in the Board Room of FMCI Research Centre. Depending on the load of research proposals, the frequency of meeting may be increased.
2. The research proposal should be accompanied by other documents (budget form, patient information sheet, informed consent form, undertaking, questionnaire, proforma of data collection) as applicable to the study. Parental consent form should be submitted for studies involving subjects of 18 years or below. For subjects of 12 to 18 years, child assent form also should be enclosed.
3. For case reports, a copy of the informed consent form signed by the patient should be submitted to FMIEC, along with a copy of the abstract and findings in the case study.
4. The research proposals will be categorized for review as : exempt review, expedited review and full committee review.
5. For the proposals categorized for full review, the principal investigator will be asked to present the proposal in the ethics committee meeting.
6. Principal investigator should be available for presentation of the proposal in the meeting in case of full committee review. Co investigators may accompany the principal investigator. Under no circumstances principal investigator will be exempted from presentation except in extraordinary circumstances. Under such circumstances the principal investigator should inform the Member Secretary in writing. The Chairperson of FMIEC will decide on this matter.
7. Research proposals are sent to members of FMIEC for review atleast a week before the meeting. Investigators should keep this in mind while submitting proposals to FMIEC.
8. Decision of the committee will be communicated to principal investigator within two working days after the meeting.
9. Research proposals “approved “/ “approved with suggestions” are permitted to start the work. Research proposals for “resubmission” need to revise the proposals and resubmit the proposals. For “Rejected” proposals, whole process of submission should be repeated considering the reasons for rejection
10. If the ethics committee asks the investigators to do CTRI registration, it should be done and CTRI reg.no. should be communicated to the committee .
11. Ethical clearance is initially issued for one year; after one year the investigator has to request for continuation of ethical approval.
12. Ethics committee has every right to monitor the research study at any point of study duration. The principal investigator should submit a report on progress of the study. Progress report should be submitted every year .
13. Any serious adverse events should be notified to the FMIEC within 24 hours. All protocol deviations, violations and amendments should be informed promptly**.**

 **Protocol Submission Form for Clinical Trials (Homeopathy Clinical studies)**

1. **Proposal Title :**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name, Designation & Qualifications** | **Address Tel & Fax Nos. Email ID** | **Signature** |
| Principle Investigator |  |  |  |
| Co-Investigator |  |  |  |
| Please attach detailed curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years) |

|  |
| --- |
| II. **Sponsor information:**1. Indian a) Government Central State Institutional b) Private |
| 2. International Government Private UN agencies |
| 3. Industry National Multinational |
| Contact Address of Sponsor: |
| Total Budget (mention here and enclose the budget form) |

|  |
| --- |
| **III. Type of Study :** Epidemiological Basic Sciences Animal studies Clinical: Single center Multicentric Behavioral  |
| **IV. Status of Review :**  New Revised |
| **V. Clinical Trials:**Drug/Vaccines/Device/Herbal Remedies:1. Does the study involve use of :

 Drug Devices VaccinesIndian Systems of Medicine/Alternate System of Medicine Any other NA   |
| 1. Is it approved and marketed

 In India UK & Europe USA Other countries, specify  |
| 1. Does it involve a change in use, dosage,

 route of administration ?If yes, whether DCGI’s/Any other Regulatory authority’s Permission is obtained ?If yes, Date of Permission: | Yes Yes |  NoNo |
| 1. Is it an Investigational New Drug ?

If yes, IND No: | Yes | No |
| * 1. Investigator’s Brochure submitted
 | Yes | No |
| * 1. In vitro studies data
 | Yes | No |
| * 1. Preclinical Studies done
 | Yes | No |
| Clinical Study is : Phase I Phase II Phase III Phase IV  |
| * 1. Are you aware if this study/similar study

 is being done elsewhere ?If Yes, attach details | Yes | No |
| VI. Brief description of the proposal – Introduction, review of literature, aims(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale  |
| 1. Subject selection:
	1. Number of Subjects :
 |
| * 1. Duration of study:
 |
| * 1. Will subjects from both sexes be recruited
 | Yes | No |
| * 1. Inclusion / exclusion criteria given
 | Yes | No |
| * 1. Type of subjects Volunteers Patients
 |
| (vi) Vulnerable subjects Yes No (Tick the appropriate boxes) Pregnant women children elderly Fetus illiterate handicapped Terminally ill seriously ill mentally challengedEconomically & socially backward any other |
| (vii) Special group subjects Yes No (Tick the appropriate boxes) Captives Institutionalized employees Students Nurses/dependent armed forces Any other staff |
| 1. Privacy and confidentiality

(i) Study involves - Direct Identifiers  Indirect Identifiers/coded Completely anonymised/delinked |
| (ii) Confidential handling of data by staff | Yes | No |
| 1. Use of biological/hazardous materials

(i) Use of fetal tissue or abortus | Yes | No |
|  (ii) Use of organs or body fluids | Yes | No |
|  (iii) Use of recombinant /gene therapy If yes, has department of Biotechnology (DBT) approval for  DNA products been obtained ? | Yes | No |
|  (iv) Use of pre-existing/stored/left over samples | Yes | No |
|  (v) Collection for banking/future research | Yes | No |
| 1. Use of ionizing radiation/radioisotopes

If yes, has Bhaba Atomic Research Centre (BARC)approval for Radioactive Isotopes been obtained ? | Yes | No |
|  (vii) Use of Infectious/biohazardous specimens | Yes | No |
| (viii) Proper disposal of material | Yes | No |
| (ix) Will any sample collected from the patients be sent abroad ? If yes, justify with details of collaborators | Yes | No |
| 1. Is the proposal being submitted for clearance from

 Health Ministry’s Screening Committee (HMSC) /ICMR  for International Collaboration ? | Yes | No |
| 1. Sample will be sent abroad because ( Tick appropriate box)

Facility not available in IndiaFacility in India inaccessibleFacility available but not being accessedIf so, reasons …………………… |
| 8. Consent : Written Oral Audio-visual i. Consent form : (tick the included elements)Understandable language Alternatives to participation**Statement that study involves research Confidentiality of records**Sponsor of study Contact informationPurpose and Procedures Statement that consent is voluntaryRisks & Discomforts Right to withdrawBenefits Consent for future use of biological materialCompensation for participation Benefits if any on future commercializationCompensation for study related injury eg: genetic basis for drug development* If written consent is not obtained, give reasons:
 |
| (ii) Who will obtain consent ? PI/Co-PI Nurse / Counsellor Research staff Any other |
| 9.Will any advertising be done for recruitment of Subjects ?( posters, flyers, brochure,websites – if so kindly attach a copy | Yes | No |
| 10. Risks & Beneifts : (i) Is the risk reasonable compared to the anticipated benefits subjects/community/country ? | Yes | No |
| (ii) Is there physical/social/psychological risk/discomfort If Yes, Minimal or no risk More than minimum risk High risk | Yes | No |
| (iii) Is there a benefit a) to the subject ? Direct Indirect b) Benefit to society  |
| 11. Data Monitoring (i) Is there a data & safety monitoring committee/Board (DSMB) ? | Yes | No |
|  (ii) Is there a plan for reporting of adverse events ? If Yes, reporting is done to : Sponsor Ethics Committee DSMB | Yes | No |
| (iii). Is there a plan for interim analysis of data ? | Yes | No |
| (vi) Are there plans for storage and maintenance of all trial database ?If Yes, for how long ? | Yes | No |
| 12. Is there compensation for participation ?If yes Monetary In kindSpecify amount and type: | Yes | No |
| 13. Is there compensation for injury?If Yes, by Sponsor by Investigator By insurance by any other company | Yes | No |
| 14. Do you have conflict of interest ? (financial/non-financial) If Yes, specify: | Yes | No |
| 15. . 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) |  |  |
| 16 . GCP training certificates of principal investigator and coordinators (Enclose the copies of certificates) | Yes  | No |
| 1. 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 |

**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.\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_ 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)

 **Checklist for Submission of Documents:**

|  |  |  |  |
| --- | --- | --- | --- |
| Sl.No. | Document | Yes | No |
| 1 | Protocol Submission Form Duly Filled |  |  |
| 2 | Covering Letter |  |  |
| 3 | Protocol - hard copies as required |  |  |
| 4 | Protocol – soft copy by e mail or CD |  |  |
| 5 | CV of all investigators |  |  |
| 6 | Fee for Review |  |  |
| 7 | Informed Consent Documents in English |  |  |
| 8 | Informed Consent Documents in Kannada |  |  |
| 9 | Informed Consent Documents in Other Regional Languages as Applicable |  |  |
| 10 | Translation and back translation certificates |  |  |
| 11 | Case Record Forms/Proforma |  |  |
| 12 | Research participants recruitment procedures: advertisement, notices (If applicable) |  |  |
| 13 | Patient instruction card, identity card, diary etc. |  |  |
| 14 | Research Participants Questionnaire/s (If applicable) |  |  |
| 15 | Research participants confidentiality statement |  |  |
| 16 | Investigator Brochure |  |  |
| 17 | Insurance certificate and policy |  |  |
| 18 | Investigator’s undertaking to DCG(I) |  |  |
| 19 | DCG(I) approval [if DCGI approval is awaited, the same is mentioned in the covering letter to the IEC] |  |  |
| 20 | 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) |  |  |
| 21 | FDA marketing/manufacturing license for herbal formulations/ nutraceutics |  |  |
|  | Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations |  |  |
| 22 | 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) |  |  |
| 23 | 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) |  |  |
| 24 | Budget Sheet for the Proposed Study (Format for budget sheet stated below) |  |  |
| 25 | Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator ) (one copy only) |  |  |
| 26 | Ethics Committee clearance of other centres (Total No \_\_\_\_\_) |  |  |
| 27 | Current Status of Ongoing Studies approved by IEC and IEC conducted by principal investigator (information may be submitted separately ) |  |  |
| 28 | Documentation of clinical trial registration (in Clinical Trial Registry of India) / any other WHO platform registry (whenever applicable) |  |  |
| 29 | GCP training certificates of principal investigator, co investigator/s, study coordinator/s for interventional clinical trial sponsored by pharmaceuticals companies of training taken in last 5 years (one copy only) |  |  |
| 30 | Any other Documents submitted |  |  |

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

 **E MAIL :** fmciiec@fathermuller.in

**APPLICATION FORM FOR SUBMISSION OF RESEARCH PROTOCOL (OTHER THAN CLINICAL TRIALS)**

**For Office Use Only :**

FMIEC :

1. Received on :
2. Protocol No. :
3. Categorized for : Full Review/Expedited Review/Exempted from Review
4. Signature of Member Secretary , FMIEC with Date :

|  |  |
| --- | --- |
| **I** | **INVESTIGATOR INFORMATION** |
|  | 1. NAME OF THE INVESTIGATOR

(in block letters) |  |
|  | 1. Official Address
 |  |
|  | 1. MOBILE NUMBER
 |  |
|  | 1. EMAIL ID
 |  |
| **II** | **PROTOCOL INFORMATION** |
|  | 1. TITLE OF THE RESEARCH PROJECT
 |  |
|  | 2. NAME OF THE GUIDE1. (only for UG and PG students)
 |   |
|  | 3. NAME OF THE COGUIDE/ CO INVESTIGATOR |  |
|  | 4. NATURE OF SUBMISSION |
|  | 1. UNDERGRADUATE
 | ICMR /OTHERS |
|  | B. POSTGRADUATE / PhD | THESIS / PAPER /POSTER/ CASE REPORTS/OTHERS  |
|  | C. STAFF | SPONSORED TRIAL/ ORIGINAL STUDY/ POSTER / CASE REPORTS |
| **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. PATIENT INFORMATION SHEET ( in English and Kannada ) |  |
|  | L. BUDGET FOR THE PROJECT  (fill up the budget estimation form) |  |

 **SIGNATURE OF THE INVESTIGATOR SIGNATURE OF GUIDE**

**SIGNATURE OF CO INVESTIGATOR/CO GUIDE**

**SIGNATURE OF THE HOD WITH SEAL SIGNATURE OF PRINCIPAL WITH SEAL**

**------------------------------------------------------------------------------------------------------------**

 **ESTIMATED BUDGET FOR THE PROJECT**

**NOTE:**

1. This application should contain the total cost of routine and special tests done for the project
2. This form should be submitted along with the application form .

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **AMOUNT IN RUPEES** | **YEAR 1** | **YEAR 2** | **YEAR 3** | **TOTAL** |
| **PARTICULARS**  |
| **STATIONERY, PHOTOCOPYING,****BINDING** |  |  |  |  |
| **CONSUMABLES** |  |  |  |  |
| **EQUIPMENTS** |  |  |  |  |
| **INVESTIGATIONS** |  |  |  |  |
| **ROUTINE** |  |  |  |  |
| **TESTS DONE FOR PROJECT (SPECIAL TESTS-IN HOUSE)** |  |  |  |  |
| **TESTS SENT OUTSIDE (SPECIAL TESTS OUTSOURCED)** |  |  |  |  |
| **ANY OTHER MEDICAL DEVICES/MEDICATIONS ADDITIONALLY USED** |  |  |  |  |
| **GRAND TOTAL** |  |  |  |  |
| **SL NO**  | **NAME OF THE INVESTIGATION** | **NO OF TESTS** | **TOTAL AMOUNT** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Source of Funding for the Research:**

**Declare Self-funding: Rs.--------------------------**

I declare that the study subjects will not be made to pay for the special investigations/devices/medications. The cost will be born by me or procured from research grants of ---------------------------------------------------------.

Name and Signature of Principal Investigator.

Name and Signature of Co investigators :

Name of signature of Guide (for PhD/ PG/UG research)

Date :

 **FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE:**

**Format for Patient Information Sheet and Informed Consent Form**

**Title of the Study :**

**Names of Researchers/Investigators**

**Name of Organization :**

**Name of Sponsor (Grant agency):**

**Name of Project and Version**

**This Informed Consent Form has two parts:**

* Information Sheet (to share information about the study with you)
* Certificate of Consent (for signatures if you agree to participate)

You will be given a copy of the full Informed Consent Form

**Introduction**

Briefly state who you are and explain that you are inviting them to participate in research which you are doing. Inform them that may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure them that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later

**Purpose**

Explain **in lay terms** why the research is being done and what is expected from the results. Explain why you need to conduct the research with children.

**Type of Research Intervention**

Briefly state the intervention. This will be expanded upon in the procedures section

**Selection of Participants**

State clearl*y* why you have chosen them to participate in this study. Patients may wonder why they have been chosen for a study and may be fearful, confused or concerned

**Voluntary Participation**

Indicate clearly that they can choose to participate or not and reassure they will still receive all the services they usually do if they choose not to participate.. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Participants may also be more alert at the beginning.

 **Procedure**

Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

**Duration**

Include a statement about the time commitments of the study for them. Include both the duration of the study and follow-up, if relevant

**Risks and Discomforts**

Explain any risks or discomforts including any limits to confidentiality.

 **Benefits**

Describe any benefits to them, to the community, or any benefits which are expected in the future as a result of the research.

**Reimbursements**

State clearly what you will provide the participants with as a result of their participation. You will not be entitled to any compensation beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost..

**Confidentiality:**

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality

**Sharing of Research Findings**

Include a statement indicating that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for examples, through publications and conferences.

**Right to refuse or withdraw**

Explain again the voluntary nature of consent.

**Whom to Contact**

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

Provide the contact number and address of the researchers

Mention that –This research project is reviewed and approved by Ethics Committee of Father Muller Charitable Institutions, Kankanady, Mangalore. This is a committee whose task it is to make sure that research participants are protected from harm.

The contact details of ethics committee are as follows:

Dr. Shivashankara A.R.,

Member Secretary,

 Father Muller Institutional Ethics Committee,

 Kankanady, MANGALORE-02.

Phone : 08242238399; 9880146133. Mail : fmciiec@fathermuller.in;

 arshiva72@gmail.com.

Dr.Shalini Shenoy,

Chairperson of Father Muller Institutional Ethics Committee,

Professor of Microbiology ,

Kasturba Medical College, Mangalore -01.

Phone : 9845497072 . Mail : shenoyshalini@gmail.com

**INFORMED CONSENT**

I have read and understood the information/ it has been read to me and explained in an understandable language about the research project : ------------(title). I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

 Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Day/month/year

If illiterate

*A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.*

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

*Name of witness\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AND Thumb print of participant*

*Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Day/month/year

 Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the procedures to be done:

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

   A copy of this ICF has been provided to the participant.

 Name of Researcher/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Researcher /person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Day/month/year

 **Child Assent Form and Parental Consent Form**

**FATHER MULLER INSTITUTIONAL ETHICS COMMITTEE**

**ASSENT FORM FOR CHILDREN**

**Name of Principle Investigator :**

**Name of Organization :**

**Name of Sponsor :**

**Name of Project and Version:**

**This Informed Assent Form has two parts:**

* **Information Sheet (gives you information about the study)**
* **Certificate of Assent (this is where you sign if you agree to participate)**

**You will be given a copy of the full Informed Assent Form**

**Part I: Information Sheet**

**Introduction**

This is a brief introduction to ensure the child knows who you are and that this is a research study. Give your name, say what you doand clearly state that you are doing research. Inform the child that you have spoken to their parents and that parental consent is also necessary. Let them know that they can speak to anyone they choose about the research before they make up their mind.

**Purpose: Why are you doing this research?**

Explain the purpose of the research in clear simple terms.

**Choice of participants: Why are you asking me?**

Children, like adults, like to know why they are being invited to be in the research. It is important to address any fears they may have about why they were chosen.

**Participation is voluntary: Do I have to do this?**

State clearly and in child-friendly language that the choice to participate is theirs. If there is a possibility that their decision not to participate might be over-ridden by parental consent, this should be stated clearly and simply.

**Information on the Trial Drug [Name of Drug]: What is this drug and what do you know about it?**

Include the following section only if the protocol is for a clinical trial:

1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.

2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

3) explain the known experience with this drug

4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

**Procedures: What is going to happen to me?**

Explain the procedures and any medical terminology in simple language. Focus on what is expected of the child. Describe which part of the research is experimental.

**Risks: Is this bad or dangerous for me?**

Explain any risks using simple, clear language.

**Discomforts: Will it hurt?**

If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

**I have checked with the child and they understand the risks and discomforts \_\_\_\_(initial)**

**Benefits: Is there anything good that happens to me?**

Describe any benefits to the child.

**Reimbursements: Do I get anything for being in the research?**

Mention any reimbursements or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. These expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

 **Confidentiality: Is everybody going to know about this?**

Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

**Compensation: What happens if I get hurt?**

Describe to the ability of the child to understand and explain that parents have been given more information.

**Sharing the Findings: Will you tell me the results?**

Describe to the ability of the child to understand that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly, i.e. in a book, journal, conferences, etc.

**Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?**

You may want to re-emphasize that participation is voluntary and any limits to this.

**Who to Contact: Who can I talk to or ask questions to?**

List and give contact information for those people whom the child can contact (name and contact details of the members of the research team). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

**If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.**

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

**PART 2: Certificate of Assent**

This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one identified as 'suggested wording' below. If the child is illiterate but gives oral assent, a witness must sign instead . A researcher or the person going over the informed assent with the child must sign all assents.

**I have read this information ( or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.**

**I agree to take part in the research.**

***OR***

**I do not wish to take part in the research and I have not signed the assent below.\_\_\_\_\_\_\_\_\_\_\_(initialled by child/minor)**

**Only if child assents:**

**Print name of child \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of child: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ day/month/year**

***If illiterate:***

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

**I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

**Print name of witness (not a parent)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AND Thumb print of participant**

**Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Day/month/year**

**I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.**

**Print name of researcher\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of researcher\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Day/month/year**

**Statement by the researcher/person taking consent**

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done:**

**1.**

**2.**

**3.**

**I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

 **A copy of this assent form has been provided to the participant.**

**Print Name of Researcher/person taking the assent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Researcher /person taking the assent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Day/month/year**

**Copy provided to the participant \_\_\_\_\_\_\_\_(initialed by researcher/assistant)**

**Parent/Guardian has signed an informed consent \_\_\_Yes \_\_\_No \_\_\_\_\_(initialed by researcher/assistant)**

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

***Informed Parental Consent Form for***

***Research Involving Children***

**Name of Principal Investigator :**

**Name of Organization :**

**Name of Sponsor :**

**Name of Proposal and version :**

**This Informed Consent Form has two parts:**

* **Information Sheet (to share information about the study with you)**
* **Certificate of Consent (for signatures if you agree that your child may participate)**

**You will be given a copy of the full Informed Consent Form**

**ha C**

**PART I: Information Sheet**

**Introduction**

Briefly state who you are. and explain that you are inviting them to have their child participate in research which you are doing. Inform them that may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

**Purpose**

Explain the problem/research question in lay terms which will clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, “mosquitoes help in spreading the disease” rather than “mosquitoes are the vectors”. Avoid using terms like pathogenesis, indicators, determinants, equitable etc.There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

Recognize that parents' feelings about involving their children in research can be complicated. The desire and feeling of responsibility to protect their child from risk or discomfort may exist alongside the hope that the study drug will help either their child or others. It is, therefore, important to provide clear and understandable explanations, and to give parents time to reflect on whether they will consent to have their child participate.

**Type of Research Intervention**

Briefly state the intervention if you have not already done so. This will be expanded upon in the procedures section.

**Participant selection**

State clearl*y* why you have chosen their child to participate in this study. Parents may wonder why their child has been chosen for a study and may be fearful, confused or concerned. Include a brief statement on why children, rather than adults, are being studied.

**Voluntary Participation**

Indicate clearly that they can choose to have their child participate or not. State, if it is applicable, that they will still receive all the services they usually do if they decide not to participate. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

Include the following section only if the protocol is for a clinical trial:

**Information on the Trial Drug [Name of Drug]**

1) give the phase of the trial and explain what that means. Explain to the parent why you are comparing or testing the drugs.

2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

3) explain the known experience with this drug

4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

**Procedures and Protocol**

It is important that the parents know what to expect and what is expected of them and their child. Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and the drugs that will be given. It is also important to explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Describe very clearly which procedure is routine and which is experimental or research. Explain that the parent may stay with the child during the procedures. If the researchers are to have access to the child's medical records, this should be stated.

Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

**A. Unfamiliar Procedures**

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug). A very minimal statement is provided below to give you an example. You may need to be more explicit about what is exactly involved.

2) involving a placebo it is important to ensure that the participants understand what is meant by a placebo.

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine

**B. Description of the Process**

Describe the process on a step-by-step basis.

What will be done in multiple visits /single visit of the child ?

In case of a clinical research:

Explain that there are standards/guidelines that must be followed. If a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

For any clinical study (if relevant):

If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a table-spoon full will be taken.

If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

If not, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after \_\_\_ years, when the research is completed.

**Duration**

Include a statement about the time commitments of the research for the participant and for the parent including both the duration of the research and follow-up, if relevant.

**Side Effects**

Parents should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

**Risks**

A risk can be thought of as being the possibility that harm may occur. Explain and describe any such possible or anticipated risks. Provide enough information about the risks that the parent can make an informed decision. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.

**Discomforts**

Explain and describe the type and source of any anticipated discomforts that are in addition to the

side effects and risks discussed above.

**Benefits**

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

**Reimbursements**

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

**Confidentiality**

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant, which would otherwise be known only to the physician but would now be available to the entire research team. Because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

**Sharing of the results**

Your plan for sharing the information with the participants and their parents should be provided.

If you have a plan and a timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for example, through publications and conferences.

**Right to Refuse or Withdraw**

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section well to ensure that it fits for the group for whom you are seeking consent. The example used here is for a parent of an infant at a clinic.

**Alternatives to participating**

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

**Who to Contact**

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted.) State also that the proposal has been approved and how.

***Contact Details of the Ethics Committee :***

If you have any queries /grievances/complaints on this research study, you may contact the Father Muller Institutional Ethics Committee:

Dr. Shivashankara A.R.,

Member Secretary,

 Father Muller Institutional Ethics Committee,

 Kankanady, MANGALORE-02. Phone : 08242238399; 9880146133. Mail : fmciiec@fathermuller.in;

 arshiva72@gmail.com.

Dr.Shalini Shenoy,

Chairperson of Father Muller Institutional Ethics Committee,

Professor of Microbiology ,

Kasturba Medical College, Mangalore -01. Phone : 9845497072 . Mail : shenoyshalini@gmail.com

**PART II: Certificate of Consent**

**Certificate of Consent**

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. **The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.**

 *I have been invited to have my child participate in research of a new malaria vaccine.* **I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.**

**Print Name of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Print Name of Parent or Guardian\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Parent or Guardian \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Day/month/year**

***If illiterate***

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

**I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

**Print name of witness\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AND Thumb print of parent**

**Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **Day/month/year**

 **Statement by the researcher/person taking consent**

**I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:**

**1.**

**2.**

**3.**

**I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

  **A copy of this ICF has been provided to the participant.**

**Print Name of Researcher****/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Researcher /person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Day/month/year**