RESEARCH PROJECT PROTOCOL FORM
Institutional Review Board (IRB)
Malabar Cancer Centre (MCC), Thalassery - 670103, India.

(A) GROUPING OF RESEARCH PROJECT

Project No. (For Office Use Only)		
Project Title		
Name of the Principal Investigator (PI)	1	
	2	
	3	

Please complete the questionnaire for submitting the research proposal for IRB- MCC
Study Group
(Please fill up the applicable *Yes*(**Y**)/*No*(**N**) neatly)

	Group	Detail	Yes/ No
		Controlled Trials	
01.	A1 a	Is this a Randomized Controlled trial?	
02	A1 b	Is this a Non-Randomized Controlled trial?	
03	A1 c	Is this a controlled trial that seeks new indication for establishing drug, process or a procedure?	
		Uncontrolled Trials	
04	A2 a	Is this a prospective trial testing new intervention, drug, or device on patients?	
05	A2 b	Is this a prospective trial designed to test new (unproven) indication for established drug, process, procedure or device on patients?	
06	A2 c	Is this a pilot trial on new intervention, drug, and device on patients?	
07	A3 a	Is this a Multi-centre trial?	
08	A3 b	Is this trial involves transfer of patients' data to another site (including industry)?	
09	A3 c	Is this trial involves transfer of patients' blood, serum, DNA, tissue to another site?	

10	A4 a	Are you seeking Intramural funding?	
11	A4 b	Does this trial use additional resources of MCC beyond the usual work-up (e.g., Molecular profiling, MRI or any other non- routine part of work-up)	
12	A5 a	Are you submitting application for extra-mural grant for this trial?	
13	A5 b	Is this trial partly or wholly supported by grants from sponsored industry?	
14	A5 c	Is this a phase IV/ marketing trial undertaken on behalf of the industry?	
15	A6	Are you seeking modifications in the IRB-MCC approved trial?	
16	A7 a	Are patient going to bear the cost of experimental intervention or drug therapy?	
17	A7 b	Does patient has to undergo additional blood sample collection, biopsy, endoscopy, procedure etc.?	
18	A7 c	Whether the patient has to bear the cost of complications arising from experimental treatment?	
19	A7 d	For the trial purpose, does the patient has to spend Rs. 5000/- or more above the usual expenses (for any reason such as drug therapy, additional investigation, prolonged stay or repeated travel)?	
20	A8 a	Will the trial be undertaken in the community?	
21	A8 b	Will the trial involve screening?	
22	A9	Does this trial involve conducting Genomics or Proteomics studies on patients' specimens?	
23	A10	Will this trial involve development of a device, drug or test lead to profits or patent?	
24	B1	Is this a prospective follow-up study (documentation of parameters only) of patients being offered standard treatment at MCC?	
25	B2	Is this a phase II-IV trial restricted to standard intervention/ treatments?	

26	B3	Is this a feasibility study for introduction of new treatment, recently shown in major international studies, to be beneficial / superior and need to be started at MCC?	
27	B4	Is this a retrospective or prospective analysis of charts and audit of procedures / tests / treatments?	
28	B5	Is this a retrospective or prospective review of pathology specimen (may involve some additional staining techniques)?	
29	B6	Is this a retrospective or prospective review of radiology reports and their clinical correlation?	
30	B7	Is this a retrospective or prospective review of laboratory reports and their clinical correlation?	
Procedure / demonstration at workshops etc.			
31	B8	Are you demonstrating an experimental procedure which is '*not established standards of care*' at a workshop or a public meeting?	
32	B9	Are you performing a procedure in workshop at MCC by non-MCC staff member? (Please check other requirements also)	

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Name of PI(s) **Signature with Date**

Project Submission Form for review by IRB, MCC

(B) PRJECT FACT SHEET

1. Study/Project Number(to be filled up by IRB Office, MCC)		
2. Project Title		
3. Date of receipt by IRB, MCC		
4. Keywords for Title (2 to 4 options)		
5. Principal Investigator(s)	1	
	2	
	3	
	4	
6. Number of ongoing study the PI is involved (as PI only)		
7. Full address & Contact details of PI *(provide e-mail ID & contact no. along with complete mailing address in CAPITAL LETTERS)*		
8. Co-Investigator(s)	1	
	2	
	3	
	4	
	5	
	6	
	7	
9. Name of the Study Site		
10. Agency or Sponsor or Funding resource		

11. Total estimated Budget (in Rs.)	
12. Duration of the project (in months)	
13. Total number of patients to be accrued in study (including MCC, if multi-institutional study**)**	
14. Expected Date/Month of starting the project	
15. Will biological products be sent out of the country? (Yes/No) **If yes, attached the copy of regulatory clearance obtained [DCGI/ ICMR /Health Ministry Screening Committee (HMSC)]**	Yes
16. Any Conflict of interest, (Yes/No) If Yes Please specify	Yes
---------- **Signature of PI**	**Date (dd/mm/yyyy)**

Investigators Declaration:

1. This research project (including collection of blood or tissues samples for research) will not be started until the final approval of the IRB has been obtained.
2. We agree to undertake research proposal involving human subjects in accordance with the ICH-GCP and ICMR ethical guidelines, 2006. We will not modify the research protocol, consent, etc without prior approval by the IRB.
3. The investigators agree to obtain a properly informed and understood consent for all trial subjects before their inclusion in the trial in the informed consent form that is approved by the IRB. Participants will receive an 'information sheet' which will detail the project design in simple understandable layperson's language.
4. The investigators agree to report within a week all serious adverse events (SAE) associated with the trial in the SAE form to the IRB. In the event of a death of the trial subject, the Secretary, IRB and DSMSC, will be informed within 24 hours.
5. The investigators agree to submit periodic 6 monthly progress report of the trial in the appropriate form. A final report will be submitted at the end of the trial.
6. Full details on funding and a proposed budget are included with the trial proposal. The proposed budget is presented on the specific budget sheet of this form.
7. We understand that the IRB is concerned about transparent financial transactions during the trial. A report on how the trial funds were utilized will be presented to the Academic Council of MCC along with the final project report at the end of the trial.

8. The investigators agree to transfer 15% of the total budget to MCC as service charges. This will not apply to intramural projects, those projects cosponsored by MCC/MOHFW-DHR and ICMR/CSIR-CDRI/ DBT /DST/WHO/BARC/UGC funded projects.
9. The investigators agree that the grant money will be spent in accordance with the budget proposal only. The funds will not used for any other purposes without prior approval from the IRB. Thirty percent of the surplus grant if left over at the end of the study will be credited to MCC. The remaining 70% of the surplus grant money may be used by the investigators for conducting intramural research, improving teaching facilities in the department, providing financial assistance to investigators for conferences, etc after obtaining permission from the MCC authority.
10. For all research proposals that are sponsored by a pharmaceutical or biomedical company, we the investigators will ensure that the Sponsor Company will underwrite all expenses such that neither the hospital nor the study participants are made to spend while participating in the trial. The investigators will also ensure that in the event of complications arising directly due to the trial or litigation, the cost of management or legal fees will be borne by the Sponsor Company totally.
11. The investigators state that they do not stand to gain financially from the commercial sponsor and do not have conflict of interest in the drug or product by way of consultations, shareholding, etc.
12. The investigators will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the Institutional Ethics Committee (IEC). MCC, approved protocol.
13. All data collected during the research project, including those supported by commercial sponsors (e.g. pharmaceutical company), will remain the property of Malabar Cancer Centre.
14. The salaries to staff employed for the research project will be as shown in the budget sheet and at par with the prevailing MCC salary scales.
15. The case records (source documents) will be made available to members of the SRC of IRB any time for random verification and monitoring. The case records (source documents) will be preserved in the premises of MCC for at least 5 years after the last approval of application or publication.
16. The investigators promise to ensure that there is no falsification of data when compared to the source documents. We agree to clarify any doubts or discrepancies that may arise during the data monitoring evaluation.
17. All the findings and conclusions of the proposed project such as review of case records, analysis of forms of treatment, investigations, etc will be first presented to the staff members of MCC before they are released or presented elsewhere. The investigators will submit a copy of the abstract to the SRC and IRB well in advance of any proposed presentation at national or international conferences or seminars.
18. The investigators will not issue any press release before the data and conclusions have been peer-reviewed by the MCC staff or published in a peer-reviewed journal.
19. All serious injuries arising from the trial will be the responsibility of the Investigators. The investigators agree to ensure that the sponsors undertake a product liability insurance to cover any expenses for injury or compensation arising from the study treatment.
20. The investigators will constantly inform the IRB about amendments in the study protocol, data collection forms, informed consent forms, budget expenses, salaries, other trial documents, etc. as and when they occur. No major changes in the treatment arms or the study protocol or randomization technique will be carried out without prior permission of the IRB.
21. The investigators realize that the IRB is particular that all aspects of the study are in accordance with the ICH-GCP and ICMR ethical guidelines, 2006. The investigators will comply with all policies and guidelines of the MCC and affiliating/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research.

We the investigators of the proposed trial have read all the statements listed above and agree to observe / undertake these IRB requirements while conducting our proposed project/ trial

We understand that serious protocol violations and/or non-compliance during the trial by the investigators may result in withdrawal of project approval by IRB

Study team undertaking with duties & delegation*:

	Investigator Name	Status (PI/Co-PI,CI etc.)	Role & Responsibility **	Conflict of Interest (Yes/No) **If yes, please specify as an attachment**	Signature with date
1				No	
2				No	
3				Yes	
4				No	
5				No	
6				No	
7				No	
8				No	
9				No	
10				No	

Please provide details (an one page CV) of Co-PIs , CIs, Clinical Research Coordinator, Research Nurse, Phlebotomist, other stuffs related to the study. Use separate sheets for each individual.

** Choose from the following list:

A. Concept B. Design C. Screening of patients D. Selection & Recruitment and consenting of patients E. Laboratory investigations F. Laboratory report interpretation G. Treatment decision H. Patient evaluation I. AE and SAE management, evaluation and reporting	J. Examination of patients on follow-up K. Data collection and monitoring of data L. Interpretation of data M. Statistical analysis & Interpretation N. Maintaining patients file and master file of project O. Drafting final report P. Publication Z. Any other, please specify

***Note**: Investigators may clarify any of the points in this undertaking with the IRB office of MCC.*

To
The Member Secretary
Institutional Ethics Committee
Institutional Review Board, Malabar Cancer Centre

Project Title:		
Name of PI:	1	
	2	
	3	

Conflict of Interest:
(Please tick in the appropriate box)

☐ I hereby declare that I have no conflict of interest in my project.

☐ I have following conflict of interest:

Signature of PI

Date

Consent of Head of the PI's Department

Date: (dd/mm/yyyy)……

I have reviewed the above project submitted by Principal Investigator, …… from my Department/Institution.

I endorse the project and have 'no objection' for submission for consideration by Institutional Review Board.

I concur with the participants / investigators included in the study.

Signature & date :
Name :
Department :

OFFICE SEAL