Institutional Review Board
Malabar Cancer Centre (IRB, MCC)

Title: Constitution of Institutional Review Board (IRB), MCC

Edited By : SOPs Development Team, Malabar Cancer Centre

Approved By

Chairperson **Member Secretary**
(Institutional Ethics Committee)

SOP 02/VER1 ***Pages: 1 to 17***

INTRODUCTION

Malabar Cancer Centre (MCC), an autonomous institution under Health and Family welfare department of Government of Kerala, thrives for excellence in the field of early detection, diagnosis and treatment of cancer. The Institution is been developed as a State of Art cancer centre with equal thrust on Clinical Care, Education and Research. MCC has a clear vision to establish & evolve itself as a hub for Core Research on Oncology through investigator-initiated trials, intervention studies, and development of newer technologies, experimental medications, therapeutics, processes and scientific techniques to fight against the deadly disease, Cancer.
The Institution feels to continue oncology based research by developing itself on qualities of being extremely thorough, exhaustive and accurate. This gave rise to the need for impeccable and efficient management of its research activities and clinical trials to ensure the protection of human rights as mandated by Indian law (Schedule Y), and to satisfy public scrutiny.

Keeping the above in view, the Institutional Ethics Committee (IEC) of MCC was established in August 2013 as per the Annexure VIII of Schedule Y. All research proposals are subjected to ethical review by Institutional Ethics Committee (IEC), after scientific evaluation and approval by the Scientific Review Committee (SRC). The **Scientific Review Committee (SRC)** and the **Institutional Ethics Committee (IEC)**, together, constituted ***the Institutional Review Board (IRB)*** in MCC.

Timely review and systematic maintenance of ethical standards formed the basis of the IRB review process in MCC. These are essential for clinical research including Doctoral research, collaborating academic research with MoU undersigned, student research, investigator initiated research, extramural, intramural funded research, multi-centric multinational research and CRO/SMO based clinical trials.

In view of the emerging demands for clinical research in the institution, the Director, MCC, constituted IRB to function with the specified purposes and SOPs, to expedite the review process. All research proposals are scientifically evaluated and approved by Scientific Review Committee, before ethical review is been taken up.

However, as per the decision of the Director, MCC, in order to manage the review process more efficiently, the MCC Scientific Review Committee and the Institutional Ethics Committee are been merged to form the Institutional Review Board (IRB). Therefore, in MCC, IRB works in review process for research study proposals with two mutually exclusive wings, viz., SRC & IEC.
Each IRB reviews both, the scientific and ethical aspects, if any, of the study.

A Board, named Data Safety & Monitoring Board (DSMB), is also been formed to assist IRB for monitoring patient safety and assessing data during the course of the study in a manner that contributes to the scientific and ethical integrity of the study**.**

The Institutional Review Boards (IRB) is constituted by the Director, Malabar Cancer Centre (MCC) under authority vested by the Executive Council and the Governing body of the centre.

2.1 PURPOSE

The IRB in MCC was established to give legal status and specify Institution's commitment to the development and promotion of high quality scientific and ethical standards in Research, Education and Patient Safety & Care.

2.2 MANDATE

The Institutional Review Board (IRB) through its delegated sub-committee(s) functions independently for maintaining a systematic, reliable and consistent scientific as well as in an ethical framework for patient care and research, and for communicating and integrating ethical values into organizational activities and practice.

I. The purpose of the IRB is to cultivate comprehensive and well-formalized exchange of scientific and ethical values and concerns, and to analyze them while looking for possibilities and scopes to enrich the scientific and ethical integrity and honesty of the Institution.

II. The mandate of the IRB essentially is to promote patient care and services through a scientific and ethical approach to research and education. The Terms of Reference for the IRB, MCC are as follows:

1) To ensure the highest scientific and ethical standards of research at MCC
2) Review, approve and manage proposals for clinical, basic or translational research projects (Intramural and Extra mural) for scientific and ethical content
3) To function as a Medium to advise the administration in case of any ethical issues that may arise from patients or from families or from public
4) To create and sustain in leadership as a National Standard of reference in the field of oncology Treatments, Care, Research & Professional Education.
5) To issue and periodically, update and revise SOPs and guidelines for effective functioning of IRB as and when necessary
6) Continuing education in clinical research bioethics and ethical aspects of clinical practice by National/ International Seminars / Conferences, Workshops and interactive discussions for all categories of staff members including Nursing and Paramedical staffs.
7) To initiate research studies on ethical aspects of practice in MCC

The committee does not address or interfere in matters of administration, nor does the committee function as a grievance cell for staff members of MCC.

2.3 SCOPE

This SOP applies to the formation of the IRB at Malabar Cancer Centre.

2.4 RESPONSIBILITY

The IRB has the responsibility, within the Institution, for the following objectives:

- To ensure the competent review and evaluation of all scientific and ethical aspects of research projects received, compliance with the appropriate laws, and welfare of subjects.
- Consultations for clinical science and ethics
- Education of professional, administrative, and support staff about ethical issues.
- Creation, development, revision and implementation of guidelines for the IRB (SOPs).
- Initiate research studies in ethics.
- Continuing education and training programs to ensure that IRB members are regularly acquiring knowledge & well updated qualification to perform their specific duties.

2.5 SCIENTIFIC AND ETHICAL BASIS

- The committee consists of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of a proposed research project.

- The IRB recognizes that the protocols approved may also be approved by national and/ or local ethics committees and concerned regulatory bodies prior to their implementation in specific localities.

- In evaluating protocols and ethical issues, the IRB is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world

- The IRB also seeks to be informed, as appropriate, by national / other local ethics committees and researchers of the impact of the research it has approved.

- The IRB establishes its own Standard Operating Procedures mainly based on the ICMR guidelines (2006), Schedule Y (Drugs and Cosmetics Act 1940., amendment 20th Jan 2005), Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO 2000), and ICH-GCP, 1996 and the local regulations, CFR 45 (US FDA)

- IRB seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations

2.6 COMPOSITION OF IRB (Institutional Ethics Committee)

- IRB will be multidisciplinary and multi-sectorial in composition. IRB-IEC is composed of a minimum of 7, and maximum of 15 members. The members are selected to have an equitable representation of all specialties in Malabar Cancer Centre. It includes scientific and non-scientific members, clinicians and non - clinicians, a clinical pharmacologist, members of the community, a lawyer-expert in ethics, a social worker / layperson / patient representative to represent different points of view.

- The committee will comprise of a Chairperson, Co-Chairperson, a Member Secretary, and 4-12 other active members who represent an appropriate balance of professional, ethical, legal, cultural, educational, and community interests
- The committee should have adequate representation of age, gender, community, etc. to safeguard the interests and welfare of all sections of the community /society. Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism

- The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by MCC.

Composition of IRB-IEC

The composition should be as follows:-
1. Chairperson (not – affiliated to MCC)
2. Member Secretary (MCC Staff member)
3. 1-2 clinicians (not affiliated to MCC)
4. 4-8 clinicians (MCC staff members)
5. Basic medical scientist
6. Clinical Pharmacologist
7. One legal expert or retired judge or medico-legal expert
8. One social scientist / representative of Non-governmental Voluntary Agency/ Philosopher/ Ethicist / Theologian
9. One lay person from the community

2.6.1 SCIENTIFIC REVIEW COMMITTEE (SRC), MCC

2.6.1 (a) Constitution:

The Scientific works under the Institutional Review Board, MCC and it is an independent sub-committee to review research project proposals in scientific point of view. The committee is formed by the Director, MCC, after a consultation with Chairperson, IRB-IEC and Academic Council of MCC. SRC reviews the scientific & technical aspects of the study proposals. It works as a first phase screening committee of IRB, MCC.

SRC will have the authority to approve a study proposal if the majority of members are agreed in a SRC meeting and recommend the study proposal to Institutional Ethics Committee (IEC) for reviewing ethical issues, if any. 8 to 15 qualified persons constitute the SRC, MCC. The entire members are directly appointed by Director, MCC with composition as follows:

2.6.1 (b) Composition of Scientific Review Committee (SRC), IRB, MCC

- Chairperson: Director of MCC
- Secretary : One Senior Professor (preferably from MCC)
- Members: Faculty members as nominated by the Director, MCC
- 2 Biostatistician/ Biostatistics Faculty Members from MCC to see the Statistical bases for the study proposals
- 1 or 2 External Experts in selected cases
- 1 or 2 Selected faculty members of high academic reputation or rare specialization

SRC meets on every 2nd Saturday of a month or on 3rd Saturday, if the 2nd Saturday falls on a holiday and as and when required.

2.6.2 MEMBERSHIP OF IRB, MCC

The Director, MCC appoints the Chairperson, IRB-IEC. The Director, MCC, will appoint all members of the IRB-IEC, after having a discussion in the Academic Council and/or in the Executive Council, in cases. The Director of MCC himself will hold the position of Member Secretary for IRB-IEC.

❖ **<u>Criteria for selection of members</u>:**

i. Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in the domain field and profile.
ii. Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests.
iii. New members will be identified according to the requirement i.e. as per the composition specified in Section 2.6. of this SOP and provided the potential member fulfils the conditions of appointment as defined in 2.6.3 of this SOP.

2.6.3 Terms of Appointment

2.6.3. (A) Duration

- The members of the IRB, MCC will be appointed for a duration of 3 years.

- The appointment procedure for membership will be followed so that it allows for continuity, development and maintenance of expertise within the review board, and the regular input of innovative ideas and dynamic approaches.
- The members can be continued and there will be no limit on the number of times the membership is extended. Extension of membership will be based on the recommendation of the Chairperson and Member Secretary of the IRB-IEC.
- In case of the resignation/discontinuation of a Member Secretary, Chairperson or member, a replacement may be newly appointed by the Director, MCC before the completion of the tenure of the existing appointed committee. This appointment will be effective for the remaining tenure of the existing committee. In case the Director, MCC resigns from the post of Member-Secretary, IRB-IEC, the Secretary of IRB-SRC will automatically be the Member-Secretary of IRB-IEC. In case of unwillingness of Secretary of IRB-SRC in becoming Member-Secretary of IRB-IEC, the IRB constitution has to be fully modified & the matter must be placed to MCC Academic Council.
- In case of the transfer/resignation/discontinuation of the Director, MCC, from his/her post at the centre, the Secretary of IRB-SRC will act as Member-Secretary (in-charge) of IRB-IEC with full office and authority as per the IRB constitution until a new Director for MCC is appointed.

2.6.3. (B) Renewal

- The membership will be renewed after the stated term of 3 years.
- The process of renewal will be as follows :

  Selection of Chairperson and other members should be done at least 3 months and 1 month in advance respectively. Member secretary designate should be inducted into the IRB as an observer before he/she takes on the mantle in the new IRB.

  Designated members of the IRB who wish to attend IRB meetings as observers should read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form *(ANX2 – VER1/SOP02/VER1)* at the beginning of the IRB meeting and/or before scientific and ethical review tasks of the IRB commence
- If a *regular member resigns*, or *ceases to be a member due to disqualification/ dissatisfaction*, or *in case of death*, a new member will be appointed for the remaining term as per the Conditions of appointment stated below – section 2.6.3

2.6.3. (C) Resignation / Replacement procedure

The members who have resigned may be replaced at the discretion of the Director, MCC. IRB members who decide to resign must provide the Director, MCC, and Chairperson, IRB-IEC, the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, Director, MCC would appoint a new member, falling in the same category of membership e.g. “NGO representative” with “NGO representative”. Recommendations may be sought from the

resigning member. Appointments may be made in consultation with Academic Council members and /or Chairperson of IRB-IEC.

2.6.3. (D) Termination / Disqualification procedure

A member may be relieved or terminated of his/her membership in case of

- Conduct unbecoming for a member of the IRB, MCC
- Failure to attend more than 3 consecutive meetings of the IRB and subsequent to review of the membership by the IRB; if deemed necessary, the IRB may decide to terminate the membership and the Chairperson, IRB may make a recommendation to the Director, MCC, for necessary action.
- Relocation to another city or any such matter

In all such situations/circumstances, Director, MCC will serve a letter of termination to the member. Documentation of the termination will be recorded in the minutes of the next duly constituted IRB meeting and the IRB membership roster and circulars will be revised.

2.6.4 Conditions of Appointment

1. Name, age, gender, profession, and affiliation of IRB members will be publicized.
2. Members must accept the appointment in writing.
3. Members must submit a one page CV and training certificates in Ethics and/or GCP.
4. Conflict of interest, if any, must be disclosed.
5. Members must apprise themselves of the relevant documents, codes, ICH -GCP guidelines and the ICMR code and IRB, MCC SOPs.
6. Members are required to sign the confidentiality agreement (*ANX1-VER1/SOP 02/VER1*) at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IRB in the course of its work.
7. An investigator can be a member of the IRB. However, the investigator-as member cannot participate in the review and approval process for any project in which he or she is present as a PI, Co-PI or CI or has any other potential conflict of interest.

2.7 OFFICE BEARER OF IRB-IEC

The IRB will have the following office bearers who have the expertise and professional qualifications to review the proposals submitted.

2.7.1 Chairperson, IRB-IEC

The IRB-IEC Chairperson should be a highly respected individual preferably from outside MCC, fully capable of managing the IRB-IEC and the matters brought before it, with fairness and impartiality. The task of making the IRB a respected part of the

institutional community will fall primarily on the shoulders of this individual. The IRB must be perceived to be fair and impartial, immune from pressure either by MCC's administration, the investigators whose protocols are brought before it, or other professional and non-professional sources. The IRB-IEC Chairperson will respect the diverse backgrounds, perspectives, and sources of expertise of all IRB members, especially the contributions of the non-scientists, and must have the ability to foster such respect among the IRB members.

Co-Chairperson- The IRB-IEC Co-Chairperson should be a highly respected individual preferably from outside MCC, with the same capabilities of the Chairperson so as to manage the IRB and the matters brought before it with fairness and impartiality, in the absence of the Chairperson.

2.7.2 Member-Secretary, IRB-IEC

The Member Secretary will be the Director of MCC, committed to the task of coordinating and managing the activities of the committee. He/she will be responsible for scheduling the meetings, describing the agenda and ensuring that the function of the committee is conducted as per the norms and policies described in this SOPs.
In the absence of the Member-Secretary of IRB-IEC, the Chairman or Vice-Chairman of IRB-IEC will function as an acting Member-Secretary of IRB-IEC and vice-versa for routine IRB work.

In the absence of a Member Secretary of IRB-IEC for any scheduled IRB meeting, Director, MCC must authenticate some distinguished staff of MCC to act as Member-Secretary (with having a decision making power) for that particular meeting only. The Chairperson/Vice-Chairman will take the help of the mention MCC staff for coordinate and manage the activities of the IRB for that meeting.

.2.7.3 The IRB Secretariat/ Office of IRB, MCC

The Secretariat is composed of the Member Secretary, IRB-IEC, and the administrative supporting staff. The supporting staff consists of staff members of MCC appointed by the Director, MCC
The secretariat shall have the following functions:

- Organization of an effective and efficient tracking procedure for each proposal received.
- Preparation, maintenance and distribution of study files.
- Organization of regular IRB meetings. .
- Preparation of the agenda and the minutes of the meetings,
- Maintenance of the IRB records and archives.
- Communication with IRB members and PIs.
- Arrangement of training for personnel and IRB members.
- Provision of the necessary administrative support for IRB related activities to the Member-Secretary, IRB.

- Receipt of IRB processing fees for pharma-funded projects and the issue of official receipts for the same.

❖ **The IRB Administrative Staff**: ***Working Rules***

1. There will be one or two faculty of *Clinical Research & Biostatistics Division* and attendant/s /helpers who will help the IRB-IEC Chairperson and/or Member-Secretary in executing functions of the IRB.
2. Additional staff may be appointed and duties assigned as and when required by the IRB. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications may be recommended by IRB members during regular IRB meeting and will be recorded in minutes. These will be forwarded to the Director, MCC.
3. The administrative staff will be appointed by conducting formal interviews as per MCC policy.

Duties of the administrative officers/staffs:

i. Organizing an effective and efficient tracking procedure for each proposal received.
ii. Organizing IRB meetings regularly, Preparing the agenda and minutes of the meetings
iii. Maintaining IRB records and archives. Providing necessary administrative support for IRB related activities to the Member-Secretary, IRB.
iv. Arranging training for personnel and IRB members.
v. Receiving IRB processing fees and issuing official receipts for the same.
vi. Corresponding with the IRB members, external experts and investigators.
vii. Preparing, maintaining and distributing study files. Communicating with IRB members and PIs.

2.8 ROLES & RESPONSIBILITIES OF IRB MEMBERS

- The members' primary responsibilities will be determining the scientific and ethical validity of the research and the protection of the safety, rights and confidentiality of the research subjects.

- Participate in the IRB meeting & review and discuss research proposals assigned for evaluation.
- Review progress reports and monitor ongoing studies. Monitor SAEs and recommend appropriate action(s).
- Maintain confidentiality of the documents and deliberations of the IRB meetings.
- Declare conflict of interest, if any.
- Carry out work delegated by the Chairperson and/or Member-Secretary of IRB-IEC.
- Participate in continuing education activities in biomedical ethics and biomedical research.

- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IRB secretariat.

2.9 QUORUM REQUIREMENT

All research projects for approval by the full board of the IRB shall be reviewed at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. The presence of the following five (5) members is required to form part of the quorum without which a decision regarding the project **should not** be taken.

These 5 members should have the following representation:

(a) basic medical scientists (preferably one clinical pharmacologist)
(b) clinicians
(c) legal expert;
(d) social scientist or representation of non-governmental voluntary agency or philosopher or ethicist or theologian or similar person
(e) lay person from the community

- A quorum should include at least one member whose primary area of expertise is in a non-scientific area, a clinician, and at least one member who is independent of MCC/research site and have no immediate family member affiliated to MCC.
- No quorum should consist entirely of members of one Profession/ one Gender.
- In the absence of the Chairperson, the Co-Chairperson will chair the meeting. In the absence of both, Member-Secretary of IRB-IEC, MCC will chair the meeting as the Acting Chairperson.
- When an alternate member attends a meeting as a substitute for a regular member, the alternate member's participation counts toward the quorum requirements.

2.10 TRAINING OF IRB MEMBERS

IRB members have a need for initial and continued education regarding the science and ethics of biomedical research. All IRB members must be conversant with ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.

IRB members will receive introductory training material in research bioethics and functioning of IRBs and will be exposed to ongoing opportunities for enhancing their capacity for ethical review.

<u>Training of the IRB members in Research Bio-Ethics:</u>

- ✓ A new member may be inducted 1 month prior to his/her appointment and will be requested to be an 'Observer' for the first board meeting. The Member Secretary or IRB Secretariat/ Office of the IRB, MCC, will impart an introductory training.
- ✓ The IRB members will be encouraged to receive ongoing training by attending workshops at least once every year.

- ✓ The IRB will conduct workshops from time to time to impart training to the IRB members and Institutional faculty members.

2.11 ANNUAL ACTIVITY REPORT

The Member-Secretary in Consultation with the Chairperson shall prepare an annual activity report of the IRB for submission to the Director, MCC and accreditation. The IRB Secretariat staff member will provide all necessary help to the Member-Secretary, IRB. This shall include:

- A Quantitative Evaluation (QE) of the activities of the committee on a yearly basis.
- List of the research proposals reviewed and approved in a year.
- Status of each research proposal.

The Annual Activity Report will be immediately put in the MCC website after the approval from Director, MCC.

2.12 HONORARIUM

All external non-MCC members should be given honorarium according to MCC norms & recommendations.

References

1. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects Retrieved from- *http://www.cioms.ch/frame guidelines nov2002.htm*
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH- GCP) 1996. Retrieved from-*http://www.ich.org/LOB/media/MEDIA482.pdf*
3. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006)- Retrieved from - *http://www.icmr.nic.in/ethical guidelines.pdf*
4. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000) Retrieved from- w*ww.who.int/tdr/publications/publications*/
5. Code of Federal Regulations 45 CFR 46.108 htttp://www.hhs.gov/ohrp/humansubjects/guidance
6. European Convention on Human rights and Biomedicine (1997). Retrieved from *http://conventions.coe.int/treaty/en/treaties/html/164.htm*
7. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005*)* Retrieved from - *http://www.cdsco.nic.in/html/Schedule-Y 20(Amended 20Version*- 2005) 20 original .htm

GLOSSARY

Confidentiality: Prevention of disclosure to other than authorized individuals, of information and documents related to IRB

Institutional Review Board (IRB): It is an independent body formally designated to review, approve, and monitor biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the subjects. It is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial and to provide public assurance of that protection.

Independent Consultants: Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed.

Scientific member : Individual who possesses the clinical and/or scientific knowledge and ability to effectively evaluate the research and clinical investigation.

Non-Scientific member: Individual who possesses expertise and/or experience outside scientific areas and serves to represent either vulnerable populations or local cultural and community attitudes relative to the rights and welfare of human research participants.

Non-affiliated member: Individual who is a scientific or non-scientific member, is knowledgeable about clinical or scientific matters or local cultural and community attitudes, and has no association with MCC.

ANX1-VER1/SOP02/VER1

CONFIDENTIALITY & CONFLICT OF INTEREST FORM
(For IRB-IEC Members Only)
INSTITUTIONAL REVIEW BOARD
Malabar Cancer Centre, Thalassery- 670 103, India

"In recognition of the fact, that I, Dr/ Mr./ Mrs. ……..... herein referred to as the "Undersigned", have been appointed as a member of the Institutional Review Board **and** would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane, scientific and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;
Whereas, the appointment of the undersigned as a member of the IRB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest; Whereas, the fundamental duty of an IRB member is to independently review research protocols involving human subjects and make a determination and the best possible
objective recommendations, based on the merits of the submissions under review;
Whereas, the IRB must meet the highest ethical standards in order to merit the trust and confidence of the communities with respect to the protection of the rights and well-being of human subjects; The undersigned, as a member of the IRB is expected to meet the same high standards of ethical behavior to carry out its mandate.
This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IRB. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.
As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRB.
The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that my performance of this agreement is consistent with MCC's policies and any contractual obligations it may have to third parties."

…….. ……
Undersigned Signature **Date**

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but has faith in the IRB-IEC of MCC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects. In accordance of the policy of the IRB-IEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of

interest, except to provide information as requested by the IRB-IEC.

The Undersigned will immediately disclose to the Chairperson of the IRB-IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.
If an applicant submitting a protocol believes that an IRB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.
The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IRB member(s) in question. The IRB may elect to investigate the applicant's claim of the potential conflict. When a member has a conflict of interest, the member should notify the Chairperson/IRB and may not participate in the IRB review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

1. *A member is involved in a potentially competing research program.*
2. *Access to funding or intellectual information may provide an unfair competitive advantage.*
3. *A member's personal biases may interfere with his or her impartial judgment*.

Agreement on Confidentiality and Conflict of Interest

In the course of my activities as a member of the IRB, I may be provided with confidential information and documentation (which we will refer to as the "*Confidential Information*").
I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the IRB's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

……..
Undersigned Signature **Date**

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, Dr./Mr./Mrs…… have read and I accept the aforementioned terms and conditions explained in this Agreement.

……
Undersigned Signature **Date**

……..
Director of MCC **Date**

ANX2-V1/SOP02/VER1

CONFIDENTIALITY AGREEMENT FORM- A
(For Independent Consultant)
INSTITUTIONAL REVIEW BOARD
Malabar Cancer Centre, Thalassery- 670 103, India

(A) For Independent Consultant

I, ……
(Name and Designation) as a non-member of IRB understand that the copy (ies) given to me by the IRB is (are) confidential. I shall use the information only for the indicated purpose as described to the IRB and shall not duplicate, give or distribute these documents to any person(s) without permission from the IRB.
Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

…… ……..
Undersigned Signature **Date**

…… ……..
Member-Secretary, IRB-IEC **Date**

I, …….. (Enter name) acknowledge that I have received a copy of this Agreement signed by Member-Secretary, IRB-IEC, MCC, and me.

_____ _____
Signature of the recipient **Date**

CONFIDENTIALITY AGREEMENT FORM- B

(For Independent Observer)
INSTITUTIONAL REVIEW BOARD
Malabar Cancer Centre, Thalassery- 670 103, India

(B) For Observer

I, …… understand that I am allowed to observe IRB activities and attend the IRB-SRC/ IRB-IEC meeting/ scheduled on …….at……..am/ pm as an Observer.

In the course of the observership / meeting of the IRB some confidential information may be disclosed or discussed.
Upon signing this form, I ensure to take reasonable measures to keep the information and discussion as confidential.

…… ……
Signature of the Observer **Date**

…… …….. ……..
Member-Secretary, IRB-IEC **Date**

I, …….. (Enter name) acknowledge that I have received a copy of this Agreement signed by Member-Secretary, IRB-IEC, MCC, and me.

_____ _____
Signature of the recipient **Date**