# Institutional Review Board, Tata Memorial Centre (IRB, TMC)

## Title: Constitution of Institutional Review Board (IRB), TMC

**SOP Code: SOP 02/V1 Date : 05/09/2012 Pages: 1 to 21**

The Hospital Ethics Committee of TMC was established in the year 1996. TMC being a premier cancer institute in the country, it has become a hub for oncology based trials. Over the years its scientific rigor and research culture led to a significant increase in the number of clinical trials being conducted. This gave rise to the need for impeccable and efficient management of its clinical trials to ensure the protection of human rights as mandated by Indian law (Schedule Y), and to satisfy public scrutiny.

In lieu of the above, the Hospital Ethics Committee of TMC was established in the year 1996. All research proposals after scientific evaluation and approval by the Scientific Review Committee were subjected to ethical review by Hospital Ethics Committee. Together, the Scientific Review Committee and the Hospital Ethics Committee constituted the Institutional Review Board (IRB). Timely review and the safeguarding of high ethical standards formed the basis of the IRB review process. These are essential for clinical research including student research, investigator initiated research, extramural, intramural funded research and multi-centric multinational research.

In view of the tremendous growth of clinical research in the institution, the Director, TMC in the year 2008, constituted two Ethics Committees to function with the same purpose and SOPs, to expedite the review process. All research proposals were scientifically evaluated and approved by Scientific Review Committee before ethical review was taken up. These two committees were renamed as Human Ethics Committee I and II.

However, as per the decision of the TMC-Research Administrative Council (TRAC), in order to manage the review process more efficiently, the TMC Scientific Review Committee and the Human Ethics Committees viz HEC-I and HEC-II, were merged to form the Institutional Review Board. In view of the large number of projects to be reviewed, two Institutional Review Boards (IRBs) were instituted and designated as IRB I and IRB II. Each IRB reviews both, the scientific and ethical aspects of the study. The IRBs became functional in February 2012.

The Data Safety Monitoring Subcommittee (DSMSC) is a subcommittee of the IRB, and is essentially responsible 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, Tata Memorial Centre (TMC) under authority vested by the Governing Council of the TMC

IRB has a Federal Wide Assurance (FWA) with the Department of Health and Human Services (DHHS) through the Office for Human Research Protections (OHRP). The assurance number is **FWA00006143**. This is periodically renewed as required.

WHO/The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) in collaboration with the Forum for Ethical Review Committees in Asia and the Western

Pacific Region Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP) was awarded recognition to the Tata Memorial Centre Human Ethics Committee (TMC-HEC) in November 2009.

## 2.1 Purpose

The IRB was established to formalize and specify Institution's commitment to the promotion of high scientific and ethical standards in patient care, professional education, clinical research, and community interests.

## 2.2 Mandate

The IRB through its delegated sub-committees functions independently for maintaining a consistent scientific and ethical framework for patient care and research, and for integrating ethical values into practice, policy relationships, and organizational activities.

- The purpose of the IRB is to cultivate a pluralistic and democratic exchange of scientific and ethical values and concerns, and to critically analyze them while looking for opportunities to enhance the scientific and ethical integrity of Institution.
- The mandate of the IRB essentially is to promote patient care through a scientific and ethical approach to research and education.

The terms of reference for the IRB are as follows:

1. Ensure the highest scientific and ethical standards of research at TMC
2. Review and approve, proposals for clinical, basic or translational research projects (Intra and Extra mural) for scientific and ethical content
3. Improve ethical standards and issue guidelines on ethical dilemmas related to patient care services
4. To function as a forum to advise the administration in case of any ethical issues that may arise from patients, families or public
5. To maintain our leadership as a national standard of reference in all fields
6. To issue and periodically, update and revise SOP s and guidelines for effective functioning of IRB as and when necessary
7. Continuing education in clinical research bioethics and ethical aspects of clinical practice by seminars, workshops and interactive discussions for all categories of staff members including nursing and paramedical staff
8. To initiate and commission research studies on ethical aspects of practice in TMC
    - The IRB endeavours to provide guidance on a broad range of topics such as disclosures of diagnosis, diagnosis of brain death, indications for stopping resuscitation, true informed consent, etc.
    - The committee does not address or interfere in matters of administration, nor

does the committee function as a grievance cell for staff members.

## 2.3 Scope

The SOP applies to the formation of the IRB

## 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 IRBs (SOPs).
- Initiate research studies in ethics.
- Continuing education and training programs to ensure that IRB members are qualified 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 is guided in its reflection, advice and decision by the
  - Ethical principles expressed in the Declaration of Helsinki (Adopted by the 18$^{th}$ World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29$^{th}$ World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September 1989; 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd World Medical Assembly, Edinburgh, Scotland, October 2000; Note of

Clarification on Paragraph 29 added by the World Medical Assembly, Washington 2002; Note of Clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004, 59th WMA general Assembly, Seoul, October 2008)

- It makes further reference to the International Ethical Guidelines for e.g. The Nuremburg Code (1945), the Council of International Organizations of Medical Sciences (CIOMS), the Belmont Report 1979, the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 2002), and the European Convention on Human Rights and Biomedicine 1977
- The IRB establishes its own Standard Operating Procedures 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

- Each IRB will be multidisciplinary and multi-sectorial in composition.
  Each IRB is composed of a minimum of 7, and maximum of 19 members. The members are selected so as to have an equitable representation of all specialties in TMC. 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.

- Each committee will comprise of a Chairperson, Co-Chairperson, a Member Secretary, and 4-16 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 TMC.

Composition of IRB

The composition should be as follows:-

1. Chairperson (not – affiliated to TMC)
2. Co-Chairperson (not – affiliated to TMC)

3. Member secretary (TMC Staff member)
4. 1-2 clinicians (not affiliated to TMC)
5. 4-8 clinicians ( TMC staff members)
6. DSMSC Member Secretary
7. Basic medical scientist
8. Clinical Pharmacologist
9. One legal expert or retired judge or medico-legal expert
10. One social scientist / representative of non-governmental voluntary agency/ philosopher / ethicist / theologian
11. One lay person from the community

### 2.6.1 Membership

The Director, TMC appoints the Chairperson, IRB and the Member Secretaries. All members will be appointed by the Director, TMC in consultation with the Member Secretaries.

Criteria for selection of members:

- 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.
- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests.
- 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.

The following qualities are sought in IRB members:

- experience and education
- interest and motivation
- commitment and availability
- respect for divergent opinions
- integrity and diplomacy

### 2.6.2 Terms of Appointment

### 2.6.2. a Duration

- The members of the IRB, TMC will be appointed for a duration of 2 years.
- The appointment procedure for membership will be followed so that it allows for continuity, development and maintenance of expertise within the IRB, and the regular input of fresh ideas and 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 IRBs.
- To ensure an appropriate quorum is maintained, all IRB-I members will be alternate members for IRB-II and vice versa. Alternate members will serve in the same representative capacity as the member for whom they substitute. The IRB minutes will document when an alternate member replaces a primary member. When an alternate member substitutes for a primary member, the alternate member will receive and review the same material that the primary member would have received and reviewed.
- In case of the resignation/discontinuation of a Member Secretary, Chairperson or member, a replacement may be newly appointed by the Director, TMC before the completion of the tenure of the existing appointed committee. This appointment will be effective for the remaining tenure of the existing committee

**2.6.2. b Renewal**

- The membership will be renewed after the stated term of 2 years.
- The process of renewal will be as follows :
  Selection of Member Secretary 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. Other members designate may attend the board meeting as observers before starting their tenure as IRB members.
  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 *(AX2 – V1/SOP02/V1)* 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, or death, a new member will be appointed for the remaining term as per the Conditions of appointment stated below – section 2.6.3

**2.6.2. c Resignation / Replacement procedure**

The members who have resigned may be replaced at the discretion of the Director, TMC. IRB members who decide to resign must provide the Director, TMC, and Chairperson, IRB, the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, Director, TMC 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 the Member

Secretary and /or Chairperson

### 2.6.2. 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
- Inability to participate in the meetings on any grounds
- 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, TMC, for necessary action.
- Relocation to another city or any such matter .

In all such situations/circumstances, Director, TMC 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.

### 2.6.3 Conditions of Appointment

- Name, age, gender, profession, and affiliation of IRB members will be publicized.
- Members must accept the appointment in writing.
- Members must submit a one page CV and training certificates in Ethics and/or GCP.
- Conflict of interest, if any, must be disclosed.
- Members must apprise themselves of the relevant documents, codes, ICH GCP guidelines and the ICMR code and IRB TMC SOPs.
- Members are required to sign the confidentiality agreement (AX1-V1/SOP 02/V1) 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.
- 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

### 2.6.4 Independent Consultants

- The IRB may call upon, or establish a standing list of, independent consultants who may provide special expertise to the IRB on proposed research protocols, when the Chairperson / Member secretary or the IRB members determine that a study will involve procedures or information that is not within the area of expertise of the IRB members. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies

(e.g. genetic disorders, stem cell research etc.), or they may be representatives of communities, patients, or special interest groups. These consultants must sign the confidentiality agreement *(AX2-V1/SOP02/V1*) regarding meeting, deliberations, and related matters. These consultants or subject experts cannot vote for a decision.

### 2.7 Office Bearers

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

#### 2.7.1 Chairperson

The IRB Chairperson should be a highly respected individual preferably from outside TMC, fully capable of managing the IRB 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 TMC's administration, the investigators whose protocols are brought before it, or other professional and non-professional sources. The IRB 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 Co-Chairperson should be a highly respected individual preferably from outside TMC, 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

The Member Secretary will be a staff member of TMC, 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-I, the member-secretary of IRB-II will function as acting Secretary of IRB-I and vice-versa for routine IRB work.

In the absence of a Member Secretary of IRB for scheduled IRB meeting, another member of the IRB will be nominated by the Chairperson for that meeting to coordinate and manage the activities of the IRB for that meeting.

#### 2.7.3 Secretariat

The Secretariat is composed of the Member Secretary, IRB, and the administrative supporting staff. The supporting staff consists of staff members of TMC appointed by the Director, TMC.

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 administrative officer/s and attendant/s /helper/s who will help the IRB Chairperson and Member Secretary in executing functions of the IRB. Additional staff may be appointed and duties assigned as and when deemed necessary 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, TMC.
2. The administrative staff will be appointed by conducting formal interviews as per TMC policy.

Duties of the administrative officer/s/staff:

a. Organizing an effective and efficient tracking procedure for each proposal received.
b. Preparing, maintaining and distributing study files.
c. Organizing IRB meetings regularly
d. Preparing the agenda and minutes of the meetings
e. Maintaining IRB records and archives.
f. Communicating with IRB members and PIs.
g. Arranging training for personnel and IRB members
h. Providing necessary administrative support for IRB related activities to the Member Secretary, IRB.
i. . Receiving IRB processing fees and issuing official receipts for the same.
j. Corresponding with the IRB members, external experts and investigators.

l. Making the pre and post arrangements of IRB meetings.
m. Preparing the agenda and minutes of the IRB meetings.
n. Answering queries of the investigators.
o. Filing study related documents.
p. Archiving and maintaining the study files.

3. Duties of the attendant/s /helper/s

    a. Assisting the secretariat in arranging the IRB meetings.
    b. Dispatching sets of study documents to IRB members and external experts.
    c. Receiving the study related documents from and dispatching the IRB letters to the investigators.
    d. Filing study related documents.
    e. Archiving and maintaining the study files
    f. Corresponding with the IRB members and external experts.

4. The administrative staff will report to the Chairperson and/or Member Secretary.
5. The office timings for the administrative staff will be as per TMC rules and regulations.
6. The administrative staff will avail leave as per TMC norms.

## 2.8 Roles and Responsibilities of the 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, Co-Chairperson and/or Member Secretary.
- 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 Requirements

- 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 TMC/research site and have no immediate family member affiliated to TMC.
- No quorum should consist entirely of members of one profession or one gender.
- In the absence of the Chairperson, the Co-Chairperson will chair the meeting. In the absence of both, a member who is independent of the institution 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 Decision making**

- Decisions are arrived at by consensus. If a consensus is not possible voting is carried out.
- Voting may be in the form of voice vote, show of hands, or by secret ballot, as determined by the Chairperson, IRB.
- All members except the Chairperson are entitled to one vote.
- However, in case of a tie, the Chairperson will have the casting vote.
- The IRB minutes will document each alternate member's status, vote, and attendance as they relate to IRB actions and quorum requirements.
- Opinions of absent members that are transmitted by mail or telephone or fax may be considered by the attending members during discussion but may not be counted as votes or quorum for formally convened full board meetings.
- Any committee member with a conflicting interest in a proposal will abstain from deliberations and in the decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.

**2.11 Education for 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.

Training of the IRB members in Research Bioethics:

- A new member will be inducted 1 month prior to his/her appointment and will be requested to be an 'Observer' for the first board meeting. An introductory training will be imparted by the Member Secretary.
- 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.
- The training programmes should be scheduled and spread over the year.

**2.12 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, TMC and accreditation. This shall include:

- A quantitative evaluation of the activities of the committee in a year.
- List of the research proposals reviewed in a year.
- Status of each research proposal.

## 2.13 Honorarium

All external non-TMC members should be given honorarium as per TRAC recommendations.

## References

1. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects Retrieved from- *http://www.cioms.ch/frame guidelines nov 2002.htm* accessed 13th September 2008)
2. European Convention on Human rights and Biomedicine (1997). Retrieved from- *http://conventions.coe.int/treaty/en/treaties/html/164.htm* accessed 13th September 2008
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996. Retrieved from-*http://www.ich.org/LOB/media/MEDIA482.pdf* accessed 13th September 2008
4. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006)- Retrieved from - *http://www.icmr.nic.in/ethical guidelines.pdf* accessed 13th September 2008
5. 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 accessed 13th September 2008
6. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000. (Geneva 2000) Retrieved from- *www.who.int/tdr/publications/publications/* accessed 13th September 2008
7. Code of Federal Regulations 45 CFR 46.108 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

## 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 TMC.

**AX1-V1/SOP02/V1**

**Confidentiality and Conflict of Interest Agreement form for IRB Members**

In recognition of the fact, that I, Dr…… 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 TMC's policies and any contractual obligations it may have to third parties.

_____ _____

Undersigned Signature Date

<u>Conflict of Interest</u>

It has been recognized that the potential for conflict of interest will always exist but has faith in the IRB 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, 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.

The Undersigned will immediately disclose to the Chairperson of the IRB 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:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- 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. …….. have read and I accept the aforementioned terms and conditions as explained in this Agreement.

| | |
|---|---|
| _____ | _____ |
| Undersigned Signature | Date |
| _____ | _____ |
| Director of the TMC | Date |

**AX2-V1/SOP02/V1**

**Confidentiality Agreement Form for Independent Consultants**

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

_____ _____
Chairperson of IRB Date

I, _____ (Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson, IRB and me.

_____ _____
Signature of the recipient Date

**AX3-V1/SOP02/V1**

**Confidentiality Agreement Form for Observer Attendees**

I, _____, understand that I am allowed to observe IRB activities and attend the IRB meeting/ scheduled on _____ at _____am/ pm as an Observer.

The meeting will be conducted in the IRB Meeting room, 3rd Floor Main Building, TMH.

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

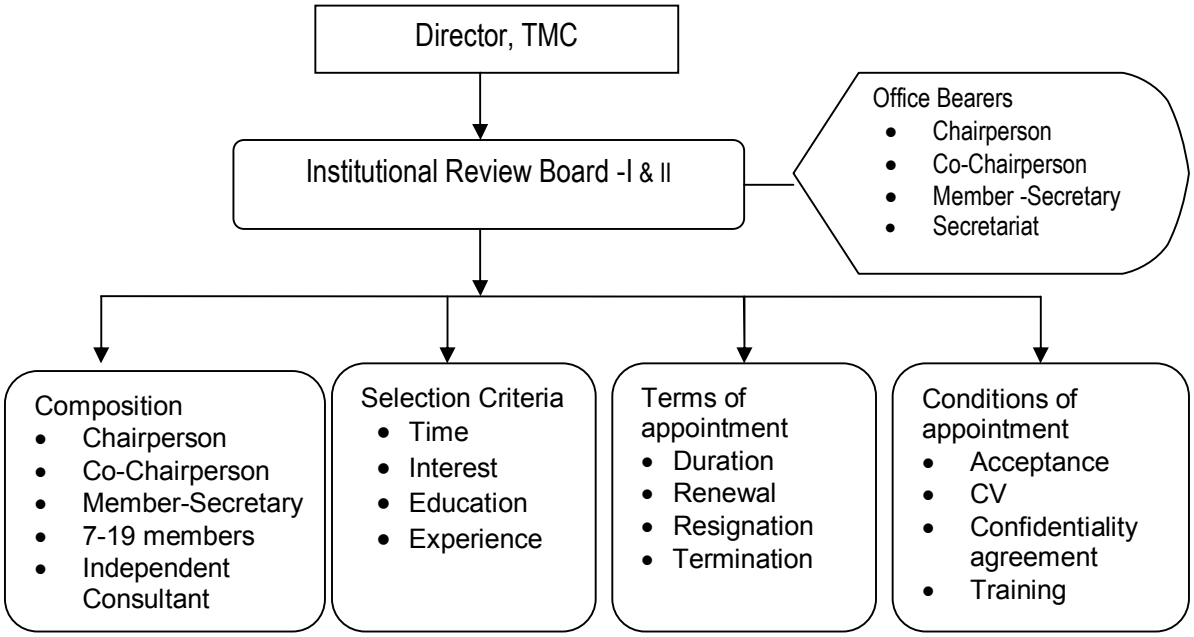
_____
Member Secretary/Chairperson of IRB

_____
Date

I, _____ (Enter name) acknowledge that I have received a copy of this Agreement signed by Member Secretary/Chairperson, IRB and me.

_____ _____
Undersigned Signature Date

# Flow Chart


Director, TMC
Institutional Review Board -I & II
Office Bearers
Chairperson
Co-Chairperson
Member -Secretary
Secretariat
Composition
Chairperson
Co-Chairperson
Member-Secretary
7-19 members
Independent Consultant
Selection Criteria
Time
Interest
Education
Experience
Terms of appointment
Duration
Renewal
Resignation
Termination
Conditions of appointment
Acceptance
CV
Confidentiality agreement
Training