Government Medical College, Surat.

Policies and Operations Manual

for the

Research Review Committee

of

Government Medical College, Surat.

Gujarat

6/12/23

Title: Standard Operating Procedures (SOP) of IRB GMC Surat

Effective Date -08/12/2023.

[TheIEC members(author/s, reviewer/s)and Chairperson will sign and date theSOPon this firstpage]

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1. Abbreviations Used in this Manual:

ADR	=	Adverse Drug Reaction
CDSCO	=	Central Drugs Standard control Organization
DSMC	=	Data Safety Monitoring Committee
EC	=	Ethics Committee
GCP	=	Good Clinical Practices
Govt.	=	Government
GMC	=	Government Medical College
HREC	=	Human Research Ethics Committee
I	=	Investigator
IP	=	Investigation Product
ICH	=	International Council for Harmonization
ICMR	=	Indian Council of Medical Research
IRB	=	Institutional Review Board
LRC	=	Local Research Committee
MHFW	=	Ministry of Health and Family Welfare
MCDS	=	Medical College Development Society
NCH	=	New Civil Hospital
NGO	=	Non Government Organization
PI	=	Principal Investigator
PICF	=	Participant Informed Consent Form
PIS	=	Participant Information Sheet
RKS	=	Rogi Kalyan Samiti
RRC	=	Research Review Committee
SAE	=	Serious Adverse Event
SRC	=	Scientific Review Committee
VNSGU	=	Veer Narmad South Gujarat University

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1. Introduction:

Authority under which the IRB has been constituted:

The Dean, Government Medical College, Surat (GMCS), had, in 2003, constituted the Human Research Ethics Committee (HREC) to oversee the research carried out at the GMC & attached New Civil Hospital Surat, keeping in view the Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO 2000),and ICH-GCP,1996.

In view of the tremendous growth of clinical research in the institution, the Dean, GMC, Surat in 2011, constituted two Committees to function as panels with clearly defined roles. These were ScientificReview Committee (SRC) and HREC.

A Local research committee (LRC) was constituted by the Dean on 28/12/2021 as per the directive of the Government of Gujarat for constituting LRC in all medical colleges of Gujarat.

There was some duplication of work. Also, it was noted that all of student research, especially time bound postgraduate dissertation work, was non interventional and observational and most did not involve vulnerable subjects. Subjecting these protocols thro' the rigorous and long drawn process of SRC and then registered HREC with external members was making it an unnecessary burden on the whole review system; as well as delaying the final approval. Hence following changes are being made in the review process of research protocols at GMC Surat.

2.1Purpose:

The purposes of this operation manual are:

- To provide basic operational guidelines, policies and procedures of Government Medical College, Surat-Institutional Review Board (IRB) in accordance with ICMR and ICH/GCP guidelines.

- To delineate the responsibilities of Institutional officials, IRB members and other staff members.

For the purposes of this manual, research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program which is considered

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research for other purposes.

Any person wishing to suggest a new or revised policy, procedure or form is invited to submit the suggestion in writing to the IRB, along with a description of the rationale for the change.

3. The IRB

3.1 Organization of IRB

This section provides an over view of the structure, responsibilities, and member ship of the IRB.

Human Research Ethics Committee (HREC)

Local Research Review Committee

Research Review Committee (RRC)1 & 2.

The IRB is responsible for reviewing research involving human subjects at this institution, and their affiliates, to ensure that subjects' safety, rights, and welfare are protected in conformity with applicable regulations and guidance as applicable.

Two committees, the RRC 1 & 2 , each convene on fortnightly basis or more frequently to review research involving human subjects. Additional meetings may be scheduled, as needed, to accommodate a high volume of research submitted to the IRB. In the event that there is no new research to be presented to a convened committee and no studies that require continuing review by a convened RRC, the Institutional Officials and the RRC Chair may cancel or reschedule a meeting.

3.2 IRB Office

The IRB office will facilitate the IRB's fulfillment of its review responsibilities. Meetings are to be conducted in College Council Room/Medical Education Unit room of the institute.

Membership requirements of the RRC.

- RRC members are appointed as per the ICMR guidelines (2017).

  The composition should be as follows:-

  1. Chair person(Senior faculty member of GMC)
  2. 1/2 / 3 facultyfrom all the departments of the institute

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 domain field and profile.

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and/or scientific knowledge and expertise. experience in domain field and profile.

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

The following qualities are sought in RRC members:

- Interest and motivation.
- Willingness to give time and effort.
- Commitment and availability.
- Experience and education.
- Respect for divergent opinions and willingness to accept the same if scientific.
- Integrity.

3.3The terms of reference of the committee (RRC)

The appointment procedure for membership will be followed so that it allows for continuity, the development and maintenance of expertise within the RRC, and the regular input of fresh ideas and approaches.The head of the institution will appoint all RRC members, including the Chairperson.

1. All members will serve for a period of 3 years on a renewable basis. New members will be included in the RRC in such a way that there will be a mix of recently included members and members with some years of experience.
2. During the term, Dean, in consultation with the Chairperson can remove any member if, the contribution is not adequate and/or there is a long period of non-availability.
3. A member can tender resignation of her/his membership from the RRC to the Dean through the Chairperson after serving one month advance notice, with valid and justifiable reason for resignation.
4. Dean can replace the member of RRC as and when required.
5. Each member is required to sign the declaration and confidentiality agreement regarding RRC activities.
6. 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 of RRC.

The members who have resigned may be replaced at the discretion of the appointing authority. In case of resignation, Dean, GMC would appoint a new member, falling in the same category of membership.

Termination/Disqualification procedure

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

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- Conduct unbecoming for a member of the Research Review Committee.
- If a member fails to attend more than 3 meetings of RRC in a row without information. The membership shall be reviewed by the RRC if the member is a regular defaulter.
- If deemed necessary, the chairperson & member secretary may decide to terminate the membership and recommend to the Dean, GMC, for necessary action.
- Relocated to another institute or any such similar matter.

3.3.1Every RRC member must:

1. Provide a recent signed CV and training certificates on human research Protection and good clinical practice (GCP) guidelines, at-least BCBR training of basic research methodology.
2. Either be trained in human research protection and/or GCP at the time of induction into the RRC or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
3. Be trained forinstitutional SOP of RRC and relevant guidelines /regulations periodically.
4. Be willing to undergo training or update their skills/knowledge during their tenure as an RRC member;
5. Read, understand, accept and follow the conflict of interest policy of the and declare it, if applicable, at the appropriate time;
6. Sign a confidentiality and conflict of interest agreement/s;
7. be willing to place her/his full name, profession and affiliation to the RRC in the public domain; and
8. be committed and understanding to the need for research and for imparting protection to the participants involved in research.

3.4 Secretariat

Secretariat is composed of Chairperson of respective RRC and the administrative supporting staff. The supporting staff consists of staff members of the GMC appointed by the Dean, GMC. The secretariat shall have the following functions:

- Organizing an effective and efficient tracking procedure for each proposal received
- Preparation, maintenance and distribution of study files
- Organizing RRC meetings regularly
- Preparation of agenda and minutes of the meetings

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- Communicating with RRC members and researchers
- Arrangement of training for personnel and IRB members
- To receive IRB processing fees and issue official receipts for the same, as per the current rules and regulations of Medical College Development Society (MCDS). Current rules are as follows:

Fee structure for research proposals

Name of Study			
Research or Degree under/for		**Faculty**	**Student**
UG Research of GMCS student under guidance of GMCS faculty		-	Free
PG dissertation Thesis GMCS		-	Free
PhD Thesis	Guide from GMCS and PhD student from GMCS	Free	Free
	Guide from GMCS Student other than GMCS but VNSGU registered	Free	Rs. 5000
Non-Funded Research Project/Paper of GMC student and/or faculty		Free	Free
Funded Research Project(Observational study)/ paper by GMC student and/or faculty		Rs. 5000+5% of expenditure to MCDS+5% to RKS	
State/Central Government Funded research Project/Drug Trial/Program where institutional overheads are sanctioned		Rs. 5000	
Drug Trial/Pharmaceutical company Funded Interventional Study		Rs. 25000+ 5% of expenditure to MCDS+5% to RKS	

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Institutional policy for PhD thesis study review

	Researcher	PhD Guide	Research Site	Can be accepted for HREC review	Processing fee
1	GMC student GMC faculty	GMC faculty	GMCS NCHS	Yes	No
2	GMC student GMC faculty	GMC faculty	Only community or field study	Yes	No
3	GMC student GMC faculty	Other(Not GMC faculty)	Other place	No	-
4	GMC student GMC faculty	Other(Not GMC faculty)	GMCS NCHS	No	-
5	**Other**(not GMC student or faculty but registered VNSGU student with official allotment of PhD guide from GMC by VNSGU)	GMC faculty with official allotment as PhD guide by VNSGU for VNSGU registered PhD student	GMCS NCHS	Yes Only after submission of undertaking from PhD guide for taking responsibility of research study	Yes
6	Other (not GMC student or faculty)	Other (Not GMC faculty)	GMCS NCHS	No	-
7	Other (not GMC student or faculty)	GMC faculty	Other than GMCS or NCHS	No	-

3.5 The IRB Administrative Staff: Working Rules

1. There will be administrative officer/s and attendant/s /helper/s who will help the HREC Chairperson and Member Secretary/alternate member secretary, Chairperson RRCand Coordinator LRC 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 RRC members during regular RRC meeting and will be recorded in minutes; these are forwarded to the Dean, GMC.

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3.6 Roles and Responsibilities of the RRC members.

a. The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research subjects.
b. Participate in the RRC meeting.
c. Review & discuss research proposals submitted for evaluation.
d. Review progress reports and monitor ongoing studies.
e. Maintain confidentiality of the documents and deliberations of the RRC meetings.
f. Declare conflict of interest, if any.
g. To carry out work delegated by Chairperson.
h. To participate in continuing education activities in biomedical ethics and biomedical research.
i. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IRB secretariat.

To support the members to remain up to date with current standards in the field of ethics in human research, IRB will supervise training of all its members on induction and at 3 yearly interval (or earlier if changes mandate so) either in the institute or by deputing them to training workshops/conferences, on institute expense.

3.7 Scope of IRB Review Responsibility

3.7.1 IRB responsibilities for research at GMC Surat

The IRB reviews all human subject research conducted at Govt. Medical College and New Civil Hospital, Surat. Research designed to use human subjects, tissues or materials from living humans or data about humans must be formally reviewed and approved, or granted an exemption by the IRB before the research begins, if any of the following are true:

- Institutions become -- 'engaged' in human subject research when its employees or agents intervene or interact with living individuals for research purposes; or, obtain individually identifiable private information for research purposes.
- An institution is automatically considered to be "engaged" in human subject research whenever it receives a direct Government award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.

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- Government Medical College, Surat includes all clinical and biomedical services incorporated within the Government Medical College, Surat and the affiliated New Civil Hospital, Surat and other academic institutions.
- The research is conducted by, or under the direction of, any health care personnel, employee, or agent of the institutions in connection with his or her institutional responsibilities, or by students under the formal guidance of an academic mentor(s).
- The research is conducted by, or under the direction of, any health care personnel, employee, agent, student, or affiliated individual or entity requiring access to, or using any property of, the institutions' facilities.
- The research involves the use of any of the institutions' nonpublic information (e.g. paper or electronic medical records, research data bases, address or class lists, etc.) to identify or contact existing or prospective human research subjects.

3.7.2 IRB responsibilities for Post Graduate DNB course related research at Government institutes other than GMC Surat

- Post Graduate DNB courses have been initiated at District General Hospitals and sub district hospitals under Human Resource development scheme of Government of India from May 2019.
- Government Medical Colleges have been selected as annexed secondary nodes for providing support for various academic activities including research as per the directive from Department of Medical Education, Health and Research, MOHFW of Government of Gujarat.
- GMC Surat has been assigned General Hospitals of Vyara, Navsari and Mandvi as secondary node for DNB Courses.
- General hospital Vyara has applied for PG courses of DNB in subjects of General Surgery, General Medicine & Anesthesia.
- The HREC of Government Medical College, Surat will do the review process of post graduate thesis proposals of DNB students of these centers and subject which are included in the Government order. In future, any other Government Hospitals starting the DNB course, in any other subject with Government of Gujarat order of affiliation will also be included in the purview of scope of work of HREC, GMC, Surat.
- The DNB students will have to undergo basic training for research methodology, (ICMR-NMC mandated Courses) ethical aspect of human research and dissertation protocol writing.
- PG guide for dissertation will be the local DNB teaching faculty of the DNB center. They will be guided and trained in necessary areas of GCP, proposal submission and processing.

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- Interventional studies and Clinical Trials will not be permitted as PG Dissertation. Only observational studies will be allowed, as the onsite monitoring for interventional studies is not feasible by HREC due to the locations of these centers.
- All the rules and regulations of GMCS PG thesis will apply to the DNB centre PG thesis also.

5.

5.1 Responsibilities of RRC:

To ensure that the research project/dissertation/ thesis carried out at Government Medical College & New Civil Hospital, Surat,

- is sound in design, have statistical validity and are conducted according to the ICMR and ICH/GCP guidelines.
- is conducted under the supervision of trained medical/biomedical persons with the required expertise
- Includes solely participants who have given voluntary and informed consent.
- The researcher and the team take the responsibility for protecting the dignity, rights, safety and well-being of the participants enrolled in the study.
- The RRC would ensure that latest ICMR guidelines are followed for,

1. Review of PIS and PICF
2. Benefit-risk assessment
3. Privacy and confidentiality
4. Payment for participation
5. Ancillary care to be given to study participants
6. Publication
7. Post research access and benefit sharing
8. Collaborative research
9. International collaboration

No research project may be started unless approval has been obtained. No retrospective/post facto ethical clearance or approval can be provided to research projects which were neither submitted nor approved by the Institutional Review Board.

Thecommittee expects the investigator/s to strictly observe the following:

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- Lucidly written research projects.
- A progress report on annual basis or more frequently as the committee decides.
- A report of any adverse event when observed during the conduct of the study.
- To keep the committee informed of any amendment to the study or in the study documents.
- To keep the committee informed of study discontinuation along with reasons for the same.

5.2 Meetings of RRC:

RRC will hold regular meetings for review and discussion of submitted research proposals every fortnight. If a member is unable to attend a meeting his/her opinion on the project / on the agenda may be submitted in writing to the chairperson of the committee before the date of the meeting or decision. If the chairperson is unable to chair any meeting due to any reason he/she shall nominate one of the members of the Committee to chair the meeting.The notice of each meeting with the agenda is sent out to the members at least two days before the meeting.

- **Quorum" requirement for RRC meetings for review process:-**

1. A minimum of seven members must be present in the meeting room.
2. At least one member will be lady.
3. No decision is valid without fulfilment of the quorum.

5.4 Procedures:

5.4.1 Criteria for Selection of proposals for IRB (RRC, LRC & HREC) review:

The IRB routinely reviews all bio-medical research protocols submitted for review by the convened IRB. The basic requisite for requiring IRB review is a protocol that has not previously undergone an independent peer review process. The types of protocols that fall under this category are usually investigator initiated, from a single site pharmaceutical company sponsored studies, or early phase clinical trials.

A bulk of protocols submitted to IRB are PG thesis, all of which are non interventional and most do not involve vulnerable subjects. These do not require rigorous scrutiny by the LRC and registered HREC with external members. So, the Research Review Committees are being formed to review, rectify and approve such protocols, independently. This will shorten the time from application to approval, will remove duplication of work and improve the quality of review and research output.

5.4.2 Details of documents for submission of research proposal:

The applicant of a research proposal is required to be submitted in soft and hard copies of his/ her application letter and copies of the following documents.

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1) Covering letter (through the Head of Department)
2) All Undertakings as specified,
   - Certificate that no work has started before approval
   - Certificate that work will be done as per ICMR/GCP guidelines.
3) All relevant Permissions –MS, Dean, Collaborator, Resource site*, Higher authority#
4) Duly filled format for application for approval.
5) Copy of the Research Protocol
6) All relevant Participant Information Sheets in Gujarati, English and Hindi(if needed)
7) All relevant Participant Informed Consent Forms in Gujarati, English and Hindi(if Needed)
8) Permission to use copy righted questionnaire or Performa, if necessary.
9) Detailed budget (if applicable)
10) CTRI registration number and details(if applicable)
11) Permission from Drug Controller General of India (DCGI) (if Applicable)
12) Insurance Policy with extent of coverage and validity period (if applicable)
13) Investigator's agreement with the sponsor (if applicable)
14) Principal investigator's current Curriculum Vitae in case of student /faculty observational study research other than PG dissertation.
15) Duly filled Title page of Protocol with signatures of student and guide/co-guides wherever applicable
16) References: at least 2 main relevant National and International references full articles
17) Any other relevant annexures
    - Letter to other department Head informing about study being carried out, using their department data which is obtained from public domain or hospital record office.
    - Permission from concerned other department HOD if the researcher is going to generate data, retrieving data from individual department sources, involving study participants from other department.
    - Dean and MS permission is not mandatory for all observational dissertation studies.
    - Dean and MS permission is required for interventional studies, studies involving participants from vulnerable population, HIV, COVID/other pandemics, MLC cases, studies requiring access to all such data

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5.4.3 Review Process:

The researcher (PG student, faculty, other) submits a study application to the IRB office. IRB staff performs a preliminary assessment of the submission to determine whether it meets the criteria for assessment, including the required attachments.

The protocol is forwarded to the RRC Chairperson/Member secretary.

Protocol is evaluated to fulfill the ToR of RRC

Protocol shall be for PG/Ph.D thesis or for submission of case report/case series which

1) Are observational(not interventional).

2) Shall not involve vulnerable subjects.

If the protocol submitted meets these criteria, the same is processed by RRC member secretary . If the protocol involves interventional methodology, the same is referred to LRC and HREC for review.

Process by RRC

Member secretary RRC will refer the protocol to one reviewer. If the protocol requires any revision/modification, it will be sent back to the researcher.

The ChairpersonRRC assigns a reviewer to each protocol that is being reviewed.

The reviewer evaluates the protocol, communicates with the researcher &/or PG guide for necessary changes, if any. After the reviewer is satisfied with the protocol. He/she informs/forwards the same to the Chairperson;to be included in the list of protocols to be discussed in next meeting of RRC.

A list of all protocols scheduled for review are made available to the RRC members at least 2(two) working days prior to the meeting.

RRC will review the study for,

1) The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation),and the potential for reaching sound conclusions with the smallest number of research participants with analysis plan.

2) The adequacy of the site, including the supporting staff, available facilities and

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emergency procedures;

3) Schedule for regular monitoring, follow up and submission of interim progress report.

4) The manner in which the results of the research will be reported and published.

5) Any other relevant scientific matter and ethical issue of the study proposal.

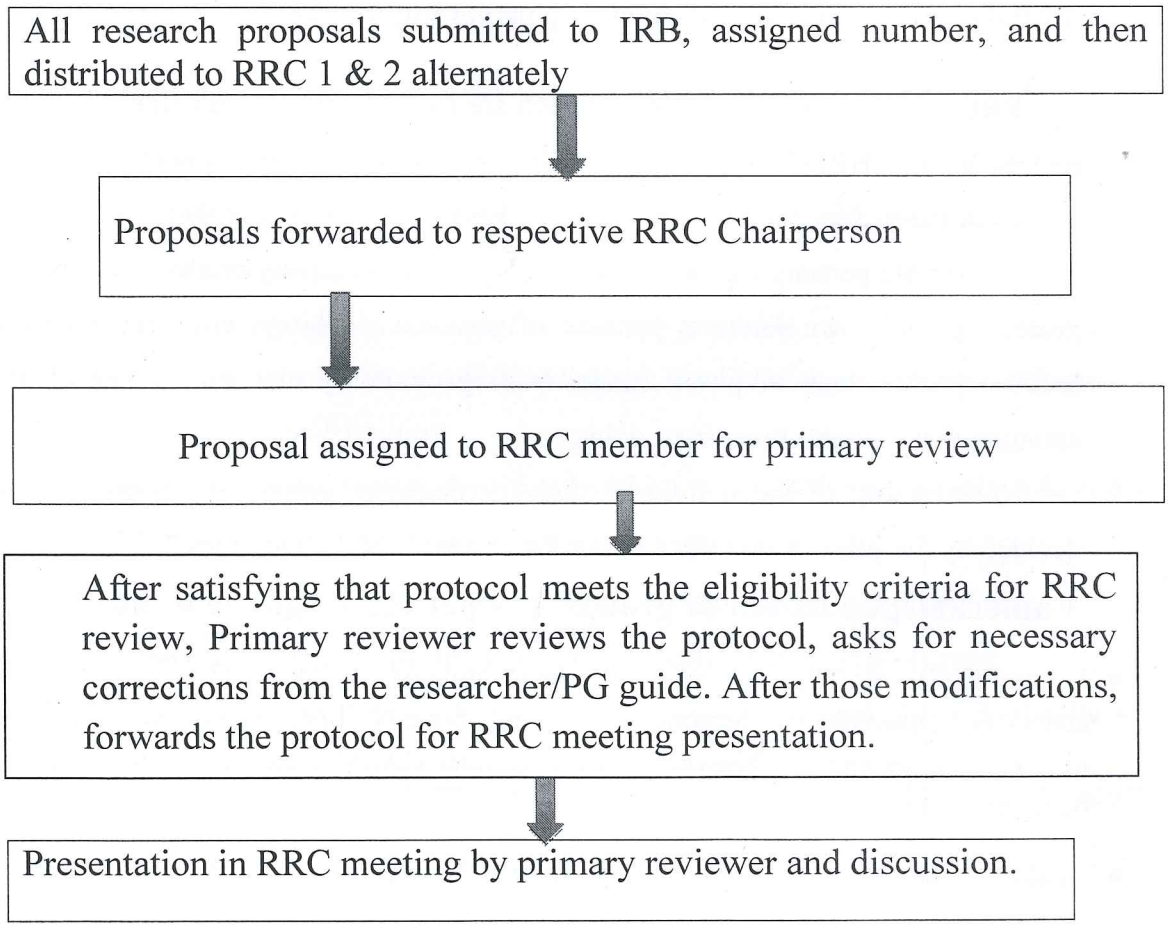
Approval of a research proposal requires consensus or voting by a show of hand by members present at the meeting. Confidential notes shall be maintained on voting details.

Chairpersonwill be responsible for writing the minutes of the Committee meeting.

After approval from Committee, the letters to the applicants will be issued with the signature of the Member Secretary/chairperson of the RRC, on letterhead of RRC.

6. Flow Chart for Protocol approval process:

- All proposals to have declaration by researcher and guide regarding nature of research (Interventional/non-interventional) and type of subjects (vulnerable/non-vulnerable)
- All proposals to be first scrutinized by the Chairperson of respective RRC
- Further process:



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If needed, modification by researcher, and verification review.

Committee decision for approval.

7. Policies of RRC

8.1 Policy to monitor or prevent the conflict of interest:

Any committee member with a conflicting interest in a proposal will declare it before hand and then abstain from deliberation and decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.

All members will sign an agreement (Annexure 1) to fulfill this obligation.

8.2 Policy to review protocols involving vulnerable population:

RRC will forward all proposals which are likely to recruit vulnerable population to review by the HREC which has, among its members, representatives from different groups of the society(senior citizens, ladies, lawyers, NGO representative.)

Vulnerable persons are those individuals who are relatively or absolutelyincapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so.

Vulnerability of the individual study participants, groups and population will be decided by the Ethics Committee as per the current ICMR Guidelines

Vulnerablepopulation or groups: (As per ICMR guideline 2017)

- Economically, socially and politically disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/gay/bisexual and transgender (LGBT), etc.) therefore susceptible to being exploited,
- unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent;

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- children (up to 18 years);
- women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
- Tribals and marginalized communities;
- refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;
- incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled,
- able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions,
- afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;
- terminally ill or are in search of new interventions having exhausted all therapies;
- suffering from stigmatizing or rare diseases; or
- have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

8.5 Policy for using placebo(To be referred to HREC)

- Use of placebo control will not be permitted, when an effective therapy is available in preventing death or irreversible morbidity in a clinical trial population.
- Placebo may be used only ,
  - When there is no established effective therapy available
  - Withholding an established effective therapy would not cause any serious harm
  - If the disease is self-limiting
  - Use of established therapy would not yield any scientifically reliable results and use of placebo would not add any additional serious risk.
- Following studies using placebo may be considered as per discretion of HREC,
  - Add-on trial design, where IP or placebo are added to standard of care.
  - unbalanced randomization i.e fewer participants in placebo group with ratio 2:1 for IP v/s placebo
  - Inclusion of active comparator as additional arm in ratio of 2:2:1 (ie.IP : active comparator : placebo)
  - The protocol must have added safeguards to protect participants e.g. Intensive Monitoring and rescue medication.

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- The researcher has to ensure transition to standard of care/active medicine after Clinical trial is over.

8.8 Policy for approval of post-graduation dissertation involving RandomizedControlled Trials, Academic clinical trials. (To be referred to HREC)

- Randomized Controlled Trials involving interventions other than standard of care shall not be permitted.
- Policy for Randomized Controlled Trials other than PG dissertation, involving standard of care
- The researcher has to provide standard reference and evidence for a favorable risk benefit ratio for the study.
- This will be referred by HREC to a selected subject expert. This expert shall give his/her opinion which might be considered by the HREC committee.
- Final decision after due consideration of the risk/benefit ratio, expert opinion, the HREC can give approval at their discretion **on a case to case basis.**
- In these studies, the guide has to give a written undertaking that any unforeseen adverse event arising related to the study will be the sole responsibility of the guide, along with financial and legal liabilities and other compensations.
- Trials related to public health intervention, health education, social and behavioral science studies would be evaluated and approved by the HREC at their discretion.

Annexure 1

Agreement on Confidentiality and Conflict of Interest.

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Annexure 1

Agreement on Confidentiality and Conflict of Interest.

In the course of my activities as a member of the RRC, 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 Committee'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.

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.

Signature

Date

Name

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