Government Medical College, Surat.

Policies and Operations Manual

for the

Institutional Review Board

of

Government Medical College, Surat.

Gujarat

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

Effective Date -01/11/2023.

[The IEC 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**
SAE	=	**Serious Adverse Event**
SRC	=	**Scientific Review Committee**
VNSGU	=	**Veer Narmad South Gujarat University**

EC and HREC nomenclatures are used interchangeably in the document

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 Scientific Review 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.

These committees are revised and strengthened as per the regulations and/or the need, by the appointing authority.

2.1 Purpose:

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 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 Committee (LRC)

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 HREC and the LRC, each convene on a monthly 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 IRB committee, the Institutional Officials and the IRB committee 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 of the institute.

Membership requirements of the Human Research Ethics Committee.

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

The composition should be as follows:-

1. Chair person (not–affiliated to GMC)
2. 2 / 3 clinicians (GMC Staff member/affiliated to GMC)
3. Basic medical scientist
4. Pharmacologist.
5. One /two legal expert or retired judge or medico-legal expert
6. One/two social scientist/ representative of non-governmental voluntary agency
7. One/two philosopher/ ethicist/ theologian/ lay person from the community
8. Member secretary (GMC Staff member)
9. Alternate member secretary (Affiliated faculty of institute) GMC faculties will function as alternate member secretary of the Human Research Ethics committee and will share all the responsibilities of the member secretary of the committee.

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.
- 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 HREC 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.

3.3 The terms of reference of the committee (HREC)

The appointment procedure for membership will be followed so that it allows for continuity, the development and maintenance of expertise within the HREC, and the regular input of fresh ideas and approaches. The head of the institution will appoint all EC 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 HREC 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 Chairman can disqualify 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 his office of membership from the HREC to the Dean through the Chairperson after serving one month advance notice.
4. Dean can replace the member of HREC as and when required.
5. Each member is required to sign the declaration and confidentiality agreement regarding HREC 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 & Member Secretary of HREC.

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 ex. NGO representative with NGO representative. The recommendations may be sought from the resigning member. Appointment may be made in the consultation with Member Secretary and /or Chairperson.

Termination/Disqualification procedure

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

- Conduct unbecoming for a member of the Ethics Committee.
- If a member fails to attend more than 3 meetings of HREC in a row without information. The membership shall be reviewed by the HREC if the member is a regular defaulter.
- If deemed necessary, the HREC may decide to terminate the membership and recommend to the Dean, GMC, by the Chairperson HREC for necessary action.
- Relocated to another city or any such similar matter.
- In all such situations/circumstances, Dean, GMC will serve a letter of termination to the member. Documentation of the termination will be read out in the next duly convened HREC meeting and recorded in the meeting minutes. HREC membership circular/ roster will be revised.

3.3.1 Every EC member must:

1. Provide a recent signed CV and training certificates on human research Protection and good clinical practice (GCP) guidelines, if applicable;
2. Either be trained in human research protection and/or GCP at the time of induction into the HREC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
3. Be trained for institutional SOP of HREC and relevant guidelines /regulations periodically
4. Be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
5. Read, understand, accept and follow the COI policy of the HREC 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 HREC 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 Member Secretary, alternate member secretary of HREC; coordinator LRC 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 HREC meetings regularly
- Preparation of agenda and minutes of the meetings
- Maintaining HREC documentation and archive
- Communicating with HREC members and PIs
- Arrangement of training for personnel and IRB members
- Providing necessary administrative support for IRB related activities to the Member Secretary, HREC
- 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	

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 plae	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 and 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 HREC members during regular HREC meeting and will be recorded in minutes; these are forwarded to the Dean, GMC.

2. Duties of the administrative officer/s/staff
   a. Correspondence with the HREC members and external experts.
   b. Correspondence with the investigators.
   c. Pre and post arrangements of HREC meetings.
   d. Preparing agenda and minutes of the HREC meetings.
   e. Answering queries of the investigators.
   f. Filing study related documents.
   g. Reminders to the PIs for progress reports.
   h. Archiving and maintaining the study files.
3. Duties of the attendant/s/helper/s
   a. Assisting the secretariat in arranging the HREC meetings.
   b. Dispatching sets of study documents to HREC members and external experts.
   c. Receiving the study related documents from and dispatching the HREC letters to the investigators.
   d. Filing study related documents.
   e. Archiving and maintaining the study files.
   f. Correspondence with the HREC members and external experts.
   g. The administrative staff will report to the Chairperson and/or Member Secretary.

3.6 Roles and Responsibilities of the HREC members.

a. The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research subjects.
b. Participate in the HREC meeting.
c. Review & discuss research proposals submitted for evaluation.
d. Review progress reports and monitor ongoing studies.
e. Monitor SAEs and recommend appropriate action(s).
f. Maintain confidentiality of the documents and deliberations of the HREC meetings.
g. Declare conflict of interest, if any.
h. To carry out work delegated by Chairperson & Member Secretary.
i. To participate in continuing education activities in biomedical ethics and biomedical research.
j. 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.
- 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.
- 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.

3.7.3 IRB responsibilities for Pandemic/Epidemic related research studies

As per the "National Guidelines for Ethics Committees Reviewing Medical and Health Research during COVID-19 Pandemic" has been issued by the ICMR in April 2020.

- Full committee review will be done by HREC for COVID and other epidemic /Pandemic related observational, interventional studies and Clinical Trials.
- The HREC will do review process of all research proposals, observational and interventional, including Government initiated Clinical Trials involving COVID-19 and other epidemic /Pandemic related patients as participants, health care providers or operational research related to COVID and other epidemic /Pandemic ,as per the current ICMR guidelines for COVID research.

- Fast tracking and expedited review of COVID and other epidemic /Pandemic related research proposals will be done as per current ICMR guidelines for COVID research and State Health System Resource Center (SHLRC).
- Research related to autopsy and COVID and other epidemic /Pandemic,will be reviewed as per COVID autopsy guidelines of ICMR.
- COVID and other epidemic /Pandemic related research must have faculty of GMCS as Principal Investigator or Co-Investigator.
- Permission from Medical superintendent for access to COVID and other epidemic /pandemic related hospital data and its use for research purpose will be mandatory for all COVID and other epidemic /Pandemic related research.

4. Local Research Committee

4.1 Purpose:

The LRC has been established by the Dean as per the directive of Government of Gujarat with following objectives,

- To promote the research related activity and atmosphere in the institute.
- To encourage students and faculties to pursue research.
- To improve quality of research
- To coordinate with state research advisory committee.
- To do primary scientific scrutiny of the research proposals to be submitted to HREC for ethical approval.

The LRC will review biomedical research (on human participants) proposals submitted to the IRB to ensure that they meet an acceptable standard of scientific rigor and merit, prior to HREC review.

4.2 Composition of LRC:

Sr. No.	Name and Department	Designation	Phone No	Mail ID	Designation Role of member in Committee
1	**Dr. Ragini Verma** Head & Professor, Department of Obstetrics and Gynacology, GMC, Surat	Dean	9427829470	dean.health.surat@gmail.com ragini27@gmail.com	Chair person

2	**Dr. Ganesh Govekar** Head & Professor, Department of Forensic Medicine, GMC, Surat	Medical Superintendent	9909906019	ms.health.surat1@gmail.com ganeshgangadiyambbs@gmail.com	Member
3	**Dr. Nimesh Verma** Head & Professor, Department of General Surgery, GMC, Surat	Additional Dean	9426144123	nimeshv0@gmail.com	Member
4	**Dr. Sangita Trivedi** Head & Professor, Department of Peadiatrics, GMC, Surat	HREC Member Secretary	9265066804	sangita1567@gmail.com	Member Secretary
5	**Dr. Abhay Kavishwar,** Head and Professor, Department of Community Medicine, GMC, Surat	HOD Community medicine	9925174681	abhaykavishwar@yahoo.com	Member
6	**Dr. Purvi Desai** Head & Professor, Department of Radiology, GMC, Surat.	Radiology	9825300111	drpurvi_desai@gmail.com drpurvi_desai@yahoo.in	Member
7	**Dr. Arpita Nishal** Associate Professor, Department of Pathology, GMC, Surat	Member	9825118443	ajnishal69@gmail.com	Member
8	**Dr. Ashvin Vasava** Associate Professor, Department of General Medicine, GMC, Surat	Member	9879584442	ahvasava@gmail.com	Member
9	**Dr. Preeti Yadav** Associate Professor, Department of Pharmacology, GMC, Surat	Member	8320918716	preeti14121970@gmail.com	Member
10	**Dr. Shivani Jariwala** Assistant Professor, Department of Ophthalmology, GMC, Surat	Member	9374513114	shivupatel21@gmail.com	Member

11	**Dr. Jitendra Patel** Associate Professor, Department of Immunohematology and Blood Transfusion, GMC, Surat	Member	9898585804	onlyg2@gmail.com	Member

5. Human Research Ethics Committee (HREC)

5.1 Responsibilities of HREC:

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 (as approved by LRC) 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 HREC 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. Compensation for research-related harm
6. Ancillary care to be given to study participants
7. Publication
8. Post research access and benefit sharing
9. Collaborative research
10. International collaboration

No research project may be started unless ethical clearance or 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. Following is the list of members of HREC, Govt. Medical College, Surat.

5.2 Composition of HREC:

(in accordance with the ICMR guidelines)

Sr. No.	Name of the Member	Gender	Qualification	Affiliation	Role
1.	**Dr. Pankaj Hiradhar** D-208, Prajeet Appartment, Icchanath,Umra,Surat-295007. Ph.0261-2322729.	Male	M.Sc. PhD	Retired Dean, CDC,VNSGU	Chairman(Ethicist)
2.	**Dr. Jignesh Shah** B,-303, Hampton park, opposite Agam Arcade, Vesu Main Road, Surat.395007	Male	M. S. (General Surgery)	GMC Surat	Alternate member secretary-1 & Clinician
3.	**Dr. Jignesh Vaishnani** C -503, Millennium Residency Near Ayodhyanagari, B/H Shyam Complex, Adajan, Surat -395009	Male	M. D. (Dermatology)	Dermatologist.	Non affiliated Clinician
4.	**Dr. Chetna Patel** 203, Moon tower, Rajhans campus, Pal hazira road, Pal - Surat. 395009	Female	M.D. (Pharmacology)	GMC Surat	Alternate member secretary-2 & Basic Med Scientist
5.	**Dr. Neeta Kavishwar** Flat 2/ B Prarthana Apartment Ravishankar Sankul Bhatar charrasta Surat 395017	Female	M. D. (Anesthesiology)	GMC Surat	Clinician
6.	**Dr. Arpita Nishal** 202,Madhuvan park, Nandanvan Soc.,Ghod Dod road, Surat 395001	Female	MD (Pathology)	GMC Surat	Basic Med Scientist
7.	**Dr. Bhagvatiben Vrajlal Ukani** A/701, Suryam Villa, Near Kiran Motor workshop Galaxy circle, Pal Surat.	Female	MD (Radiology)	GMC Surat	Clinician
8.	**Dr. Mamtarani Verma** E -11 Associate Professor Quarters, New Civil Hospital Campus, Majura Gate, Surat. Pin code 395001	Female	M.D. (Community Medicine)	GMC Surat	Basic Med Scientist
9.	**Mr.AshishA.Shah** LegalExpert, Adv.16,Nikunj Society, Opp.KadampalliSociety , Nanpura,Surat-395001.	Male	B.Com. LLB	Practicing Lawyer	Honorary Legal Expert
10.	**Dr. Vibha Saumil Marfatia** 301, Meghani Towers, Cinema Road, Surat – 395 00	Female	PhD (Immunology)	Social Scientist	Social Scientist
11	**Dr. M.H.Parabia** 12/1768a, Vakil Street, Shahpore, Surat - 395 003	Male	Ph.D. (Proc. Biology)	Social Scientist	Social Scientist

12	**Mrs. Jagruti Patel** 1002,10th Floor, Prayag Flats, B/h Sargam Shopping Centre, Somnath Mahadev Road, Athwalines , SURAT – 395007	Female	M.Sc. LL.M. Ph.D. (Law) PGDHRL	Practicing Lawyer	Honorary Legal Expert
13.	**Mrs. Meeta Jhaveri** 602,JaldarshanAppartment NanpuraMainRoad,Surat.	Female	M.A. (Economics)	---	Person from community
14.	**Dr. Sangeeta Trivedi** AdditionalProfessor,Pediatrics, GMC.,Surat.	Female	M.D.(Pediatrics)	GMC Surat	Clinician

The committee expects the investigator/s to strictly observe the following:

- 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 ethics committee informed of any amendment to the study or in the study documents.
- To keep the ethics committee informed of study discontinuation along with reasons for the same.

5.3 Meetings of HREC:

HREC will hold regular meetings for review and discussion of submitted research proposals every month. 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 chairman is unable to chair any meeting due to any reason he shall nominate one of the members of the Ethics Committee to chair the meeting. The notice of each meeting with the agenda is sent out to the members at least one week before the meeting.

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

Quorum requirement for HREC meetings for review process will be as per current ICMR guidelines.

1. A minimum of seven members must be present in the meeting room.
2. The quorum should include both medical, non-medical or technical or/and non-technical members.
3. Minimum one non-affiliated member should be part of the quorum.
4. Preferably the lay person should be part of the quorum.
5. At least one member will be lady.
6. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.

7. No decision is valid without fulfilment of the quorum.

5.4 Procedures:

5.4.1 Criteria for Selection of proposals for IRB (HREC and LRC) 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.

Prior to review by the HREC, the LRC will routinely review all bio-medical research protocols except the following:

- Research approved for Governmental funding.
- Research approved for corporation/ foundation/organization/association funding utilizing an adequate peer review mechanism, as determined by the LRC Chair.

The EC and/or the Institutional Officials may, at their discretion, forward any protocol to the LRC at any point during the review process.

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.

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 of Ethics Committee
5) Copy of the Research Protocol
6) All relevant Participant Information Sheets in Gujarati, English and Hindi
7) All relevant Participant Informed Consent Forms in Gujarati, English and Hindi
8) Permission to use copy righted questionnaire or Performa, if necessary.
9) Detailed budget
10) CTRI registration number and details
11) Permission from Drug Controller General of India (DCGI)
12) Insurance Policy with extent of coverage and validity period
13) Investigator's agreement with the sponsor

14) Principal investigator's current Curriculum Vitae
15) Departmental Protocol discussion meeting minutes – dated and signed wherever applicable.
16) Duly filled Title page of Protocol with signatures of student and guide/co-guides wherever applicable
17) References: at least 2 main relevant National and International references.
18) Any other relevant annexures
19) Application should be submitted online at gmcsurat.edu.in irb.gmcs@gmail.com.

5.4.3 Review Process:

The Principal Investigator 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 if the protocol has undergone prior scientific review.

The protocol is forwarded to the LRC Chair.

LRC will review scientific design and conduct of the study for,

- The appropriateness of the study design in relation to the objectives of the study
- The statistical methodology (including sample size calculation),
- The potential for reaching sound conclusions with the smallest number of research participants with analysis plan.
- Any other relevant scientific matter of the study proposal.

Actions by the LRC

Based on the review of the proposed research, LRC may vote to take either of the following actions:

- Protocol is forwarded to the HREC for review of ethical aspect.
- Protocol is returned to the PI or I for further action.

Process by HREC

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

The Member secretary HREC assigns a reviewer to each protocol that is being reviewed .If necessary, an expert content reviewer will also be assigned to review the protocol (see Expert Content Reviewer section below).

All protocols scheduled for review are made available to the HREC members at least 7 (seven) working days prior to the meeting.

HREC 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 justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities;

3) The justification for the use of control arms;

4) Criteria for prematurely with drawing research participants;

5) Criteria for suspending or terminating the research as a whole

6) The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring committee(DSMC).

7) The adequacy of the site, including the supporting staff, available facilities and emergency procedures;

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

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

5.5 Content Expert Reviewers:

During the course of conducting its review of proposed protocols, the HREC may need the assistance of members of the faculty or other expert reviewers who possess specific expertise relevant to the disease or condition in question. These questions may concern the relevance of the proposed study to the field or other technical issues beyond the expertise of the committee members. The role of the expert reviewer would be to address the specific questions posed by the HREC. Expert reviewers will be expected to provide written comments.

When this need is identified, either by the Member secretary HREC in consultation with the HREC Chair, will contact the Department Head and ask for his/her assistance in identifying a willing and available expert. The Department Head is responsible for identifying and contacting the expert reviewer. The Member secretary HREC should contact the expert to verify that she/he:

a. Possesses the requisite expertise.

b. Not a member of the research team whose protocol has to be reviewed

c. Is available to perform the review in a timely manner.

d. Is willing to undertake the task.

e. There is no conflict of interest, (This along with confidentiality document, has to be submitted by the expert reviewer)

The Member secretary HREC should document the above points in the study file when an expert reviewer has been identified. Once the expert has been identified, the HREC will invite the expert to attend its next meeting, at which time the protocol will be discussed or communicated with the expert in writing and obtain the opinion. The final decision regarding the question will be taken by the HREC. The HREC recommendation will be communicated to the Principal Investigator.

5.6 HREC Correspondence:

The Member secretary HREC will draft the initial letter that will be sent to the Principal Investigator.

The final letter shall be mailed to the Principal Investigator within one (1) week of holding the HREC meeting. It shall be sent to the Principal Investigator and HREC members via email.

Notes of HREC meetings will be recorded to assist with the preparation of the review letters; notes may only be accessed by the Institutional Officials, IRB office staff, and members of the HREC.

5.7 Responses to HREC Reviews:

If the protocol was returned to the Principal Investigator for further action, the Principal Investigator may submit a response and revised protocol to the HREC for review.

The Principal Investigator may revise the protocol per the HREC comments and re-submit for review.

At any time during this process, the Principal Investigator may contact the reviewer for assistance.

The researcher should respond within 30 working days after receipt of comments or suggestions from HREC.A reminder will be sent after 45 days. Proposal will be removed from review process in case PI fails to respond within the stipulated time.

5.8 Decision making process

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.

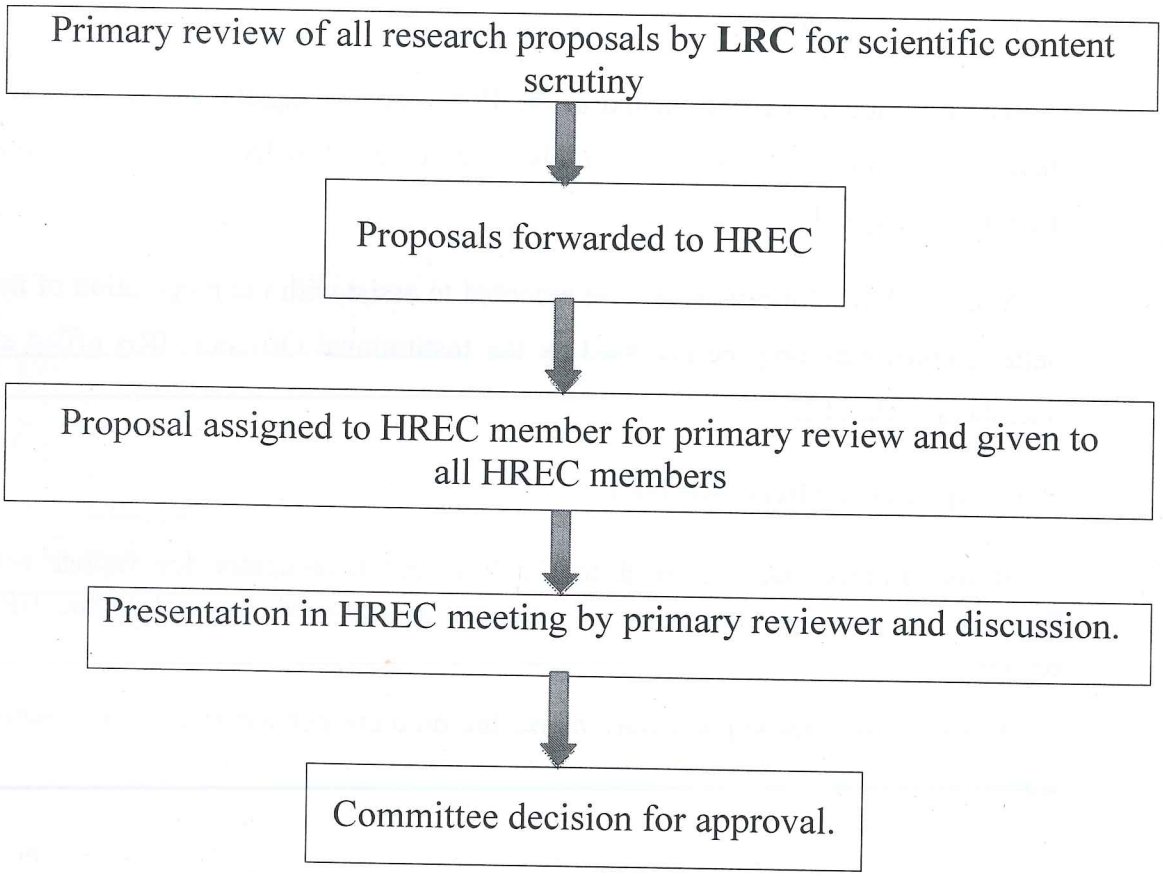
Member secretary will be responsible for writing the minutes of the Ethics Committee meeting.

After approval of the chairman, the minutes will be circulated by the Member Secretary of Ethics Committee. The Minutes will be circulated to all the members of Ethics Committee within two weeks of the meeting.

After approval from Ethics Committee, the letters to the applicants will be issued with the signature of the Member Secretary/chairman of the Ethics Committee.

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 LRC
- Further process:



7. Types of review

- The Member Secretary/Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types,
  1. Exemption from review
  2. Expedited review
  3. Full committee review
- A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.
- The decision on the type of review required rests with the EC and will be decided on a case-to-case basis.
- Expedited review can be conducted by Chairperson, Member Secretary and one or two designated members
- Approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next full committee meeting

8. Policies of EC

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 sand indecision 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 x) to fulfill this obligation.

If an applicant submitting a protocol believes that a HREC 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 HREC member(s) in question.

The committee may elect to investigate the applicant's claim of the potential conflict.

8.2 Policy to review protocols involving vulnerable population:

HREC has, among its members, representatives from different groups of the society(senior citizens, ladies, lawyers, NGO representative.)Even though, if a special group of participants are to be included in the research, member secretary, with prior permission of the chairperson may request a representative of the group to remain present while the protocol is being presented/discussed and express concerns on behalf of the group. The same will be recorded in the minutes.

Review process of Research proposals involving vulnerable population.

Vulnerable persons are those individuals who are relatively or absolutely incapable 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

Vulnerable population 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;
- 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).

Review process

- HREC will determine whether the prospective participants for a particular research are vulnerable.
- Review of research proposals involving participants from above mentioned list and any other vulnerable population as decided by the HREC, will be done as per current ICMR guidelines.
- Only the full committee will do initial and continuing review of proposals involving vulnerable population
- Empowered representatives from the specific populations will be invited during deliberations.

Care of following points will be taken at every step.

Obligations/duties of stakeholders
(Based on ICMR guideline 2017)

Stakeholders	Obligations / duties
Researchers	• Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study. • COI issues must be addressed. • Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. • Ensure that prospective participants are competent to give informed consent. • Take consent of the LAR when a prospective participant lacks the capacity to consent. • Respect dissent from the participant. • Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. • Research should be conducted within the purview of existing relevant guidelines/regulations.

Ethics Committee	• During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits. • Only the full committee will do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • EC has special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment and should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. EC will ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD.
Sponsors	• The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

Full Committee will perform the initial and ongoing review of the research proposals involving vulnerable population.

8.3. Policy for ownership of Biological samples and Data,

- For biological samples, donors (participants) maintain the ownership of the samples. He/she can withdraw permission to use biological material and data any time.
- Institutions implementing the research are custodians of the samples and data.
- Secondary or extended use of biological samples and data needs consent.
- Primary clinician is the custodian of patient case records.
- Ownership issues and responsibilities need to be carefully worked out well before the data are collected and researchers should ensure clarity about data ownership, publication rights and obligations following data collection. This should be clearly defined in the protocol submitted to the head of the institution for getting permission; and to EC for approval.

8.4 Policy regarding review of clinical trial and academic trials:

As per the amended schedule (2005) of the Drugs and Cosmetics Rules, 1945, a clinical trial refers to systematic study of new drugs on human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including dynamic and kinetic) and/or ADR, efficacy and safety.

The HREC has to ensure that clinical trials are conducted as per ICMR 2017 guidelines and all amendments as well as according to CDSCO regulatory guidelines.

- Any systematic study of new drugs on human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including dynamic and kinetic) and/or ADR, efficacy and safety will be considered as clinical trial As per the amended schedule (2005) of the Drugs and Cosmetics Rules, 1945.
- The academic clinical trial as per GSR313(E) dated 16 March 2016 is a clinical trial intended for academic and non-commercial purposes in respect of approved drug formulation for any new indication or new route of administration or new dose or new dosage form.
- EC has to approve such studies after due consideration of
  -Benefits
  -Risks
  -and all other ethical aspects
- licensing authority has to be informed as per the prescribed procedure
- When academic clinical trials are planned for "off-label" use of a drug for purely academic purposes and not for commercial use, then such clinical trials may not currently require regulatory approval.
- However EC has to approve such studies after due consideration of benefits, risks and all other ethical aspects and licensing authority has to be informed as per GSR313(e) dated 16-3-2016 issued by CDSCO.
- The broad aim of the process of clinical development of new drug is to find out
  - Whether there is a dose-range
  - Benefit-risk relationship should be acceptable.
- Researchers will have to submit adequate evidence like preclinical investigation and previous clinical studies to ensure safety of intervention to be studied, before the trial is planned.
- SAE reporting and management has to be as per ICMR guidelines.

- Compensation policy for each clinical trial must be put in place meeting CDSCO guidelines in the trial documents submitted for EC approval.
- For investigator initiated clinical trials, principal investigator must take responsibility for compensation and institute shall ensure free management of all trial related injuries.

8.5 Policy for using placebo

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

8.6 Policy for Multicentric clinical trial

- Multicentric clinical trial generally follows common protocol. This trial should safeguard dignity, right, safety and well-being of participants.
- EC of all participants site should establish communication. If any EC does not grant approval for a study reasons must be shared with other EC.
- EC can suggest site specific protocols as per the local needs. Separate review may be requested if there is higher degree of risk or any other reason
- The EC can decide to have one designated main EC, the decisions of which may be acceptable to other ECs.
- The site EC, however retain their rights to review any additional requirements to ensure need-base protection of participants and make changes in the informed consent document.

- The EC have all the rights to monitor research as per local requirements. The protocol may be modified to suit the local requirements.
- Ongoing research will be reviewed at regular interval at least once a year or more.
- Clinical trials under the purview of a licensing authority must comply with all regulations applicable to SAEs.
- The EC will examine the measures taken for medical management of SAEs. .
- Monitoring can be routine or "for cause" e.g. Higher number of protocol violation, large number of SAE, complaints received from participants, etc.

8.7 Policy for traditional system of medicine

- Research on AYUSH should be conducted in accordance with all the ethical principles described as per ICMR Guidelines.
- However, if IPs of more than one traditional system of medicine are to be investigated then investigator from respective system should be included.

8.8 Policy for approval of post-graduation dissertation involving Randomized Controlled Trials, Academic clinical trials.

- 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.

The committee will give its opinion on the project in writing in one of the following ways:

- Approval
- Disapproval
- Modification before approval
- Discontinuation of previously approved project
- The committee members felt that the proposal, in its present form was not fit to be given ethical clearance.
- The Principal Investigator shall correct the deficiencies & re-submit the proposal for approval. The recommendations and reasons for the same shall be given in writing to the Principal Investigator.

The chairman/ member secretary of the committee may provisionally approve without calling a full meeting in cases where only administrative amendment has been made. The chairman will inform other members of the committee of the amendments and his decision. The decision will be ratified at the next full committee meeting and this will berecordedintheminutes.AlldocumentspertainingtotheEthicsCommitteewillbe held in the office of the Ethics Committee under charge of the Secretary, Ethics Committee.

Annexure 1

Agreement on Confidentiality and Conflict of Interest.

In the course of my activities as a member of the HREC, 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

Annexure 2

Confidentiality and Conflict of Interest Agreement Form for Independent Consultants

Agreement on Confidentiality

I, Dr./Mr./Ms. ..... (Name and Designation) as a non-member of HREC, understand that the copy (ies) given to me by the HREC is (are) confidential. I shall use the information only for the indicated purpose as described to the IHEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the HREC.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

Agreement on Conflict of Interest

In the course of my activities as an Independent Consultant of the HREC, whenever I have a conflict of interest, I shall immediately inform the committee about it and / or shall refrain from giving my expert comments on the project on this ground.

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

Signature

Date

Annexure 3

To,
Member Secretary
Human Research Ethics Committee
Govt Medical College, Surat

Project entitled: .....

Name of PI:

Conflict of Interest

I hereby declare that I have no conflict of interest in my project./ I have following conflict of interest:

Signature of PI
Date

Consent of Head of the PI's Department

Date...

I have reviewed the above project submitted by..... Principal Investigator from my Department. I endorse the project and have 'no objection' for submission for consideration by Scientific & Ethics committee.

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

Signature & date
Name
Department