Government Medical College, Surat.

Policies and Operations Manual

for the

Institutional Review Board

of

Government Medical College, Surat - Gujarat.

Title: Revision of SOPs.

Effective Date: 15th March, 2019.

[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

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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

I = Investigator

I P = Investigation Product

NCH = New civil hospital

VNSGU = Veer Narmad South Gujarat University

HREC = Human Research Ethics Committee

ICH= International Council for Harmonization

ICMR = Indian Council of Medical Research

IRB = Institutional Review Board

MCDC = Medical College Development council

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

EC and HREC nomenclatures are used interchangeably in the document.

2. 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 NCH 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 are SRC & HREC.

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. Organization

This section provides an overview of the structure, responsibilities, and membership of the IRB.

Scientific Review Committee (SRC)

Human Research Ethics Committee (HREC)

4. The IRB

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 SRC, 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.

4.1 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 Scientific Review Committee /Ethics Committee.

- SRC members are faculty members of GMC Surat. They are selected to make committee representative of all the sections of the institute.
- HREC members are appointed as per the ICMR guidelines (2017).The composition should be as follows:-
    1. Chairperson (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)

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 SRC/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.

The terms of reference of the committee

Duration

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.

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.

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 willing to undergo training or update their skills/knowledge during their tenure as an EC member;
4. be aware of relevant guidelines and regulations;
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.

Secretariat

Secretariat is composed of Member Secretary, HREC; coordinator SRC 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 SRC/HREC meetings regularly
- Preparation of agenda and minutes of the meetings
- Maintaining HREC documentation and archive
- Communicating with SRC/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 Committee (MCDC). Current rules are as follows:
  - Students of GMC Surat are exempted from paying processing fees.
  - Students of colleges from VNSGU, other than GMC Surat need to pay processing fees of Rs. 2000/-
  - Students of colleges outside VNSGU, need to pay processing fees of Rs. 5000/-
  - All sponsored /funded projects will have to pay processing fees of Rs. 25000/-.

    In addition, after approval, they will have to deposit 5% of the total expenditure at this site in to MCDC and 5% in RKS of New Civil Hospital, Surat.

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/Coordinator SRC 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.

4. **Roles and Responsibilities of the SRC/HREC members.**

   a. The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research subjects.
   b. Participate in the SRC/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 SRC/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.

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.

4.2 Scope of IRB Review Responsibility

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.

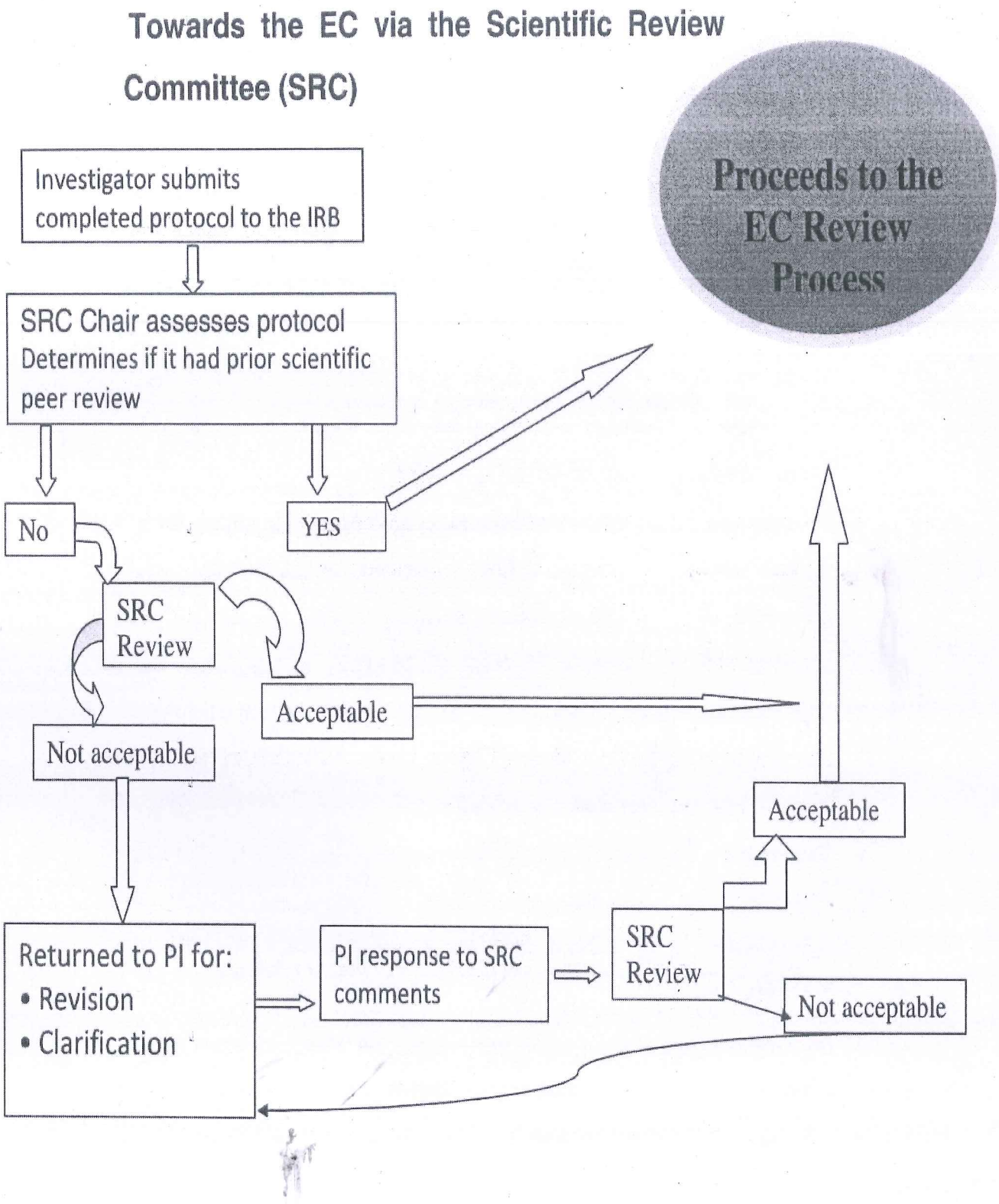
- An institution is automatically considered to be "engaged" in human subject research whenever it receives a direct Government award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human

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 databases, address or class lists, etc.) to identify or contact existing or prospective human research subjects.

5. Flow Chart for Protocol approval:

Towards the HREC via the Scientific Review Committee (SRC)



6. Schedules of submitting the proposal is as follows:

Submissions will be received on all working days. Proposals received till 15th of any month will be processed in the coming SRC meetings and those received after 15th will be processed in the next SRC meetings. All meetings of SRC will be held as far as possible on first Wednesday of all months excluding vacation period.

The applicant of a proposal for Thesis or Dissertation is required to submit 2 copies of his / her application letter and copies of the following documents.

1) Information as desired in the "Format for submission".
2) Participant Informed Consent Form (PICF) in English, Hindi and Gujarati, with space for signatures, name, and address of a witness.
3) Participant Information Sheet (PIS) in English, Hindi and Gujarati.
4) Certificate that no work has started before approval.
5) Certificate that work will be done as per ICMR/GCP guidelines.
6) Permission to use copyrighted questionnaire or Performa, if necessary.
7) Any other project / thesis / dissertation specific document.
8) Copy of the Protocol.
9) Soft copy of all of the above information via email to

   irb.gmcs@gmail.com.

7. Scientific Review Committee (SRC)

7.1 Purpose:

The SRC was established to reinforce the institutional mission in promoting research excellence. The SRC 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.

7.2 Composition of SRC:

Sr. No	Name of Members	Qualification	Department	Designation
1	Dr. J. K. Kosambiya Professor G. M. C. Surat.	M. D. (Community Medicine)	Community Medicine	Chairman
2	Dr. Ritambhara Mehta Professor & Head G.M.C. Surat	M. D. (Psychiatry)	Psychiatry	Coordinator
3	Dr. Neeta Kavishwar Professor G.M.C. Surat	M. D. (Anesthesiology)	Anesthesiology	Member
4	Dr. Neeta Khandelwal Professor & Head G.M.C., Surat.	M. D. (Microbiology)	Microbiology	Member
5	Dr. Hari Menon Professor & Head G.M.C. Surat	M. S. (Orthopedics)	Orthopedics	Member
6	Dr. Yogesh Patel Assistant Professor G.M.C. Surat.	M. D. (Skin & V. D.)	Dermatology (Venereology & Leprosy)	Member
7	Dr. Anand Chaudhari Assistant Professor G.M.C. Surat	M. S. (E. N. T.)	E.N.T.	Member
8	Dr. Parul Vadgama Associate Professor G.M.C., Surat.	M.D. (Respiratory Medicine)	Respiratory Medicine	Member
9	Dr. Anita Sinha Assistant Professor G.M.C., Surat.	M.D. (Pharmacology)	Pharmacology	Member
10	Dr. Puneet Saxena Associate Professor G.M.C., Surat.	M.D. (Biochemistry)	Biochemistry	Member
11	Dr. Saral Bhatia Associate Professor G.M.C., Surat.	M. S. (Obst. & Gynec.)	Obst. & Gynec.	Member
12	Dr. Kunjan Patel Associate Professor G.M.C., Surat.	M. S. (Ophthalmology)	Ophthalmology	Member

13	Dr. Divyang Dave Associate Professor G.M.C., Surat.	M. S. (Surgery)	Surgery	Member
14	Dr. Jigisha Patadia Associate Professor G.M.C., Surat.	M. D. (Pediatric)	Pediatric	Member
15	Dr. Sandeep Kansal Associate Professor G. M. C. Surat.	M. S. (Surgery)	Surgery	Member
16	Dr.Mandakini Patel Associate Professor G.M.C. Surat	M. D. (Pathology)	Pathology	Member
17	Dr.Meenakshi S. Modi Associate Professor G.M.C. Surat.	M. D. (Anatomy)	Anatomy	Member
18	Dr. Neeta Bachalus Associate Professor G.M.C., Surat.	M.D. (Physiology)	Physiology	Member
19	Dr. Latika Purohit Assistant Professor G.M.C., Surat.	M. D. (Microbiology)	Microbiology	Member
20	Dr. Chandresh Tailor Associate Professor G.M.C., Surat.	M. D. (Forensic Medicine)	Forensic Medicine	Member
21	Dr. Purvi Desai Associate Professor G.M.C., Surat.	M. D. (Radiology)	Radiology	Member
22	Dr. Ashvin Vasava Associate Professor G.M.C., Surat.	M. D. (Medicine)	Medicine	Member
23	Dr.Vipul Chaudhari Assistant Professor G.M.C., Surat.	M. D. (Community Medicine)	Community Medicine	Member
24	Dr. Harsha Patel Associate Professor G.M.C., Surat.	M. D. (Anesthesia)	Anesthesia	Member
25	Dr. Dhwani Desai Associate Professor G.M.C., Surat.	M. S. (Obst. & Gynec.)	Obst. & Gynec.	Member
26	Dr.Geeta Vaghela Assistant Professor G.M.C., Surat.	M. D. (Microbiology)	Microbiology	Member

7.3 Criteria for Selection:

The SRC routinely reviews all bio-medical research protocols submitted for review by the convened IRB. The basic requisite for requiring SRC 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 SRC 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 SRC Chair.

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

7.4 SRC Process:

The Principal Investigator submits a new 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 SRC Chair, as needed, for final determination of whether institutional SRC review is required and if an expert content reviewer is required. These decisions are noted in the IRB study file. SRC Chair/ Coordinator will refer the protocol to one (1) subject expert and one (1) content expert. If the protocol requires any revision/modification, it will be sent back to Principal Investigator.

If SRC Chair/ Coordinator feel that review meeting is indicated, a SRC meeting will be scheduled. To achieve a quorum of the SRC, there must be four (4) medical reviewers and one (1) statistical reviewer present.

If the quorum cannot be maintained, the meeting will be stopped until a quorum can again be achieved. The present members will discuss the protocols & give recommendations for the full board of SRC.

The SRC Chair assigns a medical and a statistical 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).

The deadline for each SRC meeting is that the protocol must have been submitted to the IRB office at least five (5) working days prior to the SRC meeting. This deadline may be shortened at the discretion of the SRC Chair to accommodate receipt of responses to prior SRC comments, provided that there is adequate time for the SRC members to review the responses prior to the meeting.

All protocols scheduled for review are made available to the SRC members at least five (5) working days prior to the meeting.

7.5 SRC will review scientific design and conduct of 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 withdrawing 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.

7.6 Actions by the SRC:

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

- Protocol is forwarded to the HREC.
- Protocol is returned to the PI or I for further action.

7.7 SRC Correspondence:

The SRC Chair/ Coordinator draft the initial letter that will be sent to the Principal Investigator. The SRC Coordinator e-mails and/or sends the letter to the SRC Chair and the Primary Reviewers for them to edit/revise.

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

Notes of SRC 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 SRC and HREC. Formal meeting minutes of SRC meetings shall not be created.

7.8 Responses to SRC 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 SRC for review. The Principal Investigator submits the response to the IRB office. The SRC Coordinator forwards the response, revised documents, and the original SRC letter to the SRC Chair and the two (2) SRC reviewers. The SRC reviewers and the SRC Chair determine if the material is acceptable or if it needs to be discussed at the next convened SRC meeting. The Principal Investigator is informed by letter of the SRC's review of the response/determination, which is also sent to the Principal Investigator and SRC members via email.

If appropriate, the SRC may require further action by the Principal Investigator.
This will be clearly mentioned in the letter forwarded to the PI/I for compliance of the

Revised

requirements spelled out by the SRC. The Principal Investigator may revise the protocol per the SRC comments and re-submit for review.

At any time during this process, the Principal Investigator may contact the SRC Chair for assistance. This is clearly documented in the letter that is forwarded to the Principal Investigator.

7.9 Content Expert Reviewers:

During the course of conducting its review of proposed protocols, the SRC 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 SRC. Expert reviewers will be expected to provide written comments.

When this need is identified, either by the SRC Chair, the SRC medical reviewer in consultation with the SRC Chair or by the SRC itself, the SRC Chair or his/her designee will contact the Division or Department Head and ask for his/her assistance in identifying a willing and available expert. The Division or Department Head is responsible for identifying and contacting the expert reviewer. The SRC Chair 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 SRC Chair should document the above points in the study file when an expert reviewer has been identified. Once the expert has been identified, the SRC will invite the expert to attend its next meeting, at which time the protocol will be discussed or communicate with the expert in writing and obtain the opinion. The final decision regarding the question will be taken by the SRC. The SRC recommendation will be communicated to the Principal Investigator in a letter (hard copy) and to the Principal Investigator and SRC members via email.

8. Human Research Ethics Committee (EC)

8.1 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 SRC) 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,
    - Review of PIS and PICF
    - Benefit-risk assessment
    - Privacy and confidentiality
    - Payment for participation
    - Compensation for research-related harm
    - Ancillary care to be given to study participants
    - Publication
    - Post research access and benefit sharing
    - Collaborative research
    - 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.

8.2 Composition of EC: (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 -295 007. Ph. 0261-2322729.	Male	M.Sc. PhD	Retired Dean, CDC,VNSGU	Chairman (Ethicist)
2.	**Dr. N.D. Kantharia** Professor & Head, Pharmacology Department, GMC.,Surat.	Male	M.D. (Pharmacology)	GMC Surat	Basic Med Scientist
3.	**Dr J A Contractor** Professor and Head ,ENT department,GMC ,Surat	Male	MS (ENT)	GMC Surat	Clinician
4.	**Dr.Ragini Verma** Professor and Head,Obstetrics and Gynecology department,GMC,Surat	Female	MS (OB&G)	GMC Surat	Clinician
5.	**Dr.Tinkal Patel** Professor and Head,Department of Medicine,GMC,Surat	Female	MD (Med)	GMC Surat	Clinician
6.	**Dr.Vasudha Bhagat** Additional Professor Pathology,GMC,Surat	Female	MD (Pathology)	GMC Surat	Basic Med Scientist
7.	**Dr. Mohua Moitra** Asso. Professor, Community Medicine, (PSM) GMC.,Surat.	Female	M.D.(PSM)	GMC Surat	Social Scientist
8.	**Dr.Chetan Achary** Associate Professor of Department Pharmacology,GMC,Surat	Male	MD (Pharmacology)	GMC Surat	Basic Med Scientist
9.	**Mr. Ashish A. Shah** Legal Expert, Adv.16, Nikunj Society, Opp. Kadampalli Society, Nanpura, Surat-395 001.	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	B. Com. L.L.B.	Practicing Lawyer	Honorary Legal Expert
13.	**Mrs. Meeta Jhaveri** 602, Jaldarshan Appartment Nanpura Main Road, Surat.	Female	M.A. (Economics)	-- --	Person from community
14.	**Dr. Sangeeta Trivedi** Additional Professor, Pediatrics, GMC.,Surat.	Female	M.D. (Pediatrics)	GMC Surat	Clinician

8.3 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.

8.4 Meetings:

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.

8.5 Procedures:

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

A quorum is required for all the meetings (7 members out of 13 will make a quorum, however at least one member from outside the institute and one lady has to be present). Approval of a project/dissertation/thesis requires consensus or voting by a show of hand by members present at the meeting. Confidential notes shall be maintained on voting details.

The notice of each meeting with the agenda is sent out to the members at least one week before the meeting. 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 of Ethics Committee.

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, exemption from review, expedited review, and 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

8.6 Policies of EC

8.6.1 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 deliberations and in 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 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.

8.6.2 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.

8.6.3. 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.

8.6.4 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.

8.6.5 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.

8.6.6 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.

8.6.7 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.

8.6.8 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.
- For Randomized Controlled Trials, involving standard of care,
  - The researcher has to provide standard reference and evidence for a favourable 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 committee 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 behavioural science studies would be evaluated and approved by the HREC at their discretion.

8.7 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 be recorded in the minutes. All documents pertaining to the Ethics Committee will be 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