H.M.Patel Centre for Medical Care & Education

Karamsad, Gujarat- 388325

Standard Operating Procedures

Human Research Ethics Committee

Of

H M Patel Centre for Medical Care and Education

Revised - December 2012

INDEX

Authors:

Name and Position in HREC	**Signature with Date**
Dr Barna Ganguly ,Member (Pharmacologist) Ex-Member Secretary	
Dr. Chiramana Haritha, Member (Clinician) Ex -Member Secretary	

Reviewed by:

Name and Position in HREC	**Signature with Date**
Dr. Ravindra Sabnis, Chairman	
Dr. Himanshu Pandya, Deputy Chairman	
Mr. Ajay Phatak, Member Secretary	
Dr. Somashekhar Nimbalkar, Member	
Dr. Nitin Raithatha, Member	
Dr. Swapnil Agarwal, Member	
Dr. Sumati Khanna, Member	
Mrs. Sangeeta Nair, Member	
Mrs. Jyoti Shah, Member	
Mr. Nilesh Panchal, Member	

Approved By:

Name and Designation	**Signature with Date**
Mr. Sandeep Desai Chief Executive Officer H M Patel Centre for Medical Care and Education Karamsad-388325, Gujarat, India	

HUMAN RESEARCH ETHICS COMMITTEE

OF

H.M.PATEL CENTRE FOR MEDICAL CARE & EDUCATION

KARAMSAD, GUJARAT -388325

Standard Operating Procedures (SOP) Revised- December, 2012
For Human Research Ethics Committee (HREC)

1. Objective:-

The objective of this SOP is to contribute to the effective functioning of the Human Research Ethics Committee of H.M.PATEL CENTRE FOR MEDICAL CARE & EDUCATION, Karamsad {HMPCMCE, henceforth referred as "Centre"} so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee as prescribed by the Ethical guidelines for biomedical research on human subjects of ICMR (2008) and Schedule Y.

2. Role of HREC:-

HREC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects. The HREC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - maleficence and Justice are taken care of in planning, conducting and reporting of the proposed research.

For this purpose, it will look into the aspects of

i) Informed consent process

ii) Risk benefit ratio,

iii) Distribution of burden

iv) Benefit and provisions for appropriate compensations wherever required.

It will (a) review the proposals before start of the study (b) examine compliance with all regulatory requirements, applicable guidelines and laws (c) monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits etc.

The mandate of the HREC will be to review

(i) (A) All research projects of staff members involving human participants to be conducted on site at the Institutions of HMPCMCE,

(B) All research proposals of postgraduate dissertations / theses of existing courses and undergraduate research proposals,

(ii) Research projects undertaken by researchers of HMPCMCE either as principal or co-investigator at sites other than HMPCMCE

(iii) Research proposals guided by staff members of HMPCMCE but conducted onsite or outside the centre.

3. Composition of HREC of H.M.Patel Centre for Medical Care & Education:-

HREC should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of HREC of HMPCMCE.

The number of persons in the ethical committee will be less in number (7-9, maximum 12-15 members). A minimum of five persons is required to compose a quorum.

As per ICMR Guidelines, the Chairperson of the Committee is from outside the institution to maintain the independence of the Committee. The Member Secretary will conduct the business of the Committee. Other members will be a mix of medical / non-medical scientific and non-scientific persons including lay public to reflect the differed viewpoints.

A subcommittee is delegated to function independently by maintaining consistent ethical framework to ensure the competent review and evaluation of ethical aspects of research proposals related to post graduate dissertation and undergraduate research projects received.

The composition will be as follows:-

HREC, HMPCMCE should be constituted in the following pattern:

i) A Chairperson

ii) A Deputy Chairman if need be,

iii) A Member Secretary,

iv) 5-15 members from different Departments / Specialties / disciplines or areas etc. (vide Annexure I)

A. FULL COMMITTEE

1.) Chairperson

2.) Deputy Chairperson

3.) 1-2 basic medical scientists.

4.) 1-2 clinicians from various Institutes

5.) One legal expert or retired judge

6.) One social scientist / representative of non-governmental voluntary agency

7.) One philosopher / ethicist / theologian

8.) One lay person from the community

9.) Member-Secretary

B. SUBCOMMITTEE: Some of members of full committee & co-opted members from different disciplines constitute Subcommittee to review proposals as per (i) (B) under # 2: Role of HREC mentioned above.

Membership: The ethics committee at HMPCMCE has as its members, individuals from other institutions or communities if required. There is adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members are required to be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. The membership of HREC will include Epidemiologist,

Sociologist, Lawyer, Theologian, Statistician, Clinicians, Basic scientists, Clinical Pharmacologist(s) etc.

4. Authority under which HREC is constituted:-

The Chief Executive Officer (CEO) of Charutar Arogya Mandal who also heads the H.M. Patel Center for Medical Care & Education and its institutions constitutes the HREC.

Reconstitution of HREC & Terms of Appointment of members

(i) The Head of the institution will appoint the members in consultation with the HREC.

(ii) Members are appointed based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country. The members will provide a copy of their Curriculum Vitae to the committee.

(iii) The letter of appointment shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member.

(iii) Members will be required to sign a confidentiality undertaking upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared.

(iv) Upon appointment, members shall be provided with the following documentation:

- HREC Standard Operating Procedures (SOP)
- Up to date list of members' names and contact information
- Any previous reports on the HREC's activities and
- Any other relevant information

(v) The duration of appointment is initially for a period of 3 years

(vi) At the end of 3 years, as the case may be, the committee may be reconstituted, and one third of the members will be replaced by a committee

constituted by the Head of the institution, the Chairperson, HREC and the Member Secretary, HREC.

(vii) A member can be replaced in the event of death or discontinued i.e someone who has not attended consecutive 3 meetings or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

(vii) A member can tender resignation from the committee with proper reasons to do so.

(viii) All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.

(ix) Conflict of interest should be declared by members of the HREC

(x) New members are expected to attend training sessions as soon as practicable after their appointment.

(xi) The costs associated with attendance at training and education sessions will be met by center.

(xii) Members may seek a leave of absence from the HREC for extended periods. Steps shall be taken to fill the vacancy.

(xiii) Membership will lapse if a member fails to attend three consecutive meetings of the HREC without prior written intimation, unless exceptional circumstances exist. The Chairman will notify the member of such lapse of membership in writing.

(xiv) Membership will lapse if a member fails to attend in full at least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.

(xv) A member may resign from the HREC at any time upon giving one months' notice in writing to the Chairman. Steps shall be taken to fill the vacancy of the former member as soon as possible.

(xvi) Orientation of new members:

Orientation will involve introduction to other HREC members prior to the HREC meeting and informal meeting with Chairman who will explain his/her responsibilities as an HREC member, the HREC processes and procedure.

5. Submission Procedure for New Applications:-

1. All applications for ethical review must be submitted to the Member Secretary of the HREC, on or before the announced closing date. The closing date for receipt of new applications onto the next HREC agenda shall be readily available to prospective applicants.
2. The closing dates for applications should normally be no earlier than 15 days after the announcement for submission and no later than 14 days prior to each HREC meeting.
3. Applications must be submitted in the appropriate format (Annexure II) as determined by the HREC, and shall include all documentation as required by the HREC as per check list (Annexure III).
4. The procedures for application to the HREC and the application format shall be readily available to applicants.
5. Fee will not be charged for applications submitted by the investigators of the institution for review EXCEPT for Clinical trials wherein fees of Rs 30,000/-will be charged for the review of the new application including initial one amendment followed by Rs. 5000 for each subsequent amendments.
6. Research projects submitted by external investigators but to be conducted within the centre will be charged Rs. 500/- and Rs. 1000/- for non funded projects of students and faculty respectively, where as Rs. 5000/- for funded projects.

6. Conduct of Meetings:-

i.) The HREC meets on a regular basis, which are normally at two monthly intervals. Meeting dates and agenda closing dates are publicly available.
ii.) Members are required to attend HREC meetings in person.
iii.) The Chairman can cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the HREC will convene within 7 working days of the cancelled meeting to ensure all agenda items are considered.
iv.) Meetings are scheduled for an allocated time. If the issues have not been completed within the allocated time, then the HREC may either continue the meeting until all agenda items have been considered or schedule an additional

meeting. If an additional meeting is called for, then the meeting should be held within 7 working days.

v) Separate meetings for subcommittee for review of proposals related to undergraduate and post graduates

v.) The HREC meetings are conducted in such a way to ensure confidentiality and open discussion between members and the researcher. Members are informed of the meeting room details in the meeting agenda.

vi.) Members who are unable to attend a meeting can contribute prior to the meeting through written submissions to the member secretary. The minutes are recorded with submission of written comments.

vii.) A quorum must be present in order for the HREC to reach a final decision on any agenda item. A quorum includes when at least 5 members are physically present. For clinical trials as per schedule Y of Drugs and Cosmetics Act, 1940 amended in 2005, one member of each of the following categories:

- Basic Medical scientist (preferably pharmacologist)
- Clinician
- Legal expert
- Social scientist/ethics expert
- Lay person

viii.) Any member of the HREC having any conflict of interest - financial or otherwise, in a project or other related matter(s) considered by the HREC should declare such interest.

7. Element of review:-

a.) Scientific design and conduct of the study.

b.) Approval of CAM research Society for proposals which have sought funding from same society.

c.) Examination of predictable risks/harms.

d.) Examination of potential benefits.

e.) Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.

f.) Management of research related injuries, serious adverse events.

g.) Compensation provisions.

h.) Justification for placebo in control arm, if any.

i.) Availability of products after the study, if applicable.

j.) Patient information sheet and informed consent form in local language.

k.) Protection of privacy and confidentiality.

l.) Involvement of the community, wherever necessary.

m.) Plans for data analysis and reporting

n.) Adherence to all regulatory requirements and applicable guidelines

o.) Competence of investigators, research and supporting staff

p.) Facilities and infrastructure of study sites

q.) Criteria for withdrawal of patients, suspending or terminating the study

8. Conflicts of Interest:-

1. An HREC member shall, as soon as practicable during the HREC meeting, inform the Chairman if he/she has a conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the HREC.
2. The HREC determines if this results in a conflict of interest for the member and if so, the member will withdraw from the meeting until the HREC's consideration of the relevant matter has been completed. The members are not be permitted to adjudicate on the research.
3. All declarations of conflict of interest and the absence of the member concerned are minuted.

9. Preparation of Minutes:-

1. The HREC member secretary prepares and maintains minutes of all meetings of the HREC.
2. The format of the minutes will include at least the following items:

i.) confirmation of quorum

ii.) Attendance reading of minutes of previous meeting

iii.) Conflicts of interest;

iv.) Review of new applications;

v.) Amendments to approved protocols;

vi.) Monitoring reports;

vii.) Any other issue--- expedited reviews, subcommittee minutes etc

3. The minutes include the recording of decisions taken by the HREC as well as a summary of relevant discussion. This includes reference to views expressed by absent members.

4. In relation to the review of new applications or amendments, the minutes record a summary of the main ethical issues considered, including any requests for additional information, clarification or modification of the project.

5. In recording a decision made by the HREC, any significant minority view (i.e 2 or more members), if any are noted in the minutes.

6. To encourage free and open discussion and to emphasis the collegiate character of the HREC, particular views do not attribute to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.

7. Declarations of conflicts of interest by any member of the HREC and the absence of the member concerned during the HREC consideration of the relevant application are minuted regarding a member's declaration of a conflict of interest.

8. The minutes are produced following the relevant meeting and are checked by either the Chairman and/or the Deputy Chairman, for accuracy.

9. The minutes then are circulated to all members of the HREC before the next meeting. All members are given the opportunity to seek amendments to the minutes prior to their ratification. The minutes are formally ratified at the next HREC meeting.

10.The original copy of each meeting's minutes are retained in a confidential 'Minutes' file.

10. Communication of Decisions of the HREC:-

1. The HREC reports in writing to the principal investigator (PI), advising whether the application has received ethical approval (including any conditions of approval), after the minutes are signed by the chairman.

2. If the HREC determines that further information, clarification or modification is required for the consideration of a project, the correspondence

to the PI should clearly articulate the reasons for this determination, and clearly set out the information that is required.

3. If the requested information is not received from the applicant within 3 months, the project may be dismissed and the applicant will be required to resubmit the project at a later date.

5. The HREC notifies the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Ethical approval is notified in writing in a standard format, and contains the following information:

- Title of project;
- Name of the PI
- HREC project code number;
- Date of HREC meeting at which the project was first considered;
- Date of HREC approval and
- Conditions of HREC approval, if any.

6. If the HREC determines that a project is ethically unacceptable, the notification of the HREC's decision will include the grounds for rejecting the project

7. The status of the project are updated on the HREC's register of received and reviewed applications.

11. Exempt review and Expedited Review:-

A. Projects will be exempt from ethical review where they:

(a) Involve only negligible risk or

(b) Involve the use of existing collections of data or records that contain only non-identifiable data about human beings.

The HREC will decide whether a project is exempt from ethical review. The member secretary provides written communication to a Principal Investigator as to whether a project is exempt from ethical review by the HREC.

B. The member secretary undertakes expedited review of:

(a) Minor amendments and extensions of approval protocols, or

(b) Urgent amendments to approved protocols for safety reasons.

(c) Urgent proposal of national interest.

C. Expedited review of research projects are undertaken between scheduled meetings at the discretion of the Chairman. The member secretary seeks advice from other HREC members or suitably qualified experts, as appropriate, before reaching a decision. The decision and minutes of this review are noted down for ratification at the next HREC meeting.

D. Research with the potential for physical or psychological harm are generally not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.

E. Where the research involves a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol is considered in the full HREC and is not dealt with expedited review.

12. Submission of Amendments:-

1. Proposed changes to approved projects are required to be reported by the PI to the HREC for review.

2. Requests shall outline the nature of the proposed changes, reasons for the request, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents must have the changes highlighted and contain revised version numbers and dates.

3. Expedited review of requests for minor amendments, and urgent amendments to approved protocols for safety reasons are undertaken by the HREC member secretary between scheduled meetings at the discretion of the Chairman which will be ratified at the next HREC meeting.

4. All other requests for amendments are reviewed by the HREC at its next available meeting, provided the request has been received by the member secretary by the agenda closing date.

5. The HREC reports in writing to the PI, advising whether the proposed amendment and/or request for extension has been given ethical approval, within 7 working days of the meeting at which the request was considered

(this may be the full committee HREC meeting or the expedited meeting).

6. Notification of the approval of amendments and extensions are conveyed in writing in a standard format.

7. If the HREC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the investigator clearly articulates the reasons for this determination, and clearly set out the information that is required.

8. All received and approved requests for amendments and extensions are recorded, and the status of the project is updated on the HREC's register of received and reviewed applications.

13. Concerns and Complaints about the Conduct of a Project:-

Reporting

1. The HREC requires, as a condition of approval of each project, that the researchers immediately report to the HREC any concerns or complaints received.

2. The member secretary of HREC is the person nominated to receive concerns and complaints from participants in research or members of the public about the conduct of projects approved by the HREC.

3. The member secretary of HREC is responsible for obtaining, in writing, the grounds of the concern or complaint. The member secretary of the HREC will notify the Chairman of the HREC of the report as soon as possible.

4. The member secretary of the HREC acknowledges to the complainant outlining the mechanism for investigating the concern or complaint.

Investigation

5. The Chairman of the HREC examines the concern or complaint and determines whether the concern or complaint warrants a further investigation. Where there is to be no further investigation the Chairman of the HREC will inform the complainant.

6. Where the Chairman determines that the concern or complaint warrants a further investigation the Chairman will notify the head of the institution who will then convene a Review Committee to investigate and determine the consequences.

7. The member secretary of the HREC sends a letter of notification to the PI of any concern or complaint about a project received by the HREC outlining the mechanism for investigating the concern or complaint. Where the complaint concerns the conduct of the any other person, the review Committee also notifies that person.

9. The Review Committee immediately goes for an investigation into the concern or complaint. The investigation takes no longer than 2 weeks from the time of notification for the concern or complaint, unless exceptional circumstances exist.

10. The Committee has to give the complainant and the PI an opportunity to make submissions. Where the complaint concerns the conduct of any other person the Incident Review Committee also provides that person with an opportunity to make submissions.

11. The Review Committee may seek any other information it requires and may access any documents relating to the project, interview other people, and seek internal and external expert advice, as it sees fit.

Consequences

12. If the Review Committee is satisfied that the concern or complaint is justified it determines the consequences by considering the following matters:

- The severity of the matter;
- The sensitivity of any information concerned including the amount and type of information and the level of identifiability; and
- Whether any breach of the approved protocol, which may be established, was inadvertent, negligent or intentional.

13 The possible consequences include the following:

- Notation on the file of the occurrence of the matter;
- Increased monitoring of the project;
- Counseling on security practices;
- Amendments to the approved protocol;
- Suspension of approval of the project
- Reporting the individuals responsible for any breach to the head of the institute, with a complaint of misconduct in the conduct of the project;

14 The Chairman of the Review Committee will notify the institution, the PI and any other person for whom there is an individual consequence of the

outcome of the investigation and the consequences in writing.

15 The Chairman of the Review Committee will notify the HREC and any other institutional HRECs concerned with the project of the outcome of the investigation and the consequences.

16. The HREC has to review the ethical approval of any project in the light of the outcome of the investigation of any breach or complaint and will notify the responsible institution and the PI if ethical approval for the project is withdrawn.

17. The Chair of the Incident Review Committee will send a written report of the outcome of the investigation and the consequences to the complainant.

14. Reporting and Handling of Serious Adverse Events:-

A Serious adverse event refers to undesirable clinical responses to an intervention including a treatment or diagnostic procedure.

Reporting of Serious Adverse Events

1. Principal Investigators should immediately report all serious adverse events in clinical trials to the HREC the research in accordance with the reporting conditions required by Schedule Y

2. Principal Investigators should report all serious adverse events and the response to those events in the periodic and final reports for the project.

3. HREC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines.

4. In case of any new information or any SAE, which could affect any study, must be informed to HREC, and sponsors. The PI should report SAEs occurred for HREC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the HREC has to receive the SAE reporting form within 24 hours of the occurrence.

5. HREC notes the SAE and all supporting documents and communicates with the PI in accordance with ICMR guideline 2006.

15. Record Keeping:-

1. The member secretary prepares and maintains written records of the HREC's activities, including agenda and minutes of all meetings of the HREC.
2. The member secretary prepares and maintains a confidential electronic and/or paper record for each application received and reviewed and shall record the following information:

- code number;
- names of PI;
- title of the project;
- ethical approval or recommendations for modifications or rejections with date, ;
- approval or otherwise of any changes to the project proposed by the researcher;
- the terms and conditions if any, with approval of the project;
- whether approval was by scheduled full committee review or expedited review or review by subcommittee;
- Action taken by the HREC while monitoring the conduct of the research.

The physical records shall contain a hard copy of the application, any relevant correspondence between the applicant, other stake holders and the HREC, other material used to inform potential research participants and all approved documents.

3. All documents of the HREC, including applications, membership, minutes and correspondence kept confidential and in accordance with schedule Y and ICMR guidelines
4. To ensure confidentiality, all documents provided to HREC members, which are no longer required, are to be disposed of in a secure manner, such as shredding or placed in confidential bins.
5. All relevant records pertaining to research projects shall be held for sufficient time (5 years) to allow for future reference. Retention periods shall comply with the schedule Y and ICMR guidelines.

16. Monitoring of Approved Projects:-

1. The HREC monitor approved projects to ensure compliance with the approved protocol. In doing so it calls for and discusses information on any relevant aspects of the project with the investigators at any time. In particular, the HREC wants applicants to provide interim reports on stipulated dates and a final report at completion of the study. Continuing approval of the research is subject to the PI submitting an interim report by the stipulated date.

2. The HREC requires the following information in the report:

- Progress to date, publications or outcome in the case of completed research
- Maintenance and security of records and data
- Compliance with the approved protocol
- Compliance with any conditions of approval
- Changes to the protocol or conduct of the research
- Changes to the personnel of the PI /other investigators and
- Serious Adverse events or complaints relating to the project.

3. The HREC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as: random inspections of research sites, data and signed consent forms; interview, with their prior consent, of research participants.

4. The HREC requires, as a condition of approval of each project, that investigators immediately report anything which might warrant review of ethical approval of the protocol, including:

- proposed changes in the protocol
- any unforeseen events that might affect continued ethical acceptability of the project; and
- new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.

5. The HREC requires, as a condition of approval of each project, that investigators inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion, and that the investigators

comply with the approved.

6. Where the HREC is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol, the HREC may withdraw approval. In such circumstances, the HREC will inform the PI and the head of the institute, the research project be discontinued, suspended, or that other necessary steps be taken.

7. In determining the frequency and type of monitoring required for approved projects, the HREC will give consideration to the degree of risk to participants in the research project.

17. Review of Standard Operating Procedures:-

1. The Standard Operating Procedures are reviewed based on changed requirements.

2. The Standard Operating Procedures may be amended by following the procedure below:

For those proposals made by a HREC member:

- The proposal must be in writing and circulated to all HREC members for their consideration.
- The views of the members should be discussed at the next scheduled meeting of the HREC, and a vote take at that meeting. Any member unable to attend such a meeting may register his or her views in writing.
- The amendment will be incorporated after the consensus approval by the full committee. Prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded by the Head of the Departments / Institution to the ethics committee.

3. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.

4. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period: 2 weeks from the date of receiving the copy as specified in the communication or before the next meeting.

18. HREC Annual Report

The HREC provides an annual report on its progress for the financial year to the head of the institution, including:

- membership/membership changes;
- number of meetings;
- number of projects reviewed, approved, pending review, pending approval (non compliance by researcher to modifications suggested) and rejected;
- General issues raised.

19. References:-

1. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000). Retrieved from - www.who.int/tdr/publications/publications / accessed May 2012

2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (1996). Retrieved from - http://www.ich.org/LOB/media/MEDIA482.pdf accessed on May 2012.

3. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006),

4. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) retrieved from - http://www.cdsco.nic.in/html/Schedule-Y 20 (Amended 20Version- 2005) accessed May 2012

Annexure I

HUMAN RESEARCH ETHICS COMMITTEE

H M PATEL CENTRE FOR MEDICAL CARE AND EDUCATION

KARAMSAD

Member list (with effect from 17/07/2012)

A) Full Committee:

Sr.No	Name	Position	Designation
1	Dr. Ravindra Sabnis	Clinician Muljibhai Patel Urological Hospital ,Nadiad	Chairman
2	Dr.Himanshu Pandya	Clinician	Deputy chairman
3	Mr. Ajay Phatak	Biostatistician and Public Health Expert	Member secretary
4	Dr.Barna Ganguly	Pharmacologist/Basic scientist	Member
5	Dr. Nitin Raithatha	Clinician	Member
6	Dr. C.Haritha	Clinician	Member
7	Mr. Nilesh M. Panchal	Legal expert	Member
8	Dr. Sumati Khanna	Anatomist/ Basic Scientist	Member
9	Mrs. Sangeeta Nair	Social Scientist	Member
10	Mrs Jyoti Shah	Lay Person	Member
11	Dr Somashekhar Nimbalkar	Clinician	Member
12	Dr Swapnil Agarwal	Medicolegal expert	Member

B) Sub Committee:

Sr.No	Name	Position	Designation
1	Dr.Himanshu Pandya	Clinician	Deputy chairman
2	Mr. Ajay Phatak	Biostatistician and Public Health Expert	Member secretary
3	Dr.Barna Ganguly	Pharmacologist/Basic scientist	Member
4	Dr.Uday Shankarsingh	Clinician	Member
5	Dr. N. Haridas	Basic scientist	Member
6	Dr.Yojana Sharma	Clinician	Member
7	Dr. Somashekhar Nimbalkar	Clinician	Member

Annexure II

Format of Submission:

A) For Research Proposals

Page: 1

Name of the Project:

Name of the Investigator(s):

Signature(s):

Guided by (if any):

Signature of the Guide:

Name of Department :

Page: 2 onwards

- Clear research objective and rationale for undertaking the project
- Subject recruitment procedure
- Inclusion and exclusion criteria
- Methodology of the study (dosages of drugs, duration of treatment or details of invasive procedures, if any) and total duration of the study.
- Plan of statistical analysis
- Informed consent in English and Vernacular language
- Plan to provide medical therapy for any risk, injury or toxicity due to overdose
- A statement on probable ethical issues and steps taken to tackle the same
- Plan for publication of results – positive or negative maintaining the confidentiality and privacy of the study participants
- Relevant documents related to protocol (proforma, clinical research form, follow up cards)
- Details of funding agency / sponsors and fund allocation for proposed work
- Contribution of the research project

B) For Clinical Trials

Following are the minimum requirements:

- Study Protocol
- All relevant pre-clinical animal data and clinical trial data from other centers within the country /countries, if available.
- Curriculum vitae of all the investigators with relevant publications in last five years.
- Any regulatory clearances required.
- Source of funding and financial requirements for the project.
- Other financial issues including those related to insurance
- An agreement to report only Serious Adverse Events (SAE) to HREC.
- Statement of conflicts of interest, if any.
- Agreement to comply with the relevant national and applicable international guidelines.
- A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

Annexure III

Checklist of documents to be submitted:

A) For Research Proposals

Project Title	

Documents	**Status**	
	Yes	**No**
Project Proposal		
Approval Letter of Head of Institute if any (for proposals from outside the Institute)		
Informed consent form		
Case Report Form		
Documents related to grants		
Study tools if any		
References		

B) For Clinical Trials

Protocol Number	
Protocol Title	

Documents	**Status**	
	Yes	**No**
Trial Protocol		
Investigator's Brochure		
Case report form (electronic/Paper)		
Insurance Policy		
DCGI submission letter / approval letter		
Patient Information sheet and Informed consent form		
Draft Clinical Trial Agreement (Investigator's agreement with sponsor)		
Current CV and MRC of Investigator		
Investigator's Undertaking		
Others (Protocol Specific): Quality of Life Questionnaire , Patient diary, Advertisement for accrual		

Annexure IV

Checklist of review:

A) For Research Proposals

(REF: ICMR Ethical Guidelines, St Joseph's Healthcare, Hamilton, Fogarty International, NIH, USA)

1. Purpose and Background

a) Is the research question clearly stated?

b) Is suitable justification for the study with human?

Comments:

2. Social and Scientific Value

Will the research generate knowledge that could reasonably lead to improvements in health or well-being?

Comments:

3. Participant Population (s)

a) Are criteria for inclusion/ exclusion?

b) Does the study include vulnerable participants? (Circle) Minors – Pregnant women Prisoners – Fetuses - Mentally Disabled individuals - Economically or educationally disadvantaged persons?

c) Is the justification for using vulnerable participants clearly stated?

d) Are additional safeguards in place to protect vulnerable participants?

Comments:

4. Participant Recruitment

a) Do you have any concerns about inappropriate inducement?

b) Does the recruitment process violate participant's privacy in any way?

Comments**:**

5. Methodology / Data Description

a) Is the methodology/design described in sufficient detail?

b) Is the methodology / design adequate to answer the research question?

c) Is the data analysis adequately described?

d) Is the data analysis appropriate?

e) For Phase III trials, is a genuine null hypothesis present (clinical equipoise)?

Comments**:**

6. Placebo Controls in Phase III Trials:

Is a placebo control ethically justified in this trial (for criteria, refer to Page 4)

Comments**:**

7. Protocol risk / Benefit Assessment

a) Are activities involving more than minimum risk adequately described?

b) Are risks to participants minimized?

i) by sound research design?

ii) by using procedures already being performed for diagnostic or treatment purposes?

c) Are risks to participants reasonable in relation to

i) anticipated benefits to participants?

ii) the importance of the knowledge that may reasonably be expected to result?

d) Are there adequate procedures for monitoring the safety of the research participants?

e) Are there appropriate stopping rules?

f) Is an annual report to the REB adequate to monitor the safety of the research participants?

g) Are adequate provisions made to protect the privacy of participants and to maintain the confidentiality of the data?

Comments**:**

8. Information Sheet and Consent Form – General Requirements:

a) Are information/consent documents appropriately headed and printed in large enough type?

b) Are information / consent documents free of unexplained technical terms and jargon?

c) Are information/consent documents free of language that waives the participant's legal right, or that releases the investigator, institution, or sponsor from liability?

d) Is the information sheet written consistently in the second person (You / your)?

e) Is the name of the study Sponsor on the front page?

Comments**:**

Kindly submit the comments on or before (date) to the Member secretary

Reviewer's comments on the submitted projects to HREC:

Name of the reviewer: Signature:

Proposal Number	Purpose & scientific value	Participant recruitment	Method ology	Protocol risk / benefit assessment	Information sheet and consent form	Other ethical issues/ comments
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						

B) For Clinical Trials

Protocol Number	
Protocol Title	

Documents	**Status**	
	Yes	**No**
Trial Protocol		
Investigator's Brochure		
Case report form (electronic/Paper)		
Insurance Policy		
DCGI submission letter / approval letter		
Patient Information sheet and Informed consent form		
Draft Clinical Trial Agreement (Investigator's agreement with sponsor)		
Current CV and MRC of Investigator		
Investigator's Undertaking		
Others (Protocol Specific): Quality of Life Questionnaire , Patient diary, Advertisement for accrual		