INSTITUTIONAL ETHICS COMMITTEE

Standard Operating Procedures (SOPs)

M.K.C.G. Medical College, Brahmapur, Ganjam (Orissa)

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Institutional Ethics Committee of Maharaja Krishna Chandra Gajapati Medical College, Brahmapur, Ganjam, Odisha

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Introduction

The first International statement on the ethics in medical research using human subjects, the Nuremberg Code was formulated in 1947 and it laid emphasis on consent and voluntariness. In 1964, the eighteenth World Medical Assembly at Helsinki, Finland adopted a code of ethics for the guidance of doctors involved in clinical research. This is popularly known as the "Declaration of Helsinki."

In 1980, the Indian Council of Medical Research released a 'Policy Statement on Ethical Considerations involved in Research in Human Subjects' for the benefit of all those involved in clinical research in India.

In 1996, the International Conference on Harmonization (ICH) published a tripartite guideline for Good Clinical Practice (GCP) to harmonise technical requirements for registration of pharmaceutical products. Today, the ICH GCP guideline is followed globally for clinical research. This guideline elaborates the composition and functioning of an Institutional Ethics Committee to review clinical research proposals.

The Institutional Ethics Committee presently functions according to the requirements laid down in Schedule Y of Drugs & Cosmetic Act and is guided by the ICH GCP guidelines for Good Clinical Practice, ethical principles set forth in the Declaration of Helsinki and the Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research.

The IEC of MKCG Medical College, Brahmapur is formed in accordance with the principles laid down by ICMR, ICH-GCP guidelines, Schedule-Y of D&C Act & WHO guidelines for GCP.

Guidelines were laid down by IEC, MKCG Medical College, Brahmapur for submitting research projects for ethics committee approval.

1. Name

This committee will be known as the Institutional Ethics Committee of Maharaja Krishna Chandra Gajapati Medical College (MKCGMC), Brahmapur, Ganjam, Odisha.This name will remain unchanged until the members choose to change it by a vote of three-fourths of the current strength.

2. Objective

The objective of this SOP is to contribute to the effective functioning of the IEC at MKCG Medical College Brahmapur, Orissa, 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.

3. Terms of reference

MKCG Medical College Brahmapur, Orissa IEC will review research proposals involving human subjects submitted by undergraduate, postgraduate, faculty of MKCG Medical College Brahmapur, Orissa.

IEC, MKCG Medical College Brahmapur, Orissa 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 or 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 IEC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non- mal-efficiency and Justice are taken care of in research protocols. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the studies as well as monitor the research throughout the study until and after completion by examining the annual reports and final reports. The committee will also examine whether all regulatory requirements and laws are complied with or not.

4. Composition of IEC

The IECs is multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an IEC. The number of persons in an ethics committee should be kept fairly small (8-12 members). It is generally accepted that a minimum of five persons is required to form the quorum without which a decision regarding the research should not be taken. The Chairperson will be selected and appointed by the Head of the Institute and will be independent of the institution. The Chairperson will be responsible for conducting all committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals and will preside over all elections and administrative matters pertinent to the committee's functions.The Member Secretary should be from the same Institution and should conduct the business of the Committee. Other members should be a mix of medical/ non-medical, scientific and non-scientific persons including lay persons to represent the differed points of view.

The composition may be as follows:-

1. Chairperson.
2. One – two persons from basic medical science area.
3. One – two clinicians from various Institutes.
4. One legal expert or retired judge.
5. One social scientist / representative of non-governmental voluntary agency.
6. One philosopher / ethicist / theologian.
7. One lay person from the community.
8. Member Secretary.

5. Authority under which IEC is constituted

The Dean & Principal MKCG Medical College Brahmapur, Orissa constitutes the IEC.

6. Membership requirements

a. The members are appointed by the Dean & Principal MKCG Medical College Brahmapur, Orissa.
b. The members are drawn from different specialties to give a multi-sectorial, multidimensional structure.
c. The duration of appointment is initially for a period of 3 years.
d. At the end of 3 years, the term of appointment of members could be extended for another term or the committee may be reconstituted.

e. A member can be replaced in the event of death or long-term assignments outside the country or for any misconduct deemed unfit for a member.
f. A member can tender resignation from the committee with proper reasons to do so, which should be acceptable to the Dean & Principal MKCG Medical College Brahmapur, Orissa.
g. All members should maintain absolute confidentiality of all discussions during the meeting.
h. The committee members will elect a Member Secretary from among themselves. In consultation with the Chairperson, the Member Secretary will be responsible for the following functions:
   i. Receiving all research proposals.
   ii. Numbering the proposals.
   iii. Forwarding all proposals to committee members for review.
   iv. Establishing time limits for receipt of reviewers' comments.
   v. Preparation of agenda for all committee meetings.
   vi. Inviting experts from relevant therapeutic areas to the scheduled meetings.
   vii. Notification of review outcome to investigators of research proposals.
   viii. Preparation and circulation of minutes (within 14 days of the meeting).
   ix. Retention and safekeeping of all records and documentation.
   x. Performance of other duties assigned by the Chairperson.

7. Quorum requirements:

The minimum of 50% member are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals.

As per revised Schedule Y of Drugs & Cosmetics Act, 1940, amended in 2005, the ethics committee approving drug trials should have in the quorum at least one representative from the following groups:

1. One basic medical scientist (preferably one pharmacologist).
2. One clinician.
3. One legal expert or retired judge.
4. One social scientist / representative of non-governmental organization / philosopher / ethicist / theologian or a similar person.
5. One lay person from the community.

8. Conflicts of interest

In conducting human subject research, a conflict of interest is defined as a situation in which an individual (or someone in his/her immediate family) has a significant financial, professional, interest in the approval or outcome of a study and the interest could affect decisions related to either the design, conduct or reporting of the research or adversely affect the rights and welfare of research subjects. such conflicts must be identified and managed appropriately.

Any conflict of interest of an IEC member in any research project that is submitted for consideration to the IEC must be declared by the concerned member. These interests may

include any personal involvement or participation in the research, any financial interest in the outcome of the research or any involvement in competing research. In event of such a conflict of interest the concerned member will refrain from voting during the IEC meeting. E.g. an IEC member himself/herself is an investigator for a trial under review with IEC.

9. Offices

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be nominated by The Dean & Principal MKCG Medical College Brahmapur, Orissa from the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers.

The location and business address of the committee is as follows:

Member Secretary,
Institutional Ethics Committee (IEC),
Department of Pharmacology,
M.K.C.G. Medical College & Hospital,
Brahmapur – 760 004.

10. Independent consultants

IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IEC.

11. Protecting Vulnerable Subjects :

Investigators, though encouraged to design studies that broaden access to beneficial research trials for vulnerable people, there are guidelines and regulations to protect those people. The IEC will ensure that the trials under its review are designed and executed in a way that these guidelines are adhered to when protecting the rights of such vulnerable population as children, minors, pregnant and lactating women, terminally ill and so on.

12. Applications Procedures:

a. All proposals are to be submitted in the prescribed application form, the details of which are given under Documentation.
b. All relevant documents to be enclosed with application form.
c. 3/12 copies of the proposal along with the application in prescribed format to be submitted duly forwarded by the Head of the Department.
d. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.
e. The decision will be communicated in writing. If revision is to be made, the revised document in 3/12 copies to be submitted before the next meeting.

13. Documentation:

For a thorough and complete review, all research proposals to be submitted with the following documents:

1. IEC application form.
2. Summary of protocol.
3. Protocol.
4. Amendments to protocol.
5. Informed consent document in English.
6. Informed consent documents in Regional languages (Total No.:).
7. Back translations of Informed consent documents.
8. Amendments to the informed consent document.
9. Case Record Form / Questionnaire.
10. Principal investigators Current Curriculum Vitae.
11. Subject recruitment procedures: advertisement. letters to doctors. notices.
12. Investigator Brochure.
13. Ethics Committee clearance of other centers (Total No.).
14. Insurance policy.
15. Drugs Controller General (India) [DCG(I)] clearance.
16. Investigator's agreement with sponsor.
17. Investigator's undertaking to DCG(I).
18. Health Ministry Screening Committee (HMSC)approval.
19. Bhabha Atomic Research Centre (BARC) approval.
20. Genetic Engineering Advisory Committee (GEAC)approval.
21. Director General of Foreign Trade (DGFT) approval.
22. FDA marketing/manufacturing license for herbal drugs.
23. Approval letter from relevant local hospital (medical, administrative) management that the trial site has adequate facilities, including laboratories, equipments and sufficient medical, paramedical, and clerical staff to support the trial and to deal with all reasonable foreseeable emergencies in compliance with existing regulations. (As per World Health Organization WHO Technical Report Series, No. 850, 1995, Annex 3 Guidelines for good clinical practice (GCP) for trials on pharmaceutical products)
24. Other Documents relevant to the study.

14. Review procedures:

a. The committee will hold a regular meeting once every three (3) months i.e. January, April, July, October. When there are no research proposals to review, the meeting may be held less frequently.However, if need be, meetings can be held at scheduled intervals when large number of proposals are to be reviewed and in other exigencies.
b. The proposals will be sent to members at least 3 weeks in advance.
c. Decisions will be taken by consensus after discussions.
d. Researchers will be invited to offer clarifications if need be.
e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals.
f. The decisions will be minuted and Chairperson's approval taken in writing.

15. Element of review

a. Scientific design and conduct of the study.
b. Approval of appropriate scientific review committees.
c. Examination of predictable risks/harms.
d. Examination of potential benefits.
e. Procedure for selection of subjects: Exclusion/ Inclusion criteria.
f. Management of research related injuries, side effects, ADRs.
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.

16. Expedited / Interim review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Such expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review

17. Decision-making

a. Members will discuss the various issues before arriving at a consensus decision.
b. Decisions will be made only in meetings where quorum is complete.
c. Only members can make the decision. The expert consultants will only offer their opinions.
d. Decision may be to approve, reject or modify the proposals. Specific suggestions should be given for modifications.
e. Modified proposals may be reviewed by an interim review through identified members.
f. Negative decisions should always be substantiated by appropriate reasons.

18. Communicating the decision

a. Decision will be communicated by the Member Secretary in writing.
b. Suggestions of IEC, if any, should be sent for modifications.
c. Reasons for rejection should be informed to the researchers. There is no need to communicate the name of the specific expert or member who made the review.

19. Follow up procedures

a. Regular reports should be submitted for regular review.
b. Final report to be submitted at the end of study.
c. Any serious side effects, adverse drug reactions and the interventions undertaken to be intimated.
d. Protocol deviation, if any, to be informed with adequate justifications.
e. Any new information related to the study should be communicated.

f. Premature termination of study should be notified with reasons and summary of the studies done so far.

20. Archiving/Record keeping

a. Curriculum Vitae (CV) of all members of IEC.
b. Copy of all study protocols with enclosed documents, annual reports, side-effects/ADRS etc.
c. Minutes of all meetings with due signature of Chairperson.
d. Copy of all existing national and international guidelines on research ethics.
e. Copy of all correspondence with members, researchers and other regulatory bodies.
f. Final report of the approved projects.

21. Site inspection by IEC members :

a. The IEC members will perform periodically on-site inspection of relevant projects it has received for review or approved.
b. Such a visit will include but not limited to the review of study documents, study conduct and the measures taken by study team to ensure that subjects rights and well-being are protected.
c. Based in the findings of such a visit, IEC may recommend changes and/or actions, if any, to be taken by the investigator and his/her team to comply with regulatory and ethical guideline.

22. Addressing subjects requests :

The IEC will provide timely and appropriate information in response to any requests arising from the subject. A provision must be made to provide contact details of an IEC member to every participating subject so that subject can contact the IEC to know about his/her rights as a trial subject or for any other matter relevant to the IEC.

23. Training of IEC members

The IEC members shall be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body(ies), so that they become aware of their role and responsibilities. Members shall be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and to be aware of the latest developments in this area. For review of drug trials members shall have their trainings in good clinical practice.

24. Amendments to the Standard Operating Procedures

a. Amendments to the Standard Operating Procedures of the Institutional Ethics Committee shall be proposed in writing.
b. The proposal for amendment shall be submitted to the Member Secretary.
c. The proposal for amendment shall be presented to the regular members at a scheduled committee meeting.
d. Only regular members shall vote to accept or reject the proposed amendment.

e. A proposed amendment shall be approved by a vote of three-fourths of the members present in a quorum at a scheduled committee meeting, rounded to the next whole number.

25. List of committee members with their affiliations and qualifications

The present composition of the Institutional Ethics Committee (IEC) is listed in the table below:

Name of Members	Position on Ethics Committee	Designation & Affiliation	Qualification	Gender
Prof. Rabi Kumar Satapathy	Chairman	Retd. Dean & Principal, MKCG Medical College, Brahmapur	M.D.in Paediatrics	Male
Prof. C.S.Moharana	Member Secretary	Prof. & HOD of Pharmacology	M.D. in Pharmacology	Male
Prof. Srikrushna Mahapatra	Member	Prof. & HOD of Biochemistry	M.D. in Biochemistry	Male
Prof. R.M.Tripathy	Member	Prof. & HOD of Comm. Medicine	M.D. in S.P.M.	Male
Prof. Diptimayee Tripathy	Member	Prof. & HOD of Medicine	M.D. in Medicine	Female
Prof. Narendra Behera	Member	Assoc. Prof. Of Paediatrics	M.D. in Paediatrics	Male
Sri asweeni Kumar Mohapatra	Member (Lawyer)	Advocate	L.L.B.	Male
Smt. Ranjita Dash	Member (Social Scientist)	Social Worker	M.S.W.	Female
Mr. D.Rama Rao	Member (Lay person from community)	Layman	2nd Year B.A.	Male

D.C.S. Moharana	Rabi Kumar Satapathy
Member Secretary, IEC, MKCG Medical College, Brahmapur	Chairman, IEC, MKCG Medical College, Brahmapur
Date 5.9.13	Date 5.9.13