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MNR Medical College & Hospital
Institutional Ethics Committee

STANDARD OPERATING PROCEDURE

Version # 2.0 effective date 1 January 2019

MASTER

ACTIVE

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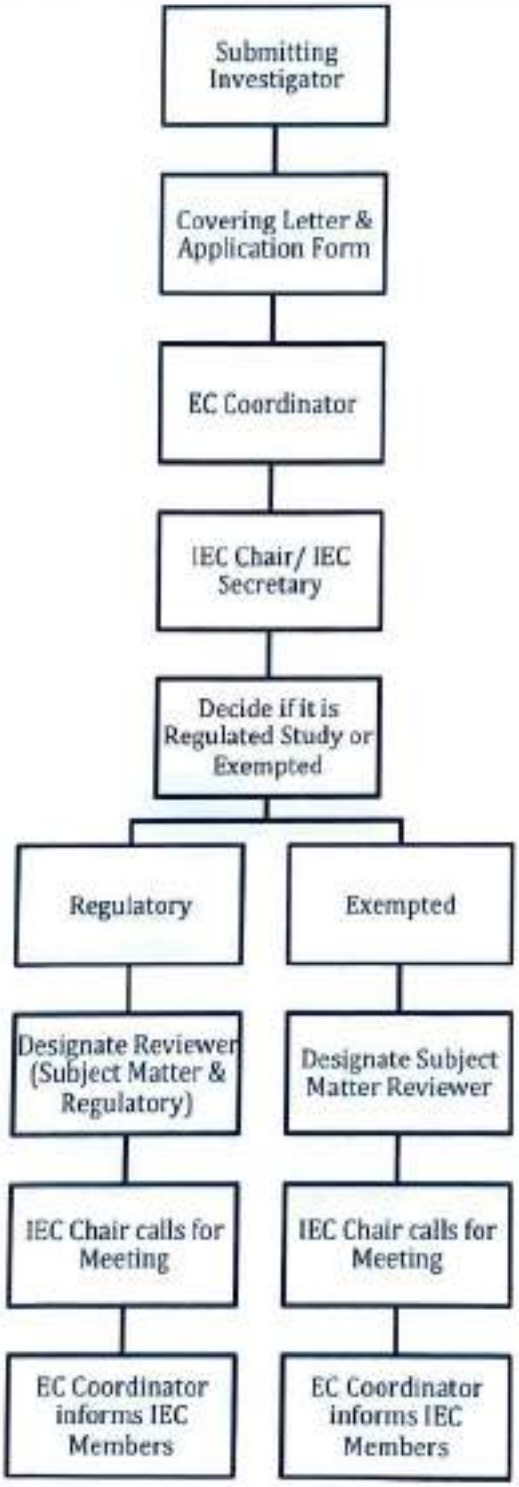

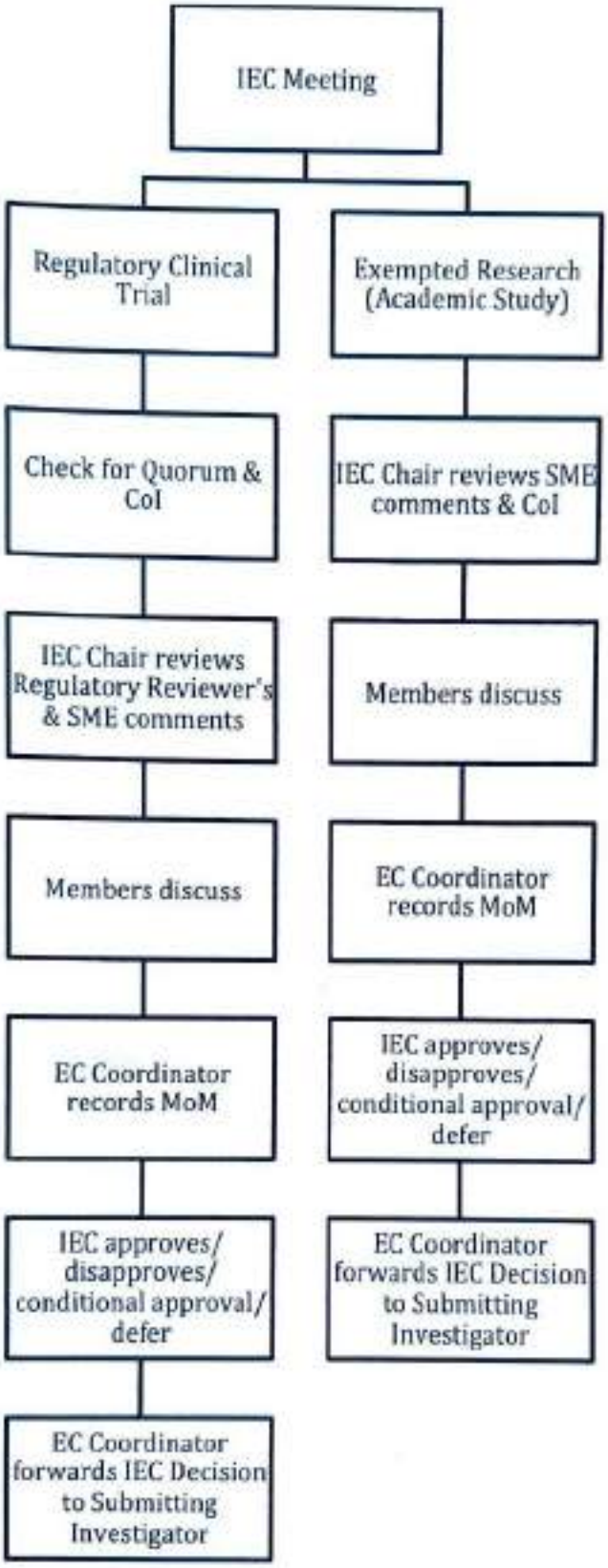
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1. PURPOSE

1.1. This procedure establishes the process to form MNR-MC IEC.
1.2. This procedure begins when the MNR Educational Trust has decided to create a new IEC at its Medical College.
1.3. This procedure ends when the new IEC has been formed.
1.4. This IEC covers research study that will be conducted at MNR Medical College Hospital and allied satellite health centers (MNR-MC)

2. POLICY

2.1. MNR Educational Trust maintains a roster of IECs.
2.2. HSR-001.

3. RESPONSIBILITY

3.1. A designee of MNR Educational Trust carries out these procedures.

4. PROCEDURE

4.1. Select at least 11 individuals to serve as regular IEC members, including an IEC Chair, IEC Vice-Chair, and an IEC Secretary.
4.2. Select at least three individuals to serve as alternate IEC members, including an IEC Chair, IEC Vice-Chair, and an IEC Secretary.
4.3. Follow "SOP: Adding a Member to MNR-MC IEC (HSR-103)" for each IEC member.
4.4. Use "WORKSHEET: IEC Composition (HSR-312)" to evaluate whether the IEC is appropriately constituted.
4.5. Revise the membership as needed.
4.6. Complete a new IEC roster.
4.7. Register and update membership with CDSCO as per regulatory requirement.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945
5.2. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
5.3. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)
5.4. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines
5.5. HSR-001.

1. PURPOSE

1.1. This procedure establishes the process to dissolve MNR-MC IEC.
1.2. This procedure begins when the organization, MNR Educational Trust has decided to disband MNR-MC IEC.
1.3. This procedure ends when the MNR-MC IEC has been removed.

2. POLICY

2.1. MNR Educational Trust maintains a roster of IEC.
2.2. HSR-001.

3. RESPONSIBILITY

3.1. A designee of MNR Educational Trust carries out these procedures.

4. PROCEDURE

4.1. Ensure that no active protocols are under review by the IEC before dissolution.
4.2. Notify each IEC member. For each IEC member who will no longer serve as an IEC member prepare and send a thank you letter signed by MNR Educational Trust.
4.3. Update the IEC roster to indicate the IEC is dissolved.
4.4. Inform CDSCO on the decision to dissolve MNR-MC IEC within 30 calendar days.

5. REFERENCES

5.1. HSR-001.

1. PURPOSE

1.1. This procedure establishes the process to add a member to MNR-MC IEC.
1.2. This procedure begins when the organization, MNR Educational Trust selects a new IEC member.
1.3. This procedure ends when the member has been added, and the IEC's registration with CDSCO has been updated.

2. POLICY

2.1. The IEC Chair should normally be an IEC member who is a respected individual with knowledge of research ethics, regulations, guidance, and ethics policies, and procedures. The Chairperson of the Committee should preferably be from outside the Organisation and not the head of the same institution to maintain the independence of the committee.
2.2. IEC Vice-Chair:
  2.2.1. Should be outside of the Organisation and not the head of the same institution.
  2.2.2. Discharge the IEC Chair's responsibilities when the IEC Chair is unable to do so.
2.3. The IEC Secretary who generally belongs to the same institution conducts the business of the committee, when delegated by the IEC Chair.
2.4. Other members should be a mix of medical, non-medical, scientific, and non-scientific persons, including lay public, to reflect the different viewpoints.
2.5. The minimum composition may be as follows:
  2.5.1. One Chairperson.
  2.5.2. One Secretary.
  2.5.3. One to two basic medical scientists (preferably one medical pharmacologist).
  2.5.4. One to two clinicians from various institutes.
  2.5.5. One legal expert.
  2.5.6. One social scientist/ representative of the non-governmental voluntary agency.
  2.5.7. One philosopher/ ethicist/ theologian.
  2.5.8. One layperson from the community.
2.6. HSR-001.

3. RESPONSIBILITY

3.1. The organization, MNR Educational Trust selects all new IEC members. The Organisation Official may delegate selection of IEC Members to the IEC Chair except for the position of IEC Chair.
3.2. The following are the responsibilities of the organization and the IEC Chair.

4. PROCEDURE

4.1. The responsibilities of the Organization are:
  4.1.1. Obtain a copy of the individuals' résumé or curriculum vitae.

4.1.2. The members representing medical scientists and clinicians have a post-graduate qualification and adequate experience in their respective fields.

4.1.3. Upon successful completion or verification of training, the IEC member is appointed, and IEC roster updated.

4.1.4. Prepare an appointment letter and signed for the appointment of all IEC members.

4.1.5. Determine whether the individual will be a regular or an alternate IEC member

4.1.6. Have the individual sign the IEC member agreement.

4.1.7. The tenure of membership of one term is of 3 years, with a scope to extend to another term, with approval from the Organisation Official.

4.1.8. No more than two terms is allowed for any IEC member.

4.1.9. Provide a copy of the résumé or curriculum vitae to IEC Chair

4.1.10. The Organisation appoint, from amongst the IEC members, a Chairperson (who is from outside the institution) and a Secretary from within the institution.

4.1.10.1. The IEC Chair should normally be an IEC member who is a respected individual with knowledge of research ethics, regulations, guidance, and ethics policies, and procedures. The Chairperson of the Committee should preferably be from outside the Organisation and not the head of the same institution to maintain the independence of the committee.

4.1.10.2. The IEC Vice-Chair is outside of the Organisation.

4.1.10.2.1. Discharge the IEC Chair's responsibilities when the IEC Chair is unable to do so

4.1.10.2.2. Discharge the duties assigned by the IEC Chair

4.1.10.2.3. Assist in the regular operation of the IEC

4.1.10.3. The Secretary, a member of the IEC appointed by the IEC Chair or Organisation and affiliated to MNR Medical College/ Hospital. The member has knowledge and experience in clinical research and ethics.

4.1.11. If the individual requires training, have the individual undergo training.

4.1.11.1. Train the new member on applicable regulations and guidelines, and MNR-MC IEC Policy, SOP, Checklist, Worksheet, and Template.

4.1.12. Use "WORKSHEET: IEC Composition (HSR-312)" to evaluate whether the IEC is appropriately constituted.

4.1.13. Revise the membership as needed.

5. REFERENCES

5.1. GSR 72(E) dated 8 Feb 2013, The Drugs & Cosmetics Rules, 2013

5.2. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945

5.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
5.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)
5.5. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines
5.6. HSR-001.
5.7. HSR-008.
5.8. HSR-312.
5.9. HSR-313.

1. PURPOSE

1.1. This procedure establishes the process to remove a member of MNR-MC IEC.
  1.1.1. An IEC member may be disqualified from continuance should IEC determine by a three-fourths majority specifically called for the purpose that the member's conduct has been unbecoming of an IEC member.
  1.1.2. An IEC member may be disqualified from IEC if they fail to attend more than three consecutive meetings without prior intimation.
1.2. This procedure begins when MNR-MC IEC Chair in consultation with the organisation has decided to remove an IEC member.
1.3. This procedure ends when the member has been removed, and the IEC's registration with CDSCO has been updated.

2. POLICY

2.1. HSR-001.

3. RESPONSIBILITY

3.1. The Organisation Official and the IEC Chair carries out these procedures.

4. PROCEDURE

4.1. The process is initiated when the IEC Chair or Secretary:
  4.1.1. Receive a communication in writing (from another IEC member or a member of the public) alleging misconduct, including breach of confidentiality by an IEC member.
  4.1.2. If an IEC Member fails to attend more than three consecutive meetings without prior intimation
4.2. The IEC Chair will satisfy himself/herself that a prima facie case exists before initiating action.
4.3. If, in the opinion of the IEC Chair, the matter is of grave significance where the integrity of IEC could be questioned, discuss with the Organisation Official.
4.4. The IEC Chair may suspend the membership of the concerned IEC member till IEC and Organisation take a final decision.
4.5. During the period of suspension, the affected individual will not have any rights, privileges, or responsibilities as an IEC member and will not perform any duties of IEC member.
4.6. If the IEC Chair opines that this requires discussion with other members, the Chair calls for a meeting to specifically discuss this issue or at a regularly convened meeting.
4.7. The meeting convened will follow the rules of a quorum.
4.8. The allegation will be presented at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself/ herself.
4.9. The member will stand disqualified if IEC members present approve of disqualification by voting (by two-thirds majority).

4.10. If not excluded, no action to be taken.
4.11. The Chair will convey the exclusion (disqualification) to the Organisation Official through written communication.
4.12. If the IEC member will no longer serve on the IEC, prepare and send a thank you letter signed by the Organisation Official and the IEC Chair.
4.13. Update the IEC's registration at CDSCO within 30 calendar days
4.14. Update the IEC roster.
4.14.1. Use "WORKSHEET: IEC Composition (HSR-312)" to evaluate whether the IEC is appropriately constituted.
4.14.1.1. Revise the membership as needed.

5. REFERENCES

5.1. HSR-001.

1. PURPOSE

1.1. This procedure establishes the process when a member resigns from MNR-MC IEC.
1.2. This procedure begins when MNR-MC IEC Chair receives the resignation letter from the IEC member and informs the Organisation Official.
1.3. This procedure ends when the resignation has been accepted, and the IEC's registration with CDSCO has been updated.

2. POLICY

2.1. None

3. RESPONSIBILITY

3.1. The Organisation Official (MNR Educational Trust) and IEC Chair carries out these procedures.

4. PROCEDURE

4.1. The Organisation Official notifies the IEC Chair on acceptance
4.2. If the IEC member will no longer serve on the IEC, prepare and send a thank you letter signed by the Organisation Official and the IEC Chair.
4.3. Update the IEC's registration at CDSCO within 30 calendar days.
4.4. Update the IEC roster.
  4.4.1. Use "WORKSHEET: IEC Composition (HSR-312)" to evaluate whether the IEC is appropriately constituted.
  4.4.2. Revise the membership as needed.

5. REFERENCES

5.1. None.

1. PURPOSE

1.1. This procedure establishes the process to evaluate and manage the financial interests of the IEC members.
1.2. This procedure begins when the 'Conflicts of Interests Officer' when an IEC member announces financial interest that can affect the conduct of research.
1.3. This procedure ends when the 'Conflicts of Interests Officer' decides that the financial interest is not a conflict of interest, or informs the IEC of the management plan.

1. POLICY

1.1. IEC Members are required to disclose their financial interests to the IEC Chair or designated 'Conflict of Interests Officer':
  1.1.1. Prior to the review of the research study protocol
  1.1.2. Every year
  1.1.3. When there are changes to financial interests
  1.1.4. The IEC has the authority to decide whether a financial interest and its management if any, allow the research to meet the criteria for approval.
1.2. HSR-002

2. RESPONSIBILITY

2.1. The IEC Chair or designated 'Conflicts of Interests Officer' carries out these procedures.

3. PROCEDURE

3.1. Update the list of investments with information about the name of the company, the names of related companies, and affected products or services.
3.2. Provide the updated list to the IEC Chair and EC Coordinator.
3.3. Stop review of the submission, if the investigator has a financial conflict of interest that could create bias in the outcome of the research.
3.4. Discuss the impact of financial conflict on the research outcome.
3.5. Once final review is completed, provide the IEC with the written report, and resume review of the submission.

4. REFERENCES

4.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945
4.2. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines
4.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
4.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)
4.5. HSR-402.

1. PURPOSE

1.1. This procedure establishes the process to designate or remove individuals (reviewers) from the list of IEC members who can review human research study protocol and other study-related documents.
1.2. This procedure begins when the IEC Chair considers adding or removing an individual designated to review human research.
1.3. This procedure ends when the IEC Chair notifies of a new individual designated to review or the removal of a previously designated individual.

2. POLICY

2.1. MNR-MC IEC Chair may designate one or more individuals to review human research study protocol based on their background and subject matter expertise.
2.2. In general, individuals designated to review are granted authority for only one category or a limited number of categories.
2.3. HSR-018.

3. RESPONSIBILITY

3.1. The IEC Chair carries out these procedures.
3.2. EC Coordinator maintains a list of individuals designated to review human research study protocol and other study-related documents and the category each individual is authorized to review.

4. PROCEDURE

4.1. To designate an individual within the IEC to review human research study related documents in one category or a limited number of categories based on the individual's background and expertise.
4.2. All IEC members must review the study protocol and other documents based on their knowledge. E.g., a 'Layperson' in the committee may not understand the scientific rationale and other technical terms, however, would understand the social and ethical aspects/ impact from the study.
4.3. IEC may make a single request for further information during the review – the clock stops until this is received.
4.4. All IEC members consider the criteria in "WORKSHEET: Criteria for Approval (HSR-301)."
  4.4.1. The principal investigator for each submission is expected to fill out applicable checklists with preliminary judgments as to whether each criterion is met.
  4.4.2. The principal investigator presents at the committee meeting.
4.5. For initial review: In advance of the meeting, all IEC members review the following materials to a depth sufficient to determine whether the criteria in applicable worksheets and checklists are met:
  4.5.1. Description of the investigational product from Investigator's Brochure

4.5.2. The research study protocol or a synopsis of the study protocol that includes a description of screening procedures, eligibility criteria, patient follow-up visits, laboratory and clinical investigations or procedures, data collection tools, and analysis of biological samples and data.

4.5.3. The participant information document

4.6. For a review of a modification:

4.6.1. In advance of the meeting, all IEC members review the modification form, determine which criteria in the applicable study protocol, worksheets and checklists are affected, and review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:

4.7. For continuing review:

4.7.1. In advance of the meeting, all IEC members review the 'Continuing Review Form,' and attachments, including any latest amendment in the study-related documents.

4.8. For a review related to an 'Unanticipated Problem Involving Risks to Subjects or Others,' 'Serious Non-compliance,' 'Suspension of IEC Approval,' or 'Termination of IEC Approval':

4.8.1. In advance of the meeting, all IEC members review the new information and attachments, determine which criteria in applicable worksheets and checklists are affected, and review the relevant sections of the following materials to a depth sufficient to determine as necessary further action.

4.9. All IEC members review written reports of external subject matter expertise if any.

4.10. The categories of review are, not limited to:

4.10.1. Social sciences
4.10.2. Health economics
4.10.3. Legal (e.g., by a legal expert)
4.10.4. Conflict of Interest (e.g., by a legal expert)
4.10.5. Clinical sciences (medicine, surgery, or other therapeutic areas)
4.10.6. Serious Adverse Event Report evaluation, including compensation
4.10.7. Research proposals involving Stem Cell
4.10.8. Research proposals involving Medical Devices
4.10.9. Research proposals involving *in vitro* Diagnostic Medical Devices

4.11. Required areas of review:

4.11.1. The relevance of trial (e.g., by a clinician)
4.11.2. Study design (e.g., by a clinician)
4.11.3. Risks and benefits (e.g., by a clinician, pharmacologist, legal, social scientist, layperson)
4.11.4. Subject information
4.11.5. Consent procedure (e.g., by a layperson)
4.11.6. The justification for including minors or adults unable to give informed consent, and vulnerable population.
4.11.7. Insurance/ indemnity (e.g., by a legal expert)
4.11.8. Rewards or compensation for investigators and subjects
4.11.9. Subject recruitment (e.g., by a clinician)

4.11.10. Suitability of the investigator and supporting staff (e.g., by a clinician)
4.11.11. Investigator brochure (e.g., by a medical pharmacologist)
4.11.12. Quality of the facilities (e.g., by IEC Secretary).

4.12. Train the individual to review in one or more categories using the following documents.
4.12.1. IEC Policy, SOP, Checklist, Worksheet, and Template.
4.12.2. Applicable regulations
4.12.3. Applicable guidelines

4.13. Notify EC Coordinator to update the list of individuals designated to review, the name of the individual and the categories on which the individual has been trained.

4.14. To remove an individual's designation as 'Reviewer' to review human research study:
4.14.1. Notify EC Coordinator to update the list of individuals, to remove the name of the individual.
4.14.2. Inform the individual that he or she may no longer review human research study protocol and other study-related documents.

5. REFERENCES

5.1. None

1. PURPOSE

1.1. This procedure establishes the process for a designating a 'Regulatory Reviewer' to review study-related documents meant for clinical trials of investigational new drug/ biological/ vaccine/ medical device/ cosmetics for regulatory compliance.

1.2. This procedure begins when a research study protocol submitted to IEC is of regulatory mandated in nature.

1.3. This procedure ends when the 'Regulatory Reviewer' has completed the review or an investigator has withdrawn the submission.

2. POLICY

2.1. As part of IEC review, all clinical trial protocols, including clinical investigation plan for a medical device that is mandated by the regulatory agency are reviewed by a designated 'Regulatory Reviewer' to:

- 2.1.1. Identify submissions with missing materials as per:
  - 2.1.1.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945 and amendments thereafter require certain minimal documents for review by IEC, and as per standards laid out for each document
  - 2.1.1.2. CDSCO-GCP requires certain minimal documents for review by IEC, and as per standards laid out for each document
  - 2.1.1.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants requires certain minimal documents for review by IEC, and as per standards laid out for each document
  - 2.1.1.4. The study related documents to be reviewed are:
    - 2.1.1.4.1. Clinical Trial Protocol/ Clinical Investigation Plan/ Clinical Performance Evaluation Plan
    - 2.1.1.4.2. Informed Consent Document
    - 2.1.1.4.3. Investigator Brochure
    - 2.1.1.4.4. Case Report Form
    - 2.1.1.4.5. Subject Diary
    - 2.1.1.4.6. Advertising material, if any
- 2.1.2. Identify and document the determinations that the IEC needs to make in order to approve research.
- 2.1.3. Identify any relevant international requirements
- 2.1.4. Arrange for consultation by an external member, if required to resolve requirements that are beyond the scope of current IEC member's understanding.
- 2.1.5. Identify other special review issues.

2.2. The 'Regulatory Reviewer' should document findings on "WORKSHEET: Review of Regulatory Compliance (HSR-306)" or equivalent.

2.3. The 'Meeting Chair' ensures that discussion at meetings covers issues raised by the 'Regulatory Reviewer.'

2.4. Changes to study personnel are not considered a modification to previously approved research when the study personnel meets the qualifications described in the IEC approved study.
2.5. HSR-018.

3. RESPONSIBILITY

3.1. The designated 'Regulatory Reviewer' carries out these procedures.

4. PROCEDURE

4.1. A study protocol is a document that describes the background, rationale for the trial objective(s), design, methodology, statistical considerations, organization of a trial and other items as expected in Appendix X of Schedule Y of the Drugs & Cosmetics Rules and GCP guidelines.
4.2. The Regulatory Reviewer is expected to review for compliance of study related documents to regulations and guidelines.
4.3. Designated Reviewers try to find answers to the following questions from the study protocol:
- 4.3.1. How will the knowledge, result, or outcome of the study contribute to human well-being?
  - 4.3.1.1. Knowledge from the basic research may benefit.
  - 4.3.1.2. A new choice of method, drug, or device that benefits the subject during the study and others in the future.
  - 4.3.1.3. Provide safety data or more competitive choices.
- 4.3.2. Will the study design be able to give answers to the objectives? Whether the endpoints are appropriately selected?
  - 4.3.2.1. The participating duration of a study participant is adequate to allow sufficient change in the endpoints
  - 4.3.2.2. The control arm is appropriately selected for best comparison
  - 4.3.2.3. The use of placebo is justified because there is a comparable standard of care in the market
  - 4.3.2.4. The number of study participants in non-treatment (or placebo) arm is minimized.
  - 4.3.2.5. Unbiased assignment (e.g., randomization, etc.) is in practice.
  - 4.3.2.6. Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.
  - 4.3.2.7. The sample group size appropriate with the given statistical assumptions
  - 4.3.2.8. Predictable risks are minimized.
  - 4.3.2.9. The tests and procedures that are more than minimal risk are cautiously used.
  - 4.3.2.10. Subject deception is avoided
  - 4.3.2.11. Instruction and counseling for study participants are included (if needed) when deception is integral to the study design.

4.3.2.12. The study participants are adequately assessed and provided follow-up care if needed.

4.3.3. Who will be the participants in the study? Whether
- 4.3.3.1. The described population is appropriate for the study.
- 4.3.3.2. Predictable vulnerabilities are considered.
- 4.3.3.3. It is vital to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
- 4.3.3.4. There will be secondary participants.

4.3.4. Do the inclusion and exclusion criteria
- 4.3.4.1. Selectively include participants most likely to serve the objective of the study?
- 4.3.4.2. Equitably include participants?
- 4.3.4.3. Properly exclude participants who can predictably confound the results?
- 4.3.4.4. Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?

4.3.5. Does the study design have adequate built-in safeguards for risks?
- 4.3.5.1. Appropriate screening of potential participants?
- 4.3.5.2. Use of a stepwise dose escalation with analysis of the results before proceeding?
- 4.3.5.3. Does the frequency of visits and biological samplings reasonably monitor the expected effects?
- 4.3.5.4. Is there defined stopping (discontinuation)/ withdrawal criteria for participants with the worsening condition?
- 4.3.5.5. Is there minimized use of medication withdrawal and placebo whenever possible?
- 4.3.5.6. Will rescue medications and procedures be allowed when appropriate?
- 4.3.5.7. Is there a defined safety committee to perform interim assessments, when appropriate?
- 4.3.5.8. Is appropriate follow-up designed into the study? For instance, gene transfer research may require following the participants for years or their entire life after they receive the gene transfer agent.

4.3.6. Is pre-clinical and/or early clinical studies sufficiently performed before this study?
- 4.3.6.1. The animal study and in vitro testing results?
- 4.3.6.2. Previous clinical results, if done?
- 4.3.6.3. Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.
- 4.3.6.4. The selected dose based on satisfactory prior results?
- 4.3.6.5. Monitoring tests designed to detect expected possible risks and side effects?

4.3.7. Do the study and the informed consent process includes issues of special concern, such as:
- 4.3.7.1. Waiver or alteration of consent
- 4.3.7.2. Delayed consent (e.g., emergency treatment, etc.)
- 4.3.7.3. Deception

4.3.7.4. Sensitive information of participants that may require a confidentiality statement?

4.3.8. What are the benefits of using a particular standard of care?

4.3.8.1. Is the standard treatment widely accepted?

4.3.8.2. Has efficacy of the treatment been consistently proven?

4.3.8.3. Does the treatment act on the basic mechanism of the disease (vs. symptoms)?

4.3.8.4. Are most (≥75%) of the patients with this condition responsive to standard treatment alternatives, except resistant or refractory cases?

4.3.8.5. Is the risk of using placebo instead of treatment life threatening?

4.3.8.6. Is the use of a placebo instead of standard treatment likely to lead to irreversible permanent damage?

4.3.8.7. Can the use of placebo instead of treatment lead to an acute emergency?

4.3.8.8. Is the risk of using placebo instead of treatment severe physical discomfort or pain?

4.3.8.9. Will, the discontinuation of previous treatment, put the participant in danger of acute relapse when transferred to placebo?

4.3.8.10. Does the protocol not allow to the protocol arm to shift to standard of care arm in the event of an SAE?

4.3.8.11. Are there no clearly defined stopping rules to withdraw the subject before the advent of severe disease progression?

4.3.8.11.1. If the answers to the above 11 points are true, having a placebo as a comparative arm is not justified.

4.3.8.12. Does the standard of care treatment cause severe AE?

4.3.8.13. Does standard treatment have contraindications that prevent some subjects from being treated?

4.3.8.14. Is there substantial (≥25%) placebo response in this disease or symptom?

4.3.8.15. Subjects are not exposed to severe or permanent harm by the use of placebo.

4.3.8.16. Subjects under placebo will benefit from the overall treatment of the disease.

4.3.8.17. Risks of the use of placebo are minimal.

4.3.8.18. Risks are adequately disclosed in the consent form.

4.3.8.18.1. If the answers to the above 18 are true, it is ethical makes sense of having a placebo in a blinded study.

4.4. Determine whether the submission is initial, continuing, or modification. If both continuing and modification, follow both procedures.

4.4.1. For initial submission:

4.4.1.1. Use "WORKSHEET: Review of Regulatory Compliance (HSR-306)" to document any Regulatory Review findings.

4.4.2. For a modification submission:

4.4.2.1. Determine whether the submission includes information that might represent 'Unanticipated Problem Involving Risks to Subjects or Others', 'Serious Non-compliance', and 'Continuing Non-compliance'.

4.4.2.1.1. If so, additionally process under "SOP: Managing New Information (HSR-118)."

4.4.2.2. Check whether consent document being used are the currently approved versions.

4.4.2.3. Use "WORKSHEET: Regulatory Reviewer's Comments (HSR-306)" to update 'Regulatory Review' findings as needed.

4.5. If the submission is limited to an updated list of study personnel, follow "SOP: Managing New Information (HSR-118)" to notify the IEC and take no further action.

4.6. If the submission is a request to transfer the study to another IEC, transfer the study and follow "SOP: Managing New Information (HSR-118)" to notify the investigator.

4.7. If the submission is a response to conditionally approved research:

4.7.1. Evaluate whether the submitter made the required modifications.

4.7.2. If the submitter made the required modifications and no others, follow "SOP: Managing New Information (HSR-118)" to recommend to IEC Chair to issue an approval.

4.7.3. Arrange for consultation by an external member, if required to resolve requirements that are beyond the scope of current IEC member's understanding.

4.7.4. Communicate with IEC Chair for any potentially resolvable contingencies to resolve the issues, or withdraw the submission and resubmit when complete.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945

5.2. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

5.3. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)

5.4. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines

5.5. HSR-306.

1. PURPOSE

1.1. This procedure establishes the fees for reviewing research study proposal, payment of reviewer and consultant fees.
1.2. The fees are different for industry-sponsored and academic studies.
1.3. The fees are reviewed on a two-yearly basis.

2. POLICY

2.1. The fees charged represent only partial recovery of the total cost of providing ethical and governance oversight.

3. RESPONSIBILITY

3.1. The EC Coordinator collects the fees from submitting investigator either through cheque, demand draft, or online transfer.
3.2. No cash payments are acceptable.
3.3. Fees are payable at the time of submission and are non-refundable.
3.4. The EC Coordinator issues the receipt for the fee after realization, in the name of the Sponsor.
3.5. The IEC Chair reserves the right to waive off 'review fees.'
3.6. The proof of payment (cheque, online transfer) is submitted along with the application form TEMPLATE: Application Form for Ethical Clearance for Research Involving Human Participants (HSR-405).

4. PROCEDURE

4.1. The annual fees will be as follows:
- 4.1.1. Pharmaceutical company-sponsored study:
  - 4.1.1.1. Phase 1 (first in human) Clinical Trial: Rs. 100,000 or US$ 1500
  - 4.1.1.2. Phase 2 & 3 Clinical Trial: Rs. 75,000 or US$ 1200
  - 4.1.1.3. Phase 4 Clinical Trial: Rs. 50,000 or US$ 1000
  - 4.1.1.4. Post-Marketing Surveillance: Rs. 40,000 or US$ 800
  - 4.1.1.5. Observational study – Rs. 20,000 or US$ 500
  - 4.1.1.6. Amendments or addition of sub-studies to trials after initial IEC approval: Rs. 10,000 for each amendment
- 4.1.2. Government or Institution (collaborative group) sponsored study:
  - 4.1.2.1. Phase 1 to 4 Clinical Trial: Nil
  - 4.1.2.2. Observational study – Nil
  - 4.1.2.3. Amendments or addition of sub-studies to trials after initial IEC approval: Nil
- 4.1.3. Investigator-initiated study
  - 4.1.3.1. Clinical Trial for approved investigational product, data not to be submitted to CDSCO or to Pharmaceutical Company, funded by Organisation: Nil
  - 4.1.3.2. Research project (academic studies):
    - 4.1.3.2.1. Funded by Organisation: Nil
    - 4.1.3.2.2. Funded by Government funds: Nil

4.1.3.2.3. Dissertation thesis: Nil

4.1.3.2.4. Amendments or addition of sub-studies to trials after initial IEC approval: Nil

4.2. The annual fees will be paid within one month before expiry of approval, if the study is continuing.

4.3. Applicable taxes are additional.

4.4. The fee includes administrative charges.

4.5. Fees are payable in full at the time of the initial submission of a study.

4.6. Fees are non-refundable after 'Designated Reviewer' and/or IEC review has taken place.

4.7. A receipt of fee will be issued within seven calendar days of IEC review. Provisional receipt will be issued on request, if required earlier, on MNR-MC IEC Letter Head

4.8. The payment is made in the name of 'MNR-Medical College & Hospital' payable at Sangareddy; Bank Name: HDFC; Branch: Sangareddy; IFSC: HDFC0000813; Account Number: 50200007005508.

4.9. The Permanent Account Number (Income Tax) is

4.10. The EC Coordinator maintains the income and expenses of this account with oversight by Organisation Finance Controller and IEC Chair/ IEC Secretary.

4.11. All expenses required by IEC are borne from this account. If no funds are available, funds are borrowed from the Organisation and to be returned, when funds available.

4.12. Expenses are for transportation, meals, training, and organising meetings to promote research and education.

4.13. All attending IEC members are compensated for their time, efforts, and expertise.

4.13.1. External members: Rs. 2500 per meeting, irrespective of type and number of proposals.

4.13.2. Internal members from Organisation: Rs. 1000 per meeting, irrespective of type and number of proposals.

5. REFERENCES

5.1. None

1. PURPOSE

1.1. This procedure establishes the process to prepare for a scheduled IEC meeting.
1.2. This procedure begins when meeting preparation, including finalization of date of meeting commences.
1.3. This procedure ends when IEC members attending the meeting have been notified of the agenda and their assignments.

2. POLICY

2.1. MNR-MC IEC does not place limits on the number of items on the agenda.

3. RESPONSIBILITY

3.1. IEC Secretary and Staff (EC Coordinator) carry out these procedures.

4. PROCEDURE

4.1. Confirm having received all application forms for review along with copies of study-related documents. Investigators to use TEMPLATE: Application Form for Ethical Clearance for Research Involving Human Participants (HSR-405).
4.2. Confirm which IEC members (IEC Chair/ IEC Vice-Chair, IEC Secretary and other regular and alternate members) will be present at the meeting.
4.3. Prepare an agenda. Use "TEMPLATE: Meeting Agenda (HSR-406)".
4.4. Check how many of the submitting investigators have paid the required fee for review of proposal.
4.5. Forward the study related documents to all the IEC members
4.6. Ensure that all IEC members are provided or have access to the materials in "POLICY: Expectations from IEC Members' For Review of Research Study Prior to Meeting (HSR-018)" at least two weeks before the meeting unless an exception is approved by the IEC Chair].
4.7. Ensure that the reviewer with relevant scientific/scholarly expertise will use "WORKSHEET: SOP: HSR-306, HSR-307, HSR-308, HSR-310 and HSR-311" and be present.
    4.7.1. If an IEC member with relevant scientific/scholarly expertise is not available, follow "SOP: Obtaining Consultation on Subject Matter from an External Individual/ Agency (HSR-115)" to obtain a consultant/ subject matter expertise.
4.8. Use "WORKSHEET: Quorum (HSR-313)" to ensure that the meeting will be appropriately convened.
4.9. If the meeting will not meet the quorum requirements, make arrangements to meet quorum requirements (e.g., arrange for alternate IEC members to attend).
4.10. Adjourn the meeting when notified by the EC Coordinator that quorum is not met.
4.11. Schedule another meeting.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945 and amendments thereafter
5.2. Medical Devices Rules, 2017
5.3. HSR-313.
5.4. HSR-315.
5.5. HSR-017

1. PURPOSE

1.1. This procedure establishes the process to review/ conduct an IEC meeting for research study protocols that require regulatory approval.
1.2. This procedure begins when the meeting is called to order.
1.3. This procedure ends when the meeting is adjourned.

2. POLICY

2.1. The opinion must be given within seven calendar days of receipt of a valid application.
2.2. IEC may make a single request for further information during the review – the clock stops until this is received.
2.3. The IEC Meeting Chair is responsible to:
  2.3.1. Lead the IEC meeting
  2.3.2. Facilitate IEC review
  2.3.3. Ensure this SOP is followed
  2.3.4. Monitor the IEC's decisions for consistency
  2.3.5. Ensure that IEC members are free to participate in discussions
  2.3.6. Ensure that IEC members attending by teleconference can actively and equally participate in all discussions
  2.3.7. Vote as an IEC member
2.4. The IEC Meeting Chair is expected to:
  2.4.1. Help IEC members meet their expectations in "POLICY: Expectations of IEC Members (Terms of Reference) (HSR-007)."
  2.4.2. Encourage IEC members to:
    2.4.2.1. Ask questions.
    2.4.2.2. Speak their minds at every protocol review
    2.4.2.3. Share information that has not been discussed.
    2.4.2.4. Listen and learn from the group.
    2.4.2.5. Respect dissenting opinions.
    2.4.2.6. Think and vote independently.
  2.4.3. Mentor and guide IEC members to use the criteria for approval by:
    2.4.3.1. Facilitating IEC members' understanding of the research to the degree sufficient to apply the criteria for approval.
    2.4.3.2. Having IEC members voice concerns, problems, and recommended changes in the criteria for approval.
    2.4.3.3. Obtaining assistance when the IEC members are uncertain on some issues.
    2.4.3.4. Taking votes on the criterion for approval that is the basis for controversy, if after sufficient discussion a controverted issue remains unresolved
  2.4.4. Encourage IEC member engagement by:
    2.4.4.1. Reinforcing IEC member expectations
    2.4.4.2. Encouraging IEC members to use their unique perspective to contribute to IEC deliberations.
    2.4.4.3. Providing recognition and praise to IEC members.
    2.4.4.4. Caring about each IEC member as a person.

2.4.4.5. Encouraging IEC members to develop in their review skills.
2.4.4.6. Ensuring the opinions of IEC members count.
2.4.4.7. Communicating the mission of the MNR-MC IEC to protect subjects.

2.5. IEC members are to know the definition of Conflicting Interest and self-identify their conflicting interests.
2.6. The IEC Meeting Chair may determine that certain IEC members have voting status and others have non-voting status.
2.6.1. The number of IEC members with voting status is not greater than the number of regular IEC members on the IEC roster.
2.6.2. All IEC members have voting rights
2.6.3. EC coordinator does not have any voting rights
2.6.4. Invited Consultants may not vote.
2.7. Ad hoc substitutes may not serve as IEC members.
2.8. Absent IEC members may submit written comments, but may not vote.
2.9. Observers may attend meetings, but:
2.9.1. May not participate in IEC deliberations unless requested by the IEC to serve as a consultant
2.9.2. May not vote
2.9.3. Must agree to maintain the confidentiality of the IEC proceedings.
2.10. When a protocol is ambiguous, the IEC may resolve the ambiguity by obtaining written information from the sponsor through investigator in advance of the meeting as an alternative to contingent approval, IEC members must be made aware of this information, either verbally or in writing.

3. RESPONSIBILITY

3.1. The IEC Meeting Chair carries out these procedures.

4. PROCEDURE

4.1. EC Coordinator will use "TEMPLATE: Meeting Agenda (HSR-406)" in preparation of the meeting.
4.2. Call the meeting to order.
4.3. The IEC Secretary will use "TEMPLATE: Attendance Sheet (HSR-407)" for recording attendance.
4.4. Ask whether anyone has a 'Conflicting Interest' related to any agenda item. Use "TEMPLATE: Conflict of Interest Form (HSR-402)" to assess conflict.
4.5. For each study review:
4.5.1. Designated IEC members must follow in "POLICY: Expectations from IEC Members' For Review of Research Study Prior to Meeting (HSR-017).
4.5.2. If there are individuals (either IEC members or consultants) with a conflicting interest related to an agenda item:
4.5.2.1. IEC Chair may ask questions of those individuals.
4.5.2.2. If physically present, ask those individuals to leave the room.

4.5.2.3. If present by teleconference, set the conference telephone equipment to block communications or ask the member to leave the call during the review.

4.5.3. Take no action on the item when noticed that quorum requirements are not met[1] or when there is insufficient time.

4.5.3.1. Move the item to another meeting.

4.5.4. If one or more consultants are involved:

4.5.4.1. Inform the IEC members of any conflicting interest.

4.5.4.2. Have those present at the meetings discuss their findings.

4.5.5. Have the Designated Reviewer(s) discuss the scientific/scholarly review.

4.5.5.1. Review relevant findings of 'Regulatory Reviewer.'

4.5.5.2. In general, all IEC members will discuss the following:

4.5.5.2.1. Relevance of trial

4.5.5.2.2. Study design

4.5.5.2.3. Risks and benefits

4.5.5.2.4. Recruitment procedures

4.5.5.2.5. Consent procedure

4.5.5.2.6. The justification for including minors or adults unable to give informed consent or vulnerable population.

4.5.5.2.7. Insurance/ indemnity

4.5.5.2.8. Rewards or compensation for investigators and subjects

4.5.5.2.9. Confidentiality and data protection

4.5.5.2.10. Retention and future uses of tissue samples • Sub-studies (e.g., genetics)

4.5.5.2.11. Radiation exposure

4.5.5.2.12. Arrangements for notifying stakeholders

4.5.5.2.13. Criteria for subject withdrawal

4.5.5.2.14. Criteria for early termination

4.5.5.2.15. Data monitoring arrangements

4.5.5.2.16. Exit strategies – continued care of subjects outside the trial.

4.5.5.2.17. Publication/dissemination of results

4.5.5.2.18. Sources of funding

4.5.5.2.19. Suitability of the investigator and supporting staff

4.5.5.2.20. Quality of the facilities

4.5.5.3. For a review related to an 'Unanticipated Problem Involving Risks to Subjects or Others,' 'Serious Non-compliance,' 'Continuing Non-compliance,' lead the IEC members through a discussion of "WORKSHEET: Managing New Information (HSR-302)."

[1] If quorum is lost during a meeting, the IEC cannot take votes until the quorum is restored. If required members (e.g. non-scientific) leave the room and quorum is lost votes cannot be taken until the quorum

4.5.5.4. Lead the IEC through a discussion of the criteria in applicable worksheets.

4.5.6. Make a motion for one of the following:

4.5.6.1. "Approve": When the IEC determines that the initial, continuing, or modification submission meets the criteria for approval.

4.5.6.1.1. For initial and continuing review, include in the motion the period of approval (not to exceed one year) and the level of risk (minimal risk or greater than minimal risk).

4.5.6.2. "Conditionally Approve": When the IEC determines that the initial, continuing, or modification submission will meet the criteria for approval with minor or administrative changes or requirements that can be verified without considering the criteria for approval.[2]

4.5.6.2.1. For initial and continuing review, include in the motion the period of approval (not to exceed one year) and the level of risk (minimal risk or greater than minimal risk).

4.5.6.2.2. Summarize the IEC's required modifications and reasons.

4.5.6.3. "Defer": When the IEC determines that the initial, continuing, or modification submission does not meet the criteria for approval and also does not meet the criteria for "Disapprove,".

4.5.6.3.1. Summarize the IEC's reasons and recommendations, if any.

4.5.6.4. "Disapprove": The initial, continuing, or modification submission does not meet the criteria for approval, and the IEC considers the research to have extensive deficiencies.

4.5.6.4.1. Summarize the IEC's reasons and recommendations, if any.

4.5.6.5. "Suspend": When the IEC determines that based on new information the previously approved research no longer meets the criteria for approval, but some research activities meet the criteria for approval, or the IEC has recommendations that may make the research meet the criteria for approval.

4.5.6.5.1. Include in the motion: Which research activities must stop or be modified

4.5.6.5.2. If the research in its entirety no longer meets the regulatory criteria for approval,

[2] Substantive changes or requirements, requests for more information for IEC consideration, and other issues related to the criteria for approval require review and approval by the convened IEC.

include in the motion: Stop all research procedures (except as noted below) and stop enrollment

4.5.6.5.3. If stopping research will adversely affect the best interests of currently enrolled subjects, include in the motion: Which subjects can continue and what procedures can be performed

4.5.6.5.4. Lead the IEC members through a discussion of "WORKSHEET: Managing New Information (HSR-302)" to consider additional actions.

4.5.6.5.5. Summarize IEC's reasons and recommendations.

4.5.6.6. "Terminate": When the IEC determines that based on new information the previously approved research no longer meets the criteria for approval and the IEC has no recommendations to make the research approvable.

4.5.6.6.1. Lead the IEC members through a discussion of "WORKSHEET: New Information (HSR-302)" to consider additional actions.

4.5.6.6.2. Summarize the IEC's reasons.

4.5.6.7. "Accept/ Acknowledge": The sponsor and the investigator require an affirmative reply in response to submitted materials but an action of "Approve" is not applicable

4.5.7. Ensure that the EC Coordinator/ staff taking minutes has recorded the IEC's actions, required modifications, reasons, recommendations, determinations, and findings on "TEMPLATE: Minutes of the Meeting (HSR-408)".

4.5.8. Call for a vote of IEC members "For," "Against," or "Abstaining." If more than half the IEC members present votes "For," the motion is approved.

4.5.8.1. A tie vote to approve a motion for "Approve" or "Conditionally Approve" is considered to be an IEC decision of "Defer."

4.5.9. Summarize IEC's consensus.

4.5.10. The IEC may decide to reverse its approval on a study in the event of receiving information that may adversely affect the benefit/risk ratio.

4.5.11. Have individuals with a conflicting interest rejoin the meeting.

4.6. Adjourn the meeting when there is no further business or when notified by the EC Coordinator that quorum for all remaining agenda items cannot be met.

4.6.1. If there are remaining agenda items, move them to another meeting.

4.7. Inform Principal Investigator. Use "TEMPLATE: IEC Decision Letter (HSR-409)".

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945

5.2. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines

5.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

5.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)

1. PURPOSE

1.1. This procedure establishes the process to monitor an IEC meeting for quorum and expertise.
1.2. This procedure begins when the meeting is called to order.
1.3. This procedure ends when the meeting is adjourned.

2. POLICY

2.1. For a review of each protocol, the quorum of MNR-MC IEC should be at least five members with the following representations:
  2.1.1. Basic medical scientist (preferably medical pharmacologist).
  2.1.2. Clinician, preferably internal medicine
  2.1.3. Legal expert
  2.1.4. Social scientist/ representation of non-governmental voluntary agency / philosopher / ethicist / theologian or similar person
  2.1.5. Layperson from the community.

3. RESPONSIBILITY

3.1. EC Coordinator carries out these procedure(s).

4. PROCEDURE

4.1. Use "WORKSHEET: Quorum (HSR-313)" to determine whether the meeting is appropriately convened:
  4.1.1. Before the meeting is called to order
  4.1.2. Before each study with special quorum requirements is reviewed
  4.1.3. When members leave the meeting for any reason.
4.2. When evaluating quorum do not count IEC members with a conflicting interest.
4.3. Notify the IEC Meeting Chair when quorum requirements are not met.
4.4. For regulatory-mandated research studies, the meeting should be postponed, if a quorum is not reached.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945
5.2. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines
5.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
5.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2).
5.5. HSR-313

1. PURPOSE

1.1. This procedure establishes the process to take IEC minutes.
1.2. This procedure begins when the meeting is called to order.
1.3. This procedure ends when the minutes are finalized.

2. POLICY

2.1. None

3. RESPONSIBILITY

3.1. EC Coordinator or any IEC member designated by the IEC Meeting Chair carry out these procedures.

4. PROCEDURE

4.1. Use the "TEMPLATE: Attendance Sheet (HSR-407)" to record attendance.
4.2. Use the "TEMPLATE: Minutes of the Meeting (HSR-408)" to record minutes.
4.3. Record at the beginning of the minutes:
  4.3.1. "Members Present": Record the following information on IEC members present at any time during the meeting and having voting status at least once during the meeting[3]:
    4.3.1.1. Name.
    4.3.1.2. Status[4]
    4.3.1.3. Whether the IEC member is an alternate or regular
    4.3.1.4. Whether the IEC member attended by teleconference.
  4.3.2. "Others Present": Record the following information on individuals present at any time during the meeting who never have voting status:[5]
    4.3.2.1. Name.
    4.3.2.2. Role
4.4. Record the total number of regular members on the current IEC roster and the number of members required for a quorum[6].
4.5. If IEC members are present by teleconference, indicate whether they received all pertinent material before the meeting and were able to actively and equally participate in all discussions
4.6. Record the time the meeting is called to order.
4.7. Record a summary of the discussion of items unrelated to the review of specific research.
4.8. For each item related to specific research:
  4.8.1. Record the type of review[7]

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[3] If an IEC member has non-voting status for the entire meeting, list as an "Others Present."
[4] For example: IEC chair, IEC vice-chair, scientific member, non-scientific member, unaffiliated member, pediatric experience, prisoner representative
[5] This may include IEC members who are present for the meeting but never vote, consultants, non-IEC members, etc.
[6] As per regulatory requirement

4.8.2. Record relevant information about the research:
- 4.8.2.1. Title
- 4.8.2.2. Principal investigator
- 4.8.2.3. IEC Approval number
- 4.8.2.4. Protocol number
- 4.8.2.5. Study title
- 4.8.2.6. Documents reviewed

4.8.3. When needed for clarity, summarize previous IEC actions.

4.8.4. If any item is not acted upon, record the reason[8].

4.8.5. If a consultant provided an oral report, summarize the key information provided.

4.8.6. If there were any controverted issues (IEC members expressed a difference of opinion), summarize the issue, label as a controverted issue, and summarize the resolution, if any.
- 4.8.6.1. If there were no controverted issues, record this.

4.8.7. Record the motion.
- 4.8.7.1. For a motion of "Approve" or "Conditionally Approve" related to an initial or continuing review submission record:
  - 4.8.7.1.1. The approval period
  - 4.8.7.1.2. Whether the risk is 'Minimal Risk' or greater than 'Minimal Risk.'
  - 4.8.7.1.3. Any required checklist determinations along with study-specific findings supporting those determinations
- 4.8.7.2. For a motion of "Conditionally Approved" record the IEC's modifications required to secure approval and the reasons for those modifications.
- 4.8.7.3. For a motion of "Defer" record the IEC's reasons and recommendations.
- 4.8.7.4. For a motion of "Disapprove" record the IEC's reasons.
- 4.8.7.5. For a motion of "Suspend" record the specific activities suspended and the IEC's recommendations, if any.
- 4.8.7.6. For a motion of "Lift Suspension," no other information needs to be recorded.
- 4.8.7.7. For a motion of "Terminate" record the IEC's reasons.

4.8.8. Record the vote as the numbers:
- 4.8.8.1. "For": Voting for the motion.
- 4.8.8.2. "Against": Voting against the motion
- 4.8.8.3. "Abstained Voting": Present for the vote, but not voting "For" or "Against"
- 4.8.8.4. "Absent": Not present for reasons other than a conflicting interest.

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[7] For example: Initial, continuing, modification, <Unanticipated Problem Involving Risks to Subjects or Others>, <Serious Noncompliance>, <Continuing Noncompliance>, <Suspension of IEC Approval>, <Termination of IEC Approval>, study progress, etc.

[8] For example: Loss of all non-scientific members, missing expertise, meeting ended early due to fire alarm

4.8.8.4.1. Record the names of absent members (members in attendance at the meeting, but absent from the room for the vote)

4.8.8.5. "Recused": Not present for discussion and voting due to a conflicting interest

4.8.8.5.1. Record the names of recused members

4.8.8.6. Non-Voting Status: Present at the meeting but not in voting status (in voting status for some items but not in voting status for all items)

4.8.8.6.1. Record the names of members present in non-voting status

4.9. Record the time the meeting is adjourned.

4.10. Provide the minutes to the IEC Meeting Chair for review and approval, and provide to the IEC as an information item.

4.11. Provide approved minutes to the IEC Meeting Chair for signature.

4.12. The Worksheets and Checklists marked accordingly to be stored with the minutes for the applicable review.

5. REFERENCES

5.1. HSR

1. PURPOSE

1.1. This procedure establishes the process to review research that is not subject to regulatory approval by CDSCO, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of the society in general, except in pregnant women, fetuses or neonates, vulnerable population, or in geriatric patients.

1.2. One or more of the following five categories are exempt from approval by CDSCO. Irrespective of the requirement of CDSCO to approve such studies, IEC approval is required for all studies that require human subjects.

1.2.1. **Academic Clinical Study:** Means a clinical study conducted for an academic purpose on a medical device, including *in vitro* diagnostic kits or pharmaceutical for approved, or new intended use, new material of construction, new improved design or new population. For medical devices, these studies are called clinical validation studies. The data generated during the study shall not be used to furnish to the Central Licensing Authority to manufacture or to import for marketing any investigational medical device in the country.

1.2.1.1. Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled:

1.2.1.1.1. Process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

1.2.1.1.2. Design validation means establishing by objective evidence that device specifications conform to user needs and intended use(s).

1.2.1.2. Is generally applicable to hardware, software, and systems.

1.2.1.3. The medical device is of investigational nature, but data obtained from the clinical validation studies are not used to submit to CDSCO for obtaining marketing authorisation.

1.2.1.4. The medical device is marketed after due marketing authorisation or has a manufacturing license.

1.2.2. **Educational Settings or Practices:** Research conducted in established or commonly accepted educational settings, involving standard educational practices, such as:

1.2.2.1. Research on regular and special education instructional strategies

1.2.2.2. Research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.

1.2.3. **Educational Tests, Surveys, Interviews, Observations:** Research involving the use of educational tests (cognitive, diagnostic,

aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

1.2.3.1. Information obtained is recorded in such a manner that study subjects can be identified, directly or through identifiers linked to the subjects; and

1.2.3.2. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

1.2.4. **Existing Data, Documents, Records, Specimens**: Research involving the collection or study of existing data, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

1.2.5. **Taste and Food Quality and Consumer Acceptance:** Taste and food quality evaluation and consumer acceptance studies

1.2.5.1. If wholesome foods without additives are consumed or

1.2.5.2. If food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by CDSCO or FSSAI.

1.3. This procedure begins when the convened IEC determines that research falls into a not otherwise approvable category.

1.4. This procedure starts when the meeting is called to order.

1.5. This procedure ends when the meeting is adjourned.

2. POLICY

2.1. In the Drugs and Cosmetics Rules, 1945, rule 122 DA, no permission for conduct of clinical trial intended for academic purposes in respect of approved drug formulation are required for any new indication or new route of administration or new dose or new dosage form where the trial is approved by the Ethics Committee; and the data generated is not intended for submission to CDSCO.

2.2. The IEC shall however inform CDSCO about the cases approved by it and also about cases where there could be an overlap between the clinical trial for academic and regulatory purposes and where the said authority does not convey its comments to IEC within a period of 30 days from the date of receipt of communication from IEC, it shall be presumed that no permission from the licensing authority is required".

3. RESPONSIBILITY

3.1. The IEC Meeting Chair carries out these procedures.

4. PROCEDURE

4.1. Determine whether to review the research.

4.1.1. If a determination is made not to review the research, inform other members, and take no further action under this SOP.

4.1.2. The research should proceed because the following criteria are met:

4.1.2.1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of society in general, except in pregnant women, fetuses or neonates vulnerable population, or geriatric patients.

4.1.2.2. The research is conducted in accordance with sound ethical principles.

4.1.2.3. Adequate provisions are made for soliciting the assent of children, the permission of their parents or guardians, and the consent of subjects as required by "POLICY: Legally Authorized Representative and Guardian for Children (HSR-009)."

4.2. Identify scientific/ scholarly expert(s) in pertinent disciplines (e.g., science, medicine, Educational, or sociology) and relevant subject advocates willing to serve on IEC meeting.

4.2.1. Determine whether any IEC member has a conflicting interest.

4.2.2. Do not use members with a conflicting interest.

4.3. Provide members with all information reviewed by the convened IEC.

4.4. Ask the expert to provide individually written recommendations.

4.5. Set a date for a meeting.

4.6. Call the meeting to order.

4.7. Ask whether anyone has a 'Conflicting Interest' related to any agenda item.

4.8. For each study review:

4.8.1. Only those IEC members who are independent of the clinical trial and the sponsor of the trial should vote/ provide an opinion in matters related to the study

4.8.2. If there are individuals (either IEC members or consultants) with a conflicting interest related to an agenda item:

4.8.2.1. IEC Chair may ask questions of those individuals.

4.8.2.2. If physically present, ask those individuals to leave the room.

4.8.2.3. If present by teleconference, set the conference telephone equipment to block communications or ask the member to leave the call during the review.

4.8.3. No quorum is required for research studies that are not mandated by CDSCO, except for those study protocols involving vulnerable population.

4.8.4. If one or more consultants are involved:

4.8.4.1. Inform the IEC members of any conflicting interest.

4.8.4.2. Have those present at the meetings discuss their findings.

4.9. The IEC Meeting Chair is responsible to:

4.9.1. Lead the IEC meeting

4.9.2. Facilitate IEC review

4.9.3. Ensure this SOP is followed

4.9.4. Monitor the IEC's decisions for consistency

4.9.5. Ensure that IEC members are free to participate in discussions
4.9.6. Ensure that IEC members attending by teleconference can actively and equally participate in all discussions
4.9.7. Vote as an IEC member

4.10. The IEC Meeting Chair is expected to:
4.10.1. Help IEC members meet their expectations in "POLICY: Expectations of IEC Members (Terms of Reference) (HSR-007)."
4.10.2. Encourage IEC members to:
4.10.2.1. Ask questions.
4.10.2.2. Speak their minds at every research study review
4.10.2.3. Respect dissenting opinions.
4.10.2.4. Think and vote independently.
4.10.3. Mentor and guide IEC members to use the criteria for approval by:
4.10.3.1. Facilitating IEC members' understanding of the research to the degree sufficient to apply the criteria for approval.
4.10.3.2. Having IEC members voice concerns, problems, and recommended changes in the criteria for approval.
4.10.3.3. Obtaining assistance when the IEC members are uncertain on some issues.
4.10.3.4. Taking votes on the criterion for approval that is the basis for controversy, if after sufficient discussion a controverted issue remains unresolved
4.10.4. Encourage IEC member engagement by:
4.10.4.1. Reinforcing IEC member expectations
4.10.4.2. Encouraging IEC members to use their unique perspective to contribute to IEC deliberations.
4.10.4.3. Providing recognition and praise to IEC members.
4.10.4.4. Caring about each IEC member as a person.
4.10.4.5. Encouraging IEC members to develop in their review skills.
4.10.4.6. Ensuring the opinions of IEC members count.
4.10.4.7. Communicating the mission of the MNR-MC IEC to protect subjects.

4.11. The IEC Meeting Chair may determine that certain IEC members have voting status and others have non-voting status.
4.11.1. The number of IEC members with voting status is not greater than the number of regular IEC members on the IEC roster.
4.11.2. All IEC members have voting rights
4.11.3. EC coordinator does not have any voting rights
4.11.4. Invited Consultants may not vote.

4.12. Ad hoc substitutes may not serve as IEC members.
4.13. Absent IEC members may submit written comments, but may not vote.
4.14. Observers may attend meetings, but:
4.14.1. May not participate in IEC deliberations unless requested by the IEC to serve as a consultant
4.14.2. Submitting an investigator's Head of Department may construe as a conflict if their academic thesis is presented
4.14.3. May not vote
4.14.4. Must agree to maintain the confidentiality of the IEC proceedings

4.15. When a protocol is ambiguous, the IEC may resolve the ambiguity by obtaining written information from the sponsor through investigator in advance of the meeting as an alternative to contingent approval, IEC members must be made aware of this information, either verbally or in writing.

4.16. Summarize the IEC's consensus.

4.16.1. Make a motion for one of the following:

4.16.1.1. "Approve": When the IEC determines that the initial, continuing, or modification submission meets the criteria for approval.

4.16.1.1.1. For initial and continuing review, include in the motion the period of approval (not to exceed one year) and the level of risk (minimal risk or greater than minimal risk).

4.16.1.2. "Conditionally Approve": When the IEC determines that the initial, continuing, or modification submission will meet the criteria for approval with minor or administrative changes or requirements that can be verified without considering the criteria for approval.[9]

4.16.1.2.1. For initial and continuing review, include in the motion the period of approval (not to exceed one year) and the level of risk (minimal risk or greater than minimal risk).

4.16.1.2.2. Summarise the IEC's required modifications and reasons.

4.16.1.3. "Defer": When the IEC determines that the initial, continuing, or modification submission does not meet the criteria for approval and also does not meet the criteria for "Disapprove."

4.16.1.3.1. Summarize the IEC's reasons and recommendations, if any.

4.16.1.4. "Disapprove": The initial, continuing, or modification submission does not meet the criteria for approval, and the IEC considers the research to have extensive deficiencies.

4.16.1.4.1. Summarize the IEC's reasons and recommendations, if any.

4.16.1.5. "Suspend": When the IEC determines that based on new information the previously approved research no longer meets the criteria for approval, but some research activities meet the criteria for approval, or the IEC has recommendations that may make the research meet the criteria for approval.

[9] Substantive changes or requirements, requests for more information for IEC consideration, and other issues related to the criteria for approval require review and approval by the convened IEC.

4.16.1.5.1. Include in the motion: Which research activities must stop or be modified

4.16.1.5.2. If the research in its entirety no longer meets the regulatory criteria for approval, include in the motion: Stop all research procedures (except as noted below) and stop enrollment

4.16.1.5.3. If stopping research will adversely affect the best interests of currently enrolled subjects, include in the motion: Which subjects can continue and what procedures can be performed

4.16.1.5.4. Summarize IEC's reasons and recommendations.

4.16.1.6. "Terminate": When the IEC determines that based on new information the previously approved research no longer meets the criteria for approval and the IEC has no recommendations to make the research approvable.

4.16.1.6.1. Summarize the IEC's reasons.

4.16.1.7. "Accept/ Acknowledge": The investigator require an affirmative reply in response to submitted materials but an action of "Approve" is not applicable

4.16.2. Ensure that the EC Coordinator/ staff taking minutes has recorded the IEC's actions, required modifications, reasons, recommendations, determinations, and findings.

4.16.3. Call for a vote of IEC members "For," "Against," or "Abstaining." If more than half the IEC members present votes "For," the motion is approved.

4.16.3.1. A tie vote to approve a motion for "Approve" or "Conditionally Approve" is considered to be an IEC decision of "Defer."

4.16.4. Have individuals with a conflicting interest rejoin the meeting.

4.16.5. If there are remaining agenda items, move them to another meeting.

4.17. Review the expert member's recommendations and write an independent recommendation for one of the following:

4.17.1. The research should proceed because it falls into approvable research. Use "CHECKLIST: HSR-201, HSR-202, and HSR-204".

4.17.2. The research does not meet the above criterion but should proceed because the following criteria are met:

4.17.2.1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of the general public, including but the safety is well known from previous clinical studies and is approved by CDSCO for marketing.

4.17.2.2. The research will be conducted in accordance with sound ethical principles.

4.17.2.3. Adequate provisions are made for soliciting the assent of children, the permission of their parents or guardians, and the consent of subjects.

4.17.3. The research with modifications should proceed under one of the above criteria.

4.17.4. The research should not proceed.

4.18. Adjourn the meeting when there is no further business or when notified by the EC Coordinator that quorum for all remaining agenda items cannot be met.

4.18.1. If there are remaining agenda items, move them to another meeting

4.19. Record Minutes in TEMPLATE: Minutes of the Meeting (HSR-408) to document minutes

4.20. Record at the beginning of the minutes:

4.20.1. "Members Present": Record the following information on IEC members present at any time during the meeting and having voting status at least once during the meeting[10]:

4.20.1.1. Name.

4.20.1.2. Status[11]

4.20.1.3. Whether the IEC member is an alternate

4.20.1.4. Whether the IEC member attended by teleconference.

4.20.2. "Others Present": Record the following information on individuals present at any time during the meeting who never have voting status:[12]

4.20.2.1. Name.

4.20.2.2. Role

4.21. Record the total number of regular members on the current IEC roster

4.22. If IEC members are present by teleconference, indicate whether they received all pertinent material before the meeting and were able to actively and equally participate in all discussions

4.23. Record the time the meeting is called to order.

4.24. Record a summary of the discussion of items unrelated to the review of specific research.

4.25. For each item related to specific research:

4.25.1. Record the type of review[13]

4.25.2. Record relevant information about the research:

4.25.2.1. Title

4.25.2.2. Principal investigator

4.25.2.3. IEC Approval number

4.25.2.4. Protocol number

4.25.2.5. Study title

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[10] If an IEC member has non-voting status for the entire meeting, list as an "Others Present."

[11] For example: IEC chair, IEC vice-chair, scientific member, non-scientific member, unaffiliated member, pediatric experience, prisoner representative

[12] This may include IEC members who are present for the meeting but never vote, consultants, non-IEC members, EC Coordinator, etc.

[13] For example: Initial, continuing, modification, unanticipated problem involving risks to subjects or others, serious non-compliance, continuing non-compliance, suspension of IEC approval, termination of IEC approval, study progress, etc.

4.25.2.6. Documents reviewed

4.25.3. When needed for clarity, summarize previous IEC actions.

4.25.4. If any item is not acted upon, record the reason[14].

4.25.5. If an expert member provided a verbal report, summarize the key information provided.

4.25.6. If there were any controverted issues (IEC members expressed a difference of opinion), summarize the issue, label as a controverted issue, and summarize the resolution, if any.

4.25.6.1. If there were no controverted issues, record this.

4.25.7. Record the motion.

4.25.7.1. For a motion of "Approve" or "Conditionally Approve" related to an initial or continuing review submission record:

4.25.7.1.1. The approval period

4.25.7.1.2. Whether the risk is lesser than 'Minimal Risk' or greater than 'Minimal Risk'

4.25.7.1.3. Any required checklist determinations along with study-specific findings supporting those determinations

4.25.7.2. For a motion of "Conditionally Approve" record the IEC's modifications required to secure approval and the reasons for those modifications.

4.25.7.3. For a motion of "Defer" record the IEC's reasons and recommendations.

4.25.7.4. For a motion of "Disapprove" record the IEC's reasons.

4.25.7.5. For a motion of "Suspend" record the specific activities suspended and the IEC's recommendations, if any.

4.25.7.6. For a motion of "Lift Suspension," no other information needs to be recorded.

4.25.7.7. For a motion of "Terminate" record the IEC's reasons.

4.25.8. Record the vote as the numbers:

4.25.8.1. "For": Voting for the motion.

4.25.8.2. "Against": Voting against the motion

4.25.8.3. "Abstained Voting": Present for the vote, but not voting "For" or "Against."

4.25.8.4. "Absent": Not present for reasons other than a conflicting interest.

4.25.8.4.1. Record the names of absent members (members in attendance at the meeting, but absent from the room for the vote)

4.25.8.5. "Recused": Not present for discussion and voting due to a conflicting interest

4.25.8.5.1. Record the names of recused members

[14] For example: Loss of all non-scientific members, missing expertise, meeting ended early due to fire alarm

4.25.8.6. Non-Voting Status: Present at the meeting but not in voting status (in voting status for some items but not in voting status for all items)

4.25.8.6.1. Record the names of members present in non-voting status

4.26. Record the time the meeting is adjourned.

4.27. Provide the minutes to the IEC Meeting Chair for review and approval, and provide to the IEC as an information item.

4.28. Provide approved minutes to the IEC Meeting Chair for signature.

4.29. The Worksheets and Checklists marked accordingly to be stored with the minutes for the applicable review.

4.30. Inform the investigator.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945

5.2. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines

5.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

5.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)

5.5. HSR-309

1. PURPOSE

1.1. This purpose of this SOP is to describe procedures to review research protocol involving a vulnerable population.

1.2. The SOP describes the requirements concerning the review of research that includes groups that could be potentially vulnerable to coercion regarding autonomy, and present conditions that may affect risk/ benefit determinations or bearing unequal burden in research.

2. POLICY

2.1. All research study protocol involving vulnerable population undergoes full IEC review.

3. RESPONSIBILITY

3.1. Particular attention should be paid to studies that may include vulnerable participants, such as children and participants who may have the capacity to make a decision but are unable to exercise that capacity, because prior consent could not be obtained in an emergency.

3.2. Vulnerable individuals/groups should not be included in research to solely benefit others who are better off than themselves

3.3. The IEC Chair/ Secretary reviews all study protocols and associated documents before setting up the meeting.

4. PROCEDURE

4.1. Vulnerable population includes:

- 4.1.1. Members of a group with a hierarchical structure:
  - 4.1.1.1. Students from MNR Educational Trust
  - 4.1.1.2. Employees of sponsor
  - 4.1.1.3. Members of the armed forces
- 4.1.2. Minors
- 4.1.3. Prisoners (persons kept in detention)
- 4.1.4. Participants with incurable diseases
- 4.1.5. Unemployed or impoverished persons
- 4.1.6. Those in emergencies.
- 4.1.7. Ethnic minority
- 4.1.8. Homeless persons
- 4.1.9. Nomads
- 4.1.10. Refugees
- 4.1.11. Tribal group
- 4.1.12. Terminally ill patients
- 4.1.13. Those incapable of giving consent (diminished autonomy, cognitive impairment, unconscious patient)
- 4.1.14. Persons or populations in conflict zones, riot areas or disaster situations

4.2. Identify a Reviewer/ Consultant, knowledgeable about or experienced in working with such participants.

4.2.1. Use "WORKSHEET: Criteria for Approval (HSR-301)

4.2.2. Review process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for a vulnerable population.

4.3. Research study protocols involving vulnerable population are subject to a full EC review, even if the risk is minimal.

4.4. A quorum is required to review such study protocols. Use "WORKSHEET: Quorum (HSR-313) to evaluate whether a quorum is available.

4.5. Assess for potential coercion

4.6. Assess justification of eligibility criteria of a vulnerable population.

4.7. Additional protections are provided as required by applicable laws, regulations, and guidance or as decided cumulatively by the IEC members to reduce coercion and allow autonomy.

4.8. Vulnerable groups may be recruited after proper justification is provided.

4.9. The study is monitored more frequently by IEC.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945

5.2. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines

5.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

5.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)

1. PURPOSE

1.1. This SOP establishes the process to obtain consultation on subject matter from an external individual/ agency.
1.2. This procedure begins when the IEC requires competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available on the IEC.
1.3. This procedure ends when the IEC is informed of the consultation.

2. POLICY

2.1. None

3. RESPONSIBILITY

3.1. The IEC Chair recommends a subject matter expert from outside the IEC.
3.2. The EC Coordinator arranges for a call or informs the member about the request from the IEC Chair.

4. PROCEDURE

4.1. Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:
  4.1.1. Contact the consultant and determine availability for review.
  4.1.2. Determine whether the consultant has a conflicting interest.
  4.1.3. Obtain the agreement of the consultant to maintain the confidentiality of information provided.
4.2. Use "POLICY: Expectations from IEC Members' For Review of Research Study Prior to Meeting (HSR-017)" to determine which documents to make available to the consultant so the IEC can obtain the additional expertise needed, and make these documents available to the consultant. If the required additional expertise needed does not require review of any materials, no materials need be provided.
4.3. If the consultant provides a written report, make the report available to other IEC members attending the meeting.
4.4. If the IEC Chair and Consultant decide to present face-to-face at the meeting, invite the consultant to the IEC meeting.
4.5. If requested by an IEC, invite the consultant to the IEC meeting.
4.6. For consultation obtained by telephone:
  4.6.1. Directly obtain the information (oral or written) from the consultant.
  4.6.2. Document information received with the name of the consultant.

5. REFERENCES

5.1. None.

1. PURPOSE

1.1. This procedure establishes the process for a waiver for obtaining informed consent.
1.2. No exemption of obtaining informed consent is allowed for regulatory-mandated clinical trials.
1.3. This procedure begins when the meeting is called to order to discuss.
1.4. This procedure ends when at the meeting the decision is taken.

2. POLICY

2.1. None

3. RESPONSIBILITY

3.1. The IEC members are responsible for reviewing and deciding.

4. PROCEDURE

4.1. The EC Coordinator receives the request letter along with other study-related documents from the submitting investigator.
4.2. The IEC Chair determines whether the request for a waiver for obtaining informed consent is justifiable.
4.3. The IEC Chair decides at a full board review.
- 4.3.1. Use "SOP: Reviewing Research Study Protocols that Require Regulatory Approval (HSR-110)".
- 4.3.2. Use TEMPLATE: Waiver for Obtaining Written Informed Consent (HSR-414).
- 4.3.3. Review relevant findings of 'Designated Reviewer.'
- 4.3.4. Focus on following criteria before a decision is made.
  - 4.3.4.1. Does not involve any investigational drug or device
  - 4.3.4.2. Research involves 'not more than minimal risk.'
  - 4.3.4.3. There is no direct contact between the researcher and the participant.
  - 4.3.4.4. The waiver will not adversely affect the rights and welfare of the participants.
  - 4.3.4.5. Research cannot practically be carried out without the waiver.
  - 4.3.4.6. The waiver is scientifically justified.
  - 4.3.4.7. A retrospective study, participants are de-identified or cannot be contacted.
  - 4.3.4.8. Research is on anonymized biological samples/ data.
  - 4.3.4.9. Public health study/ surveillance program/ epidemiological/ program evaluation studies.
  - 4.3.4.10. Research on data available in the public domain.
  - 4.3.4.11. Research during humanitarian emergencies and disasters, wherein the participant is not in a position to give consent. An attempt will be made to obtain the participant's consent at the earliest.

4.3.4.12. Waiver of assent (possible intervention is anticipated to benefit the child/ adolescent/ minor definitely).

4.3.4.13. Rights of the participants are not violated. Measures are described in the Study Protocol for protecting the confidentiality of data and privacy of research participant.

4.3.4.14. Where the participants are members of a cultural group in which signing forms is not a normal/acceptable practice.

4.3.5. It is not appropriate to request a waiver of documentation of informed consent for human subject projects that collect biospecimens

4.3.6. For some research projects, the IEC may approve a request to waive the documentation of informed consent. This means that the study team must provide a subject with the required consent information, but the study team is not required to obtain the subject's signature on the informed consent document.

4.3.6.1. The document (information sheet that describes the study and gives contact names and numbers) need to be submitted for the IEC review; or

4.3.6.2. A script for verbal consent that contains all of the elements of consent in a more informal style.

4.4. Make a motion for one of the following:

4.4.1. "Approve": When the IEC determines that the initial, continuing, or modification submission meets the criteria for approval.

4.4.1.1. For initial and continuing review, include in the motion the period of approval (not to exceed one year) and the level of risk.

4.4.2. "Disapprove": The initial, continuing, or modification submission does not meet the criteria for approval, and the IEC considers the research to have extensive deficiencies.

4.4.2.1. Summarize the IEC's reasons and recommendations, if any.

4.5. The IEC may decide to reverse its approval on a study in the event of receiving information that may adversely affect the benefit/risk ratio.

4.6. Ensure that the EC Coordinator/ staff taking minutes has recorded the IEC's actions, required modifications, reasons, recommendations, determinations, and findings.

4.7. EC Coordinator forwards the 'decision letter' signed by the IEC Chair.

5. REFERENCES

5.1. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

5.2. HSR-414.

1. PURPOSE

1.1. This procedure establishes the process to communicate the IEC's decision to the submitting investigator.
1.2. This procedure begins when the IEC has completed a review.
1.3. This procedure ends when the IEC has communicated its findings and actions to submitting Investigator, Organisation, or Regulatory Agency.

2. POLICY

2.1. Current regulations do not require ethics committees to report except for serious non-compliance, and continuing non-compliance.

3. RESPONSIBILITY

3.1. The IEC Chair and EC Coordinator carry out these procedures.

4. PROCEDURE

4.1. Use "TEMPLATE: IEC Decision Letter (HSR-409)". The 'decision' letter contains the following:
  4.1.1. Letter addressed to the submitting investigator
  4.1.2. List out the documents reviewed
  4.1.3. List of members present during the meeting
  4.1.4. Decision of IEC
  4.1.5. Instructions to the submitting investigator to let know the progress of the study, at least annually; any changes in the protocol and informed consent document, report all serious and unexpected adverse events to the Sponsor within 24 hours and to IEC within seven working days of their occurrence and a copy of the final study report.
4.2. Calculate the 'End Approval Date' following "POLICY: Calculation of End of Study Approval Date (HSR-010)".
4.3. Within seven calendar days of a decision, the following individuals or entities must receive notification from MNR-MC IEC to:
  4.3.1. The submitting investigator
  4.3.2. Agency, if it requires reporting.
  4.3.3. Other individuals or organizations determined to be appropriate by the IEC Chair.
4.4. The IEC may decide to reverse its approval on a study in the event of receiving information that may adversely affect the benefit/risk ratio.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945
5.2. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines

5.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
5.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)
5.5. HSR-409.

1. PURPOSE

1.1. This procedure establishes the process to manage new information received from the investigator or third parties.

1.2. This procedure begins when the IEC gets information that is not a request for a determination (regardless of whether the data is reportable) or receives reportable new information as part of a submission.

2. POLICY

2.1. None

3. RESPONSIBILITY

3.1. All individuals who can make decisions about new information carry out these procedures or ensure other personnel carries them out.

3.2. Individuals unsure of a decision in this SOP are to bring further information to the higher-level official, such as IEC Chair for a determination.

3.3. No deviations from approved protocol should be implemented without the prior written approval of IEC and CDSCO except when it is necessary to eliminate immediate hazards to the trial subject(s) or when a change(s) involve(s) only logistic or administrative aspects of the trial. All such exceptions must be immediately notified to IEC and CDSCO. Administrative and/or logistic changes in the protocol should be reported to the Licensing Authority within 30 days.

4. PROCEDURE

4.1. Ask the following five questions.

- 4.1.1. Does the information represent an allegation of non-compliance? If yes:
  - 4.1.1.1. Evaluate the charge of non-compliance to determine whether there is a basis in fact.
  - 4.1.1.2. If the final determination is that the allegation of non-compliance has a base in relaity, then this represents 'non-compliance'.
- 4.1.2. Does the information represent 'non-compliance? If yes:
  - 4.1.2.1. Evaluate the non-compliance to determine whether it is 'Serious Non-compliance' or 'Continuing Non-compliance'.
- 4.1.3. Does the information represent 'Serious Non-compliance?
- 4.1.4. Does the information represent 'Continuing Non-compliance?
- 4.1.5. Do the information represent an 'Unanticipated Problem Involving Risks to Subjects or Others'?

4.2. If the answers to all five questions above are "no":

- 4.2.1. Respond as needed to any complaint, query, or input. Use SOP: Responding to Research Participant's Request or Complaint
- 4.2.2. Follow any other applicable SOPs.
- 4.2.3. No further action is required under this SOP.

4.3. If the information represents 'Serious Non-compliance,' 'Continuing Non-compliance,' or an 'Unanticipated Problem Involving Risks to Subjects or Others':
  4.3.1. Discuss in the IEC meeting.
  4.3.2. Obtain a final decision
4.4. If the information represents non-compliance that is neither serious nor continuing non-compliance, evaluate any submitted corrective action.
  4.4.1. If the corrective action plan is insufficient, contact the research team to develop a sufficient correction action plan.
  4.4.2. If the research team develops an adequate corrective action, follow "SOP: Managing New Information (HSR-118)" to notify the submitter.
  4.4.3. Retract IEC approval for the study.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945
5.2. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines
5.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
5.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)

1. PURPOSE

1.1. This procedure establishes the process to institute a 'Suspension of IEC Approval' or 'Termination of IEC Approval' outside of a convened IEC meeting.
1.2. This procedure ends when the IEC notifies the investigator.

2. POLICY

2.1. The IEC may take these actions when in their opinion the rights and welfare of subjects may be at risk.

3. RESPONSIBILITY

3.1. Upon learning that there has been 'serious' allegations and confirmation, the IEC Chair convenes IEC meeting to discuss the issues.
3.2. The IEC may decide to reverse its approval on a study in the event of receiving information that may adversely affect the benefit/risk ratio.

4. PROCEDURE

4.1. Notify the investigator of the 'Suspension of IEC Approval' or 'Termination of IEC Approval' and the reasons for the action.
4.2. Ask the investigator for a list of currently enrolled subjects and their level of involvement in the research (e.g., active intervention or long-term follow-up.)
4.3. Consider whether the rights and welfare of currently enrolled subjects may be adversely affected. If so, consider the following actions:
  4.3.1. Transfer subjects to another investigator
  4.3.2. Make arrangements for clinical care outside the research
  4.3.3. Allow continuation of some research activities under the supervision of an independent Monitor.
  4.3.4. Require follow-up of subjects.
  4.3.5. Require adverse events or outcomes to be reported to the IEC.
  4.3.6. Notify current subjects.
  4.3.7. Other actions.
4.4. The decision to be documented and conveyed to the investigator.

5. REFERENCES

5.1. CDSCO Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines
5.2. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945

1. PURPOSE

1.1. This procedure establishes the process to manage allegations of undue influence on MNR-MC IEC review of research study protocol.
1.2. This procedure begins when MNR-MC IEC learns of an allegation of undue influence of MNR-MC IEC.
1.3. This procedure ends when any undue influence of the MNR-MC IEC has been mitigated.

2. POLICY

2.1. Individuals responsible for business development in MNR Educational Trust may not serve as IEC members and may not be involved in daily operations of the review process, and may not discuss business development with IEC members.
2.2. All individuals in MNR-MC IEC are required to ensure that allegations of undue influence or review process are reported to the IEC Chair within five days of becoming aware of the charge/ complaint.

3. RESPONSIBILITY

3.1. The IEC Chair carries out these procedures .

4. PROCEDURE

4.1. Gather information to determine the integrity of the report using discretion regarding the most efficient and effective methods. Methods to gather information can include, but are not limited to:
  4.1.1. Interviews of individuals inside and outside MNR-MC IEC.
  4.1.2. Review of records inside and outside MNR-MC IEC.
  4.1.3. Consultation with internal or external entities.
4.2. If the report has no basis in fact, take no further action under this SOP.
4.3. Take appropriate steps to eliminate the undue influence using discretion regarding the most efficient and effective methods. Measures may include, but are not limited to:
  4.3.1. No action
  4.3.2. Verbal counseling
  4.3.3. Educational
  4.3.4. Reassignment of duties
  4.3.5. Termination from IEC.
4.4. Document the findings and actions, if any, related to undue influence.
4.5. Provide the information to the organisation, MNR Educational Trust.

5. REFERENCES

5.1. None.

1. PURPOSE

1.1. This procedure establishes the process for handling active and those IEC records of studies that are closed.
1.2. This procedure begins every six months.
1.3. This procedure ends when all records that are no longer required to be retained are destroyed.

2. POLICY

2.1. Study files' relating to ongoing research are safely maintained at the work area to ensure retrieval at any time and ensured confidentiality.
2.2. Study files relating to research, which has been conducted are securely kept (boxed) after the completion/ termination of the study for at least 5 years, if it is not possible to maintain the same permanently.
2.3. Study files designated by legal counsel as being on "legal hold" are not to be destroyed until the legal hold is removed.
2.4. Study files relating research, which has not been conducted, are retained for at least one year.
2.5. Study files relating to research with no subject enrollment are kept for at least three years after completion of the study.
2.6. The following documents are retained indefinitely:
  2.6.1. IEC meeting minutes
  2.6.2. A resume or curriculum vitae for each IEC member
  2.6.3. Current and previous versions of IEC member rosters
  2.6.4. Current and previous versions of controlled documents (Policy, SOP, Checklist, Worksheet, and Template)

3. RESPONSIBILITY

3.1. EC Coordinator carries out these procedures upon IEC Chair's instructions.
3.2. Only current MNR-MC IEC members and EC Coordinator have access to study-related documents, internal functioning, and correspondence.
3.3. EC Coordinator will provide information or document to auditors/ assessors or inspectors upon instruction from IEC Chair/ Secretary. No other external individual or agencies will have access to IEC documents.

4. PROCEDURE

4.1. All documentation and communication of IEC are dated, filed, and preserved as mentioned above.
4.2. Maintain the confidentiality of all study-related documents, internal functioning, and correspondence.
4.3. Strict secrecy is to be maintained during access and retrieval procedures.
4.4. Records should be kept for the following:
  4.4.1. Constitution and composition of IEC.
  4.4.2. Curriculum vitae of all IEC members.
  4.4.3. Policies, SOPs, Checklists, Worksheet, and Template.
  4.4.4. Applicable regulations and guidelines.

4.4.5. Copies of the study protocol, data collection formats (CRF), investigator's brochure, etc. submitted for review.
4.4.6. All correspondence with investigators regarding the application, decision and follow up.
4.4.7. Agenda of all IEC meetings.
4.4.8. Minutes of all IEC meetings with the signature of the Chair
4.4.9. Record of all notification issued for premature termination of a study with a summary of the reasons
4.4.10. Final report of the study including microfilms, CDs and Video-recordings

4.5. When a document is requested and approved by the IEC Chair, a log is made containing the name and signature of the individual receiving the copy; the initial of the IEC Secretary/ EC Coordinator who made the copy; the number of copies made, the date that the copies were made, and reasons for request.
4.6. If an application is rejected, the same is communicated to the requestor with reasons.
4.7. Review the study files that can be destroyed.
4.7.1. Omit destruction of records on legal hold.
4.7.2. Previously approved studies: Five years after the date on which MNR-MC IEC oversees all research sites have been completed either through closure, termination of IEC approval, disapproval, or lapse of approval.
4.8. Notify information technology to save electronic documents, including IEC approvals and store in a computer or hard drive for retrieval at a later stage.
4.9. Document name and the date of destruction with the following for each study file destroyed (confidential bins, shredding, recycling, secure electronic disposal):
4.9.1. Filename
4.9.2. A brief description of the records (individual records need not be listed)
4.9.3. Date, the files were retained
4.9.4. Reason for disposal
4.9.5. The method used to destroy the records (confidential bins, shredding, recycling, secure electronic disposal). Shred paper documents that are not required. Dispose of the shredded materials securely.
4.10. Do not destroy any records pertaining to an ongoing or reasonably anticipated investigation, legal action or proceeding, audit or study review, even if the retention period or disposition date specified for the records has already expired.
4.11. Scan and save the completed form as PDF after Destructions Completed by section has been completed.
4.12. Retain a copy for records.

5. REFERENCES

5.1. CDSCO Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines

5.2. HSR-417
5.3. HSR-418
5.4. HSR-419

1. PURPOSE

1.1. This procedure establishes the process for handling when investigator team fail to:

1.1.1. Follow the procedures written in the IEC approved protocol

1.1.2. Comply with applicable regulations and guidelines, IEC instructions and Organisation policies.

1.1.3. Respond to IEC requests regarding statutory, ethical, scientific, or administrative matters.

2. POLICY

2.1. None

3. RESPONSIBILITY

3.1. IEC Chair, IEC Secretary, EC Coordinator, Investigator, Research Team member and management of the institution are responsible for bringing to the notice of the IEC that investigator or their team has failed to:

3.1.1. Follow the procedures written in the IEC approved protocol

3.1.2. Comply with applicable regulations and guidelines, IEC instructions and Organisation policies.

3.1.3. Respond to IEC requests regarding statutory, ethical, scientific or administrative matters

4. PROCEDURE

4.1. Detection of major Protocol Deviation/ Non-Compliance/ Violation

4.1.1. The IEC members while monitoring the study may detect protocol non-compliance (deviation/ violation)

4.1.1.1. Failure to comply with statutory requirements

4.1.1.2. Failure to respond to communications from IEC within a reasonable time limit

4.1.1.3. Communication/ complaint/ information received from research participant or others who have been enrolled or any individual who has been approached for enrolment

4.1.2. The monitoring IEC members inform the IEC Chair in writing within five working days, of any detection.

4.1.3. The IEC Chair scrutinises (initial scrutiny) the violation/ non-compliance/ deviation for gravity and implications.

4.1.4. The IEC Chair/ Secretary shall document the findings individually or in the form of a report.

4.1.5. Depending upon their judgment, the IEC shall:

4.1.5.1. Ask PI for written clarification as soon as the deviation is received.

4.1.6. The actions taken by IEC include one or more of the following:

4.1.6.1. Warn the Principal Investigator that IEC has noted the violation/ noncompliance/deviation and that the same

does not occur in future and follow IEC recommendations.

4.1.6.2. Enlist measures that the PI would undertake to ensure that deviations/non-compliances/ violations do not occur in future

4.1.6.3. Reprimand the PI.

4.1.6.4. Suspend the study till the additional information is made available and is scrutinised.

4.1.6.5. Suspend the study till the PI implement recommendations made by the IEC and found to be satisfactory by the IEC.

4.1.6.6. Suspend the study for a fixed duration of time.

4.1.6.7. Inform the Organisation.

4.1.6.8. Revoke approval of the current study.

4.1.6.9. Inform relevant regulatory authorities.

4.1.6.10. Keep other research proposals from the PI under abeyance.

4.1.6.11. Review and/ or inspect other studies undertaken by PI.

4.1.6.12. Refuse to review subsequent applications from an investigator cited for non-compliance for a specified duration of time.

4.1.6.13. Any other action considered appropriate by the IEC for safeguarding the interests of the research participants participating in the current trial or future trials.

4.1.7. The activities are based on:

4.1.7.1. The nature and seriousness of the non-compliance.

4.1.7.2. The frequency of non-compliance.

4.1.8. Notifying the Principal Investigator

4.1.8.1. The EC Coordinator notifies the investigator signed by the IEC Chair within 14 calendar days of the meeting

4.1.8.2. If the IEC decides to suspend/terminate the approval study progress, the Principal Investigator is notified within one working day of the meeting.

5. REFERENCES

5.1. CDSCO Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines

1. PURPOSE

1.1. This procedure establishes the process for handling the review of initial and follow-up reports of serious adverse events occurring at the site.

2. POLICY

2.1. None

3. RESPONSIBILITY

3.1. The IEC is responsible for reviewing reports of SAE that have occurred at the trial site approved by the IEC.
3.2. The IEC Chair constitutes a Sub-Committee to review SAE Reports consisting of IEC members and if required a subject matter expert (consultant/ designated reviewer).

4. PROCEDURE

4.1. The nominated head of 'SAE Review Sub-Committee' chairs the meetings of the Subcommittee.
4.2. The EC Coordinator coordinates the activities and minutes the meeting of the SAE Review Sub-Committee.
4.3. The EC Coordinator receives the SAE Report that contains data elements for reporting SAEs occurring in a clinical trial as per Appendix XI of Schedule Y.
4.4. The Principal Investigator should submit within 24 hours, SAE report to the IEC accompanied by a detailed narrative of the SAE
4.5. As per Schedule Y of the Drugs & Cosmetics Act, the Principal Investigator is required to sponsor within 14 days. A copy of this should be requested from the PI as well.
4.6. The SAE Review Sub-Committee meets within seven days of been informed of SAE occurrence.
4.7. The Sub-Committee will perform Causality Assessment with the reasoning for Relatedness/Un-relatedness.
4.8. If required, the Sub-Committee will request the Principal Investigator to give relevant information, including SAEs from other sites from same study.
4.9. The minutes of the Sub-Committee meeting is submitted to the IEC Chair within five working days after the meeting and discussed at the forthcoming regular full board IEC meeting.
4.10. The report from Sub-Committee includes the following information. Use template WORKSHEET: Sub-Committee's Report on SAE (HSR-416).
    4.10.1. Date of report
    4.10.2. Protocol number
    4.10.3. Protocol title
    4.10.4. Name of Principal Investigator
    4.10.5. General information on the number of participants enrolled, ongoing, completed and drop-outs
    4.10.6. Subject ID
    4.10.7. Age

4.10.8. Gender
4.10.9. Event (Diagnosis/ Symptom/ Sign)
4.10.10. Date and time of onset
4.10.11. Date of reporting to IEC
4.10.12. Type of report (initial or follow-up)
4.10.13. SAE criteria
4.10.14. Was the investigational product administered?
4.10.15. Is the blind broken?
4.10.16. Is the investigational product withdrawn?
4.10.17. Outcome
4.10.18. Causality as per PI and Sub-Committee
4.10.19. Recommendations, if any
4.10.20. Names of Sub-Committee members and Consultant, if available

4.11. If appropriate to the discussions, the IEC Chair call for a consensus on whether to:
4.11.1. Request further information. If required
4.11.2. Suggest changes amendments in the protocol, participant information sheet/informed consent document.
4.11.3. Suspend or terminate the study till the additional information is available if more SAEs are seen, and Principal Investigator is in concurrence
4.11.4. Suspend the study till review is completed (safety monitoring of ongoing patients to be continued).
4.11.5. Suspend the study till amendments requested by IEC are carried out.
4.11.6. Suspend enrollment of new participants.
4.11.7. Suspend certain activities under the protocol.
4.11.8. Direct the PI to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial.
4.11.9. Direct the PI to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, further investigations etc. as prescribed in the amendment.
4.11.10. Any other appropriate action

4.12. The decision of the IEC requiring an immediate response from the PI is conveyed to the PI through Letter/telephone, or email within 24 hours.
4.13. The communication is documented as minutes of the meeting (IEC decision)
4.14. Formal letter to the PI informing about the IEC recommendations in such situations is sent within five working days of the IEC meeting having taken place.
4.15. Regulations require Sponsor/ Principal Investigator to provide medical treatment for as long as needed or until such time it is established that the injury is not related to the clinical trial, whichever is earlier. When the participant suffers no permanent damage, the quantum of compensation should be proportionate to the nature of the non-permanent injury and loss of wages.
4.16. The IEC expects information on medical management given by the Principal Investigator on weekly basis till recovery or death.

4.17. The IEC communicates to CDSCO along with its opinion on relatedness or unrelated of investigational product to the event within 30 days of occurrence of SAE.

4.18. Depending on the report of expert committee, CDSCO determines the quantum of compensation of the SAE. The IEC does not specify the quantum of payment.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945

5.2. CDSCO Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines

5.3. HSR-416

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5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945
5.2. CDSCO Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines
5.3. HSR-416

1. PURPOSE

1.1. This procedure establishes the process to conduct annual tasks (January to December calendar year) related to MNR-MC IEC functioning.
1.2. This procedure begins every year in January.
1.3. This procedure ends when evaluations and corrective actions are completed.

2. POLICY

2.1. MNR-MC IEC is required to conduct annual tasks including self-assessment and monitoring of research studies (for cause or routine as decided in the meeting) that have been approved. Such a review may be based on the periodic study progress reports furnished by the investigator and/or monitoring and internal audit reports provided by the Sponsor and/or by visiting the study sites.
2.2. On-site monitoring of an approved study by the IEC ascertains ethical conduct of clinical research.

3. RESPONSIBILITY

3.1. The IEC Chair delegates IEC Member(s) to carry out these procedures.

4. PROCEDURE

4.1. Obtain updated résumés or curricula vitae from each IEC member and EC Coordinator or confirmation that there has been no change.
4.2. Evaluate in consultation with other IEC members as appropriate:
  4.2.1. General performance of MNR-MC IEC, such as:
    4.2.1.1. Feedback from Investigators, research staff, Sponsors, and Subjects
    4.2.1.2. Results of inspection of IEC by CDSCO or NABH
    4.2.1.3. Compliance with policies and procedures
    4.2.1.4. Compliance with regulatory requirements
    4.2.1.5. Status of action items from previous reviews
    4.2.1.6. Audit of IEC functioning by experienced third-party consultants.
  4.2.2. Resources for:
    4.2.2.1. Space
    4.2.2.2. Personnel
    4.2.2.3. Training of IEC members
    4.2.2.4. Documents archival
  4.2.3. Number of IECs relative to the volume and types of research reviewed
4.3. On an annual basis (routine) or for-cause, the IEC Chair designates IEC member(s) to monitor study(ies).
  4.3.1. For-cause monitoring includes any one or more of the following:
    4.3.1.1. The high number of protocol violations
    4.3.1.2. A large number of studies carried out by the investigator
    4.3.1.3. An unanticipated number of SAEs

4.3.1.4. Unusual recruitment rate
4.3.1.5. Non-compliance
4.3.1.6. Suspicious conduct
4.3.1.7. Complaints received from participants
4.3.1.8. Any other cause as decided by IEC.

4.3.2. The EC Coordinator contacts the investigator and notifies them about the IEC's decision to monitor the study and the date of visit.
4.3.3. EC Coordinator provide relevant study related documents
4.3.4. In advance, the designated IEC member reviews all the study-related documents, research team CVs, and IEC communications.
4.3.5. Use "TEMPLATE: Study Monitoring Visit Report (HSR-415)" reporting findings from monitoring of approved studies.
4.3.6. The IEC will submit the summary of the Study Monitoring Visit Report Form to the IEC Chair within 14 calendar days of conducting the visit.
4.3.6.1. The IEC Secretary presents the summary of the findings at the next full board IEC meeting.
4.3.6.2. The IEC discusses the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
4.3.6.2.1. Continuation of the project with or without changes
4.3.6.2.2. Restrictions on enrolment
4.3.6.2.3. Recommendations for additional training
4.3.6.2.4. Recruiting additional members in the study team
4.3.6.2.5. Revising/ providing qualifications/ experience criteria for members of the study team, termination of the study,
4.3.6.2.6. Suspension of the study
4.3.6.2.7. Any other, as decided cumulatively by the IEC.

4.3.7. The EC Coordinator conveys the decision to the Principal Investigator in writing within 14 days of the meeting.
4.3.8. The EC Coordinator files the report.
4.3.9. Use "WORKSHEET: IEC Composition (HSR-312)" for composition of IEC.
4.3.10. Completion of required training by IEC members and EC Coordinator

4.4. Provide a copy of the evaluation to MNR Educational Trust.
4.5. Take actions as needed to:
4.5.1. Reallocate, add, or modify resources
4.5.2. Modify the composition of IECs
4.5.3. Correct knowledge and performance gaps of individuals
4.5.4. Arrange for individuals to take missing training
4.5.5. Modify policies and procedures
4.6. Update IEC registration.
4.7. Renew IEC registration, if more than three years old.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945

5.2. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines

5.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

5.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)

5.5. HSR-415.

1. PURPOSE

1.1. This procedure establishes the process to convene unscheduled meetings.
1.2. The process begins when additional meetings need to be scheduled on urgent basis.
1.3. The process ends when the meeting is scheduled.

2. POLICY

2.1. MNR-MC IEC may convene unscheduled meetings to deal with urgent issues that the IEC cannot address in a scheduled meeting, provided members are given timely notification and a justification for convening the unscheduled meeting.

3. RESPONSIBILITY

3.1. IEC Secretary & EC Coordinator carries out these procedures on instruction from IEC Chair.

4. PROCEDURE

4.1. Based on the request, the IEC Chair decides to convene a meeting.
4.2. The IEC Chair informs IEC Secretary and EC Coordinator to schedule the meeting.
4.3. Contact by telephone or email the IEC member(s) that would be considered as sufficient.
4.4. EC Coordinator sends all the required information to all the attending IEC Members.
4.5. At the meeting, the IEC Chair will determine if there is a quorum.
4.6. If a quorum/ majority is not met, the meeting will be postponed for 15 minutes.
4.7. If there is no quorum at the end of 15 minutes; the meeting is held without a quorum provided at least three members, including the IEC Chair, IEC Secretary and another member relevant to the subject matter of the meeting are present, given the urgency of the case under consideration.
4.8. For studies that require regulatory approval, follow SOP: Reviewing Research Study Protocols that Require Regulatory Approval (HSR-110)
4.9. The 'outcome of the meeting' letter contains the following. Use SOP: Communicating IEC's Decision to Investigator (HSR-117).
    4.9.1. Letter addressed to the requestor
    4.9.2. List out the documents reviewed, if any
    4.9.3. List of members present during the meeting
    4.9.4. Decision of IEC

5. REFERENCES

5.1. None.

1. PURPOSE

1.1. This procedure establishes the process to assist investigator (now treating physician) to comply with CDSCO requirements for compassionate use of the investigational product after completion of the research study. Expanded access (also called "compassionate use") is the use of investigational drugs, biologics, or medical devices outside the clinical trial setting for treatment purposes.

1.2. This procedure begins when an investigator notifies the IEC of a situation that might involve a compassionate use.

1.3. This procedure ends when the IEC informs the submitter of whether the use complies with CDSCO requirements.

2. POLICY

2.1. Investigator (now treating physician) is to notify the IEC in advance of a proposed compassionate use.

2.2. Compassionate use of an investigational product prior to marketing cannot be used in an investigation designed to develop or contribute to generalizable knowledge.

2.3. Sponsor and IEC can inform investigator of whether a proposed use, if carried out as described, will meet CDSCO requirements or whether a user already carried out met CDSCO requirements.

2.4. The IEC has no authority to prospectively or retrospectively approve or disapprove a use.

3. RESPONSIBILITY

3.1. The IEC chair carries out these procedures when an investigator requests for continued use of an investigational product on a compassionate basis after the clinical trial has been closed.

4. PROCEDURE

4.1. Review the information provided and if needed contact the submitter or physician.

4.2. Determine whether the situation requires compassionate use. If so use, "WORKSHEET: Compassionate Use of Investigational Medicinal Product (HSR-314)."

4.3. Expanded access may be appropriate when all the following apply:

- 4.3.1. Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- 4.3.2. There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- 4.3.3. The investigational product is not available in the market.
- 4.3.4. Patient enrollment in a clinical trial is not possible.
- 4.3.5. Potential patient benefit justifies the potential risks of treatment.

4.3.6. Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.
4.3.7. There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
4.3.8. The patient cannot obtain the drug under another IND or protocol.
4.3.9. The potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated.
4.3.10. Providing the investigational drug will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

4.4. Determine whether CDSCO has approved the use.
4.5. Notify the submitter of the determination or work with the submitter to have the use comply with CDSCO requirements.
4.5.1. If a use was carried out and did not meet CDSCO requirements, handle this as 'Non-compliance' under "SOP: Managing New Information (HSR-118)."
4.6. Notify the EC Coordinator handling the submission of the decision to file the information.

5. REFERENCES

5.1. Schedule Y of the Drugs & Cosmetics Act, 1940 and Rules, 1945
5.2. Central Drugs Standard Control Organisation (CDSCO) Guidelines for Biomedical Research on Human Subjects Good Clinical Practice (GCP) guidelines
5.3. Indian Council of Medical Research (ICMR)-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants
5.4. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2)
5.5. HSR-314.
5.6. HSR-118.

1. PURPOSE

1.1. The purpose of this SOP is to provide guidelines when IEC receives a request for information about the study or complaint from research participants regarding their rights as a participant or to resolve their claim that is/ are related to their participation in research/ trial approved by IEC

2. POLICY

2.1. The MNR Medical College & Hospital Institutional Ethics Committee (MNR-MC IEC) is duly constituted to safeguard the rights, safety, and well-being of all trial subjects. Particular attention should be paid to trials that may include vulnerable subjects.

2.2. The IEC is entrusted not only with the initial view of the proposed research protocol prior to initiation of the projects but also have a continuing responsibility of regular monitoring for the compliance of the ethics of the approved program till the same is completed.

2.3. HSR-001.

3. RESPONSIBILITY

3.1. The IEC Chair may delegate IEC Secretary to give information to the participant or to identify and address any injustice that has occurred if complaints are received from research participants.

3.2. The EC Coordinator in discussion with the IEC chair carries out these procedures when a request for information is received.

4. PROCEDURE

4.1. After receiving a request for information, complaint, or query, the EC Coordinator will collect the letter/ email/ or verbal complaint and forward the request to the IEC Chair/ Secretary.

4.2. The IEC Chair will ascertain if the concerned individual has been approached to participate in the study or is already participating in the study based on documents available with IEC.

4.3. If information on the study is required, the IEC will call for relevant information and documents from the investigator, as needed.

4.4. Consider the matter for discussion at the next full board meeting, call an emergency meeting of two or more IEC members for consultation, or appoint a subcommittee of two or more IEC members for an enquiry to address the matter.

4.5. The IEC Chair will assess the situation and mediate a dialogue between the research participant and the investigator in an attempt to resolve the issue.

4.6. The IEC will insist on factual details to determine gap, if any, between truth and individual perception.

4.7. The IEC takes the final decision based on any one or a combination of processes listed below:

4.7.1. Discussions at the Full-Board meeting

4.7.2. The conclusion by selected/ designated IEC members

4.7.3. The report provided by the subcommittee appointed by IEC Chair

4.8. The IEC Secretary informs the final decision to the research participant.

4.9. The information including any action taken or follow-up will be recorded and is signed and dated.

4.10. The IEC members are informed about the action taken and the outcomes in the forthcoming IEC meeting.

4.11. If required, the IEC Chair discusses with the Organisation Official, if the complaint and findings impact the Organisation.

4.12. The EC Coordinator mentions the decision in the minutes of the meeting.

5. REFERENCES

5.1. None.