2013-2014

Institute Ethics Committee

Standard Operating Procedures -Human Studies

All India Institute of Medical Sciences (AIIMS)
Patna, Bihar – 801505

Standard Operating Procedures for Institute Ethics Committee, All India Institute of Medical Sciences, Patna

I. Standard Operating Procedures (SOPs)

AIIMSP IEC SOP Version: 1.0 Date: 04/10/2013 Pages: 33

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III. SOPs reviewed and approved by: Institute Ethics Committee

Name and designation	Signature with date
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IV. SOPs accepted by:

Name and designation	Signature with date
Dr G.K. Singh Director, AIIMS, Patna	

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I. Short Description of SOP

The following may be called as "Standard Operating Procedures for the Institutional ethics committee (IEC) of All India Institute of Medical Sciences, Patna".

II. Adoption of SOP

All India Institute of Medical Sciences, Patna herein after referred to as "AIIMS-P" has adopted these written Standard Operating Procedures (SOP) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at AIIMS-P.

III. Objectives of SOP

The objective of this Standard Operating Procedures of the Institutional ethics committee (IEC) of All India Institute of Medical Sciences, Patna is to maintain effective functioning of the AIIMS-P-IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

IV. Authority for constituting the AIIMS-P IEC

The Dean of Faculty in consultation with the Director, AIIMS-P will appoint the Chairperson and all the committee members based on their competence, experience and integrity by sending an official request letter (Annexure 1A & 1B). Members will confirm their acceptance to the Dean by providing all the required information for membership (Annexure 2). The Chairperson will furnish any information or report to the Dean of Faculty, AIIMS-P when required.

V. Role and Responsibilities of AIIMS- P IEC

The AIIMS-P-IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellb eing of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and wellb eing of the human participants.

The AIIMS-P-IEC will ascertain whether all the cardinal principles of research ethics viz., *Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons , Respect for Privacy and Confidentiality and Justice* are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of *protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations*. It will review the proposals before the commencement of the study as well as review periodically until the completion of the study through

appropriate well documented procedures. Such a review may be based on the periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and/or by visiting the study sites.

The mandate of the IEC shall be to review all research projects to be conducted at the Institution involving human beings directly or indirectly, irrespective of whether the research project is funded or non-funded, and if funded, then irrespective of the funding agency.

AIIMS-P IEC will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research.

In case AIIMS-P IEC revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator as well as to the Licensing Authority.

In case of serious adverse event or death occurring to the clinical trial participant, the AIIMS-P IEC shall forward it's report on the serious adverse event or death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission form the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Chairman of the Expert committee constituted by the Licensing authority under Appendix XII (gazette notification 30th January 2013) with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event of death. In case of serious adverse event, other than death occurring to the clinical trial subject, the AIIMS-P IEC shall forward it's report on the serious adverse event after due analysis along with its opinion on the financial compensation, if any, to be paid by the sponsor of his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, to the licensing authority within twenty one calendar days of the occurrence of the serious adverse event.

VI. Composition of AIIMS-P-IEC

AIIMS-P-IEC will be a multidisciplinary and multisectorial body in composition and independent. The number of members of the Review Board may range from 7 to 15.

The chairperson of the IEC will be from outside the Institution to maintain the independence of the Committee. The Member Secretary will belong to the same Institution and will conduct the business of the Committee. Other members will be a mix of medical / non-medical, legal, scientific and non-scientific persons and may also include members of public to reflect the different points of view.

There will be representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society. Member should be aware of local, social and cultural norms, as this is an important social control mechanism. IEC may invite subject experts to take their views, whenever it is needed.

The AIIMS-P-IEC will include

1. Chairperson –from outside the institute
2. One or more persons from basic medical science area (One pharmacologist compulsorily, one female member compulsory)
3. One or more clinicians
4. One legal expert or retired judge
5. One social scientist/ representative of non-governmental voluntary organization/agency
6. One philosopher/ ethicist/ theologian
7. One lay person (non-medical background) from the community
8. Member Secretary – from within the institute

A Sub-Board of the main IEC may review proposals submitted by undergraduate or post-graduate students or if necessary, an IEC may be separately constituted for the purpose, which will review proposals in the same manner as described above.

VII. Requirements for IEC Membership

1. All members will serve for a period of 3 years on renewable basis. New members will be Included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.
2. During the term, Dean of the Faculty in consultation with the Chairman can disqualify any member if, the contribution is not adequate and/or there is long period of non-availability.
3. A member can tender resignation of his office of membership from the IEC to the Dean of Faculty through the Chairperson after serving one month advance notice.
4. Dean can replace the member of IEC as and when required.
5. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities (Annexure 2)
6. Conflict of interest should be declared by members of the AIIMS-P-IEC prior to review meeting.

VIII. Quorum requirements

Minimum of 50% of committee strength and not less than 6 members are required to constitute the quorum for the meeting of which at least one member has to be from outside the institution, and one member will be a non-scientific member & one from opposite gender. All decisions will be taken in meetings and not by circulation of project proposals. Quorum will have 6 members with following representations:

(a) Basic medical scientists (preferably one pharmacologist).
(b) Clinician
(c) Legal expert
(d) Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
(e) Lay person from the community.

IX. Quorum requirements

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(f) Basic medical scientists (preferably one pharmacologist).
(g) Clinicians
(h) Legal expert
(i) Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
(j) Lay person from the community.

X. Conduct of AIIMS- P IEC meetings

The Chairperson will conduct all meetings of the AIIMS-P IEC. In the absence of the Chairperson an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/She will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.

XI. Independent consultants

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

XII. Application procedures

1. All proposals should be submitted on any working day ***2 weeks in advance*** of scheduled meeting in the prescribed application form, the details of which are given under "XII Documentation". The applicant may ask for copy of SOP from the IEC, if the same has not been circulated earlier or not available on the website.

2. All relevant documents should be enclosed with application form. (Documents will be available with Member - Secretary, AIIMS-P IEC and Institutional Website www.aiimspatna.org).

3. Required number of copies of the proposal along with the application and documents in prescribed

format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / Research Scholars shall be guided to the Chairperson AIIMS-P IEC, through member secretary. In his absence via any person nominated by Chairperson, receipt of the application will be acknowledged by the IEC office.

4. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.

5. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

6. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5%. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non Profitable Organizations etc.

XIII. Documentation

All Research proposals (6 copies along with 1 CD/DVD) shall be submitted along with the information and documents as specified in Annexure-3A, 3B and Annexure 5-7.

XIV. Review procedures

1. The meeting of the IEC will be held on periodic intervals, i.e. 1st Monday of Jan, March, May, July, Sep, Nov, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.
2. The proposals should be sent to the IEC at least 2 weeks in advance of scheduled meeting.
3. The IEC's member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, *exemption from review, expedited review and full review* (as described below).
4. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final.
5. Researchers will be invited to offer clarifications if need be. The PI / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will present the proposal.
6. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
7. The decisions will be minuted and Chairperson's approval taken in writing.

1. Exemption from review

Proposals which present *less than minimal risk* fall under this category as may be seen in following situations:

- Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **Exceptions**:

1. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
2. When interviews involve direct approach or access to private papers.

2. Expedited Review

The proposals presenting *no more than minimal risk* to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve -

1. Minor deviations from originally approved research during the period of approval.
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories:
   - Clinical studies of drugs and medical devices only when -
     1. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
     2. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and **the same participants should not be included** in the clinical trial that may be initiated later based on the findings of the pilot study.
   a. Research on interventions in emergency situation

      When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices / vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients -

      i. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should

be given to the relative/ legal guardian when available later;

ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;

iii. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b. Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.

ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.

iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv. Protection must be ensured so that only minimal additional risk is imposed.

v. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.

vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

6. Expedited review may also be taken up for nationally relevant proposals requiring urgent review.

3. Full Review

All research presenting with *more than minimal risk*, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:

i. From healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;

ii. From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week.

iii. From neonates depending on the hemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;

iv. Prospective collection of biological specimens for research purposes by noninvasive means. For instance:

1. Skin appendages like hair and nail clippings in a non-disfiguring manner;
2. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
3. Excreta and external secretions (including sweat);
4. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
5. Placenta removed at delivery;
6. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
7. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
8. Sputum collected after saline mist nebulization and bronchial lavages.

b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance

i. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;

ii. Weighing or testing sensory acuity;

iii. Magnetic resonance imaging;

iv. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow,

v. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

d. Collection of data from voice, video, digital, or image recordings made for research purposes.

e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

XV. Aspects considered during review of research proposal

1. Scientific design and conduct of the study.
2. Approval by appropriate scientific review committees / Research committee, if any.
3. Examination of predictable risks/harms
4. Examination of potential benefits.
5. Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.
6. Management of research related injuries, adverse events.
7. Compensation provisions.
8. Justification for placebo in control arm, if any
9. Availability of products, benefits to subjects after the study is completed if applicable.
10. Patient information sheet, informed consent form in English and in local languages.
11. Protection of privacy and confidentiality.
12. Involvement of the community, wherever necessary
13. Plans for data analysis and reporting.
14. Adherence to all regulatory requirements and applicable guidelines.
15. Competence of investigators, research and supporting staff.
16. Facilities and infrastructure of study sites.
17. Criteria for withdrawal of patients, suspension or premature termination of a study in AIIMS-P.

XVI. Decision-making

1. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.
2. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
3. Decision will be made only in meetings where quorum is complete.
4. Only the members can make the decisions. The expert consultants will only offer their opinions.
5. Decision may be to approve, reject or revise the proposals. Specific *suggestions for modifications and reasons for modifications and reasons for rejection* will be given.
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
7. *Modified proposals will be reviewed by an expedited review* through identified members.
8. Procedures for appeal by the researchers will be clearly defined.

XVII. Communicating the decision

1. Decision of the meeting on the proposals will be communicated by the Member Secretary/secretariat in writing to the PI / Research Scholar within two weeks after the meeting at which the decision was

taken in the specified format. All the approvals will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.

2. The communication of the decision will include:
    a. Name and address of IEC.
    b. The date, place and time of decision.
    c. The name and designation of the applicant.
    d. Title of the research proposal reviewed.
    e. The clear identification of protocol no., version no., date, amendment no., date.
    f. Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.
    g. List of EC members who attended the meeting- clear description of their role, affiliation and gender.
    h. A clear statement of decision reached.
    i. Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the AIIMS IEC
    j. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
    k. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
    l. Signature of the member secretary with date.

XVIII. Following up procedures for approved proposals by PI / Sponsor

1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
3. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents as specified in Annexure-4A, 4B 4C & 7 based on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.
4. Final report should be submitted at the end of study.
5. Following instances and events will require the follow-up review/ Renewed Approval:
    a. Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.
    b. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.
    c. Any event or information that may affect the benefit/risk ratio of the study.
6. Protocol deviation, if any, should be informed with adequate justifications.
7. Any new information related to the study should be communicated.

8. Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
9. Change of investigators/sites must be informed to the office of IEC.
10. Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB may also be sought.
11. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

XIX. Responsibilities of Sponsor/Investigator

Responsibilities of Sponsor

(i) The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health Services, Government of India as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.

(ii) Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.

(iii) In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of adverse drug reactions (Annexure 8), if any, and the reason for discontinuation of the study or non-pursuit of the new drug application;

(iv) Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethics committee and chairman of the expert committee constituted by the licensing authority as defined under rule 21(b) under appendix XII of gazette notification dated 30th January 2013 with a copy of the report to the Licensing authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of serious adverse event of death. The report of the serious adverse event other than death, after due analysis, shall be forwarded by the sponsor to the Licensing authority, Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event. (See Annexure 8).

(v) In case of injury or death occurring to the clinical trial subject, the sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the

manner as prescribed in Appendix XII of gazette notification dated 30th January 2013.

(vi) The sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.

Responsibilities of the Investigator(s)

(i) The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII of schedule Y. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority defined under clause (B) of rule 21 (Schedule Y and Gazette notification 30th January 2013), the sponsor or his representative, whosoever had obtained permission form the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairman of the ethics committee and Chairman of the Expert Committee constituted by the Licensing authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

(ii) The investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V of Schedule Y about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

XX. Record keeping and archiving at the office of AIIMS IEC

1. All the documents and communications of IEC will be dated, filed and archived in a secure place.
2. Only the member secretary or persons, who are authorized by the Chairman of IEC will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.
4. No document (except agenda) will be retained by any IEC member.
5. At the end of each meeting, every member must return the CD/DVD containing all the research

proposals and documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.

6. Following documents will be filed and archived with proper label on the top of file for easy identification
    a. Constitution and composition of AIIMS-P IEC
    b. Curriculum Vitae (CV) of all members of AIIMS-P IEC with records of training in Human ethics if any.
    c. Standard Operating Procedures of AIIMS-P IEC.
    d. Annual reports
    e. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members;
    f. The published guidelines for submission established by the EC.
    g. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
    h. Agendas and Minutes of all IEC meetings duly signed by the Chairperson / Member secretary.
    i. Copy of all existing relevant national and international guidelines on ethics and laws along with amendments.
    j. Copy of all correspondence with members, Principal Investigators and other regulatory bodies.
    k. Record of all notification issued for premature termination of a study with a summary of the reasons;
    l. Final report of the approved projects, including microfilms, CDs and Video recordings.

XXI. Updating AIIMS-P IEC members

1. All relevant new guidelines should be brought to the attention of the members.
2. The IEC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ bodies, so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review

XXII. Terms of reference

Terms of reference will be maintained in the office of AIIMS-P IEC. This includes

A. Membership Requirements

B. Terms of Appointment with reference to the duration of the term,

C. The policy for removal, replacement, resignation procedure,

D. Frequency of meetings, and

E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts *etc.*

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances.

XXIII. Administration and Management

A full time secretariat and space for keeping records is required for a well-functioning IEC. The members could be given a reasonable compensation for the time spared for reviewing the proposals. Reasonable fees can be charged to cover the expenses related to review and administrative processes for any third party (protocols submitted by researchers not employed by AIIMS-P) submission as described in section XI Point No 6. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

XXIV. Special Considerations / Protection of Vulnerable Population

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards / protection and specific considerations for the IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IEC will be given in writing in unambiguous terms in such instances. ICMR guidelines as applicable will be followed for protection of vulnerable population.

Letter Ref. No: Date:

From

Dean, AIIMS
Patna

To

_____
_____
_____

Sub: Constitution of Institute Ethics Committee (Human studies) - Reg.
****

Dear Sir / Madam,

On behalf of All India Institute of Medical Sciences, Patna, an Autonomous Institute under Government of India, I request your concurrence for possible appointment as a member of Institute Ethics Committee of AIIMS Patna. Kindly send your written acceptance in the enclosed format and provide short curriculum vitae along with the acceptance letter.

On receipt of your acceptance, I shall send you the formal appointment letter.
Yours sincerely,

Signature:

Name:

Annexure 1B

APPOINTMENT ORDER

Dr/ Mr. / Mrs.:_____ Date: _____

I am pleased to appoint you as_____ of the Institutional Ethics Committee (IEC) (Human research) at All India Institute of Medical Sciences, Patna (AIIMS-P) w.e.f._____ for a term of_____ year / months provided following conditions of appointment are met.

1. You should be willing to publicize your full name, profession & affiliation.
2. You are willing to record all reimbursement for work & expenses, if any, within or related to an EC & make it available to the public upon request.
3. You consent to sign confidentiality agreement between you & the IEC regarding meeting deliberations, applications, information on research participants, & related matters.

The renewal of your appointment will be by consensus & 1 month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC, AIIMS-P.

You will be paid a sum of Rs 2000/- per sitting as Honorarium for your services rendered & as per the guidelines given in Terms of Reference-IEC, AIIMS-P.

We sincerely hope your association with IEC, AIIMS will be fruitful to the Institute & the Community we serve.

Chairperson
(Name/Seal)
IEC, AIIMS,
Phulwarisharif,
Patna – 801505

Signature of Appointee
(Name & Date)

Annexure 2

From,

_____
_____
_____

To
The Dean
AIIMS
Patna-751019

Sub: Consent to be a member of Institute Ethics Committee (Human Studies) - Reg.
Ref: Your Letter No: dated:

****

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC of AIIMS Patna. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature _____

Name of the Member_____Date:

Address:

Telephone No: (Off) (Res) email:

All India Institute of Medical Sciences, Patna Institutional ethics committee

Initial Review Submission Form for Research Proposal

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualifications and designation
4. Name of the Institute / Hospital / Field area where research will be conducted
5. Forwarding letter from the Head of the Department / Guide in case of thesis proposals.
6. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants, precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, plan to withdraw or withhold standard therapies in the course of research, plan for statistical analysis of the study, ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures, if any. Informed consent process, including patient information sheet and informed consent form in English and local language(s) are mandatory. Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances should be attached. Source of funding and financial requirements for the project has to be detailed.
8. For any drug / device trial, relevant pre-clinical animal data and clinical trial data from other centers within the country / other countries, if available.
9. Usefulness of the project / trial
10. Expected 'benefits' to volunteers / community. 'Benefits' to other categories if any
11. Explain all anticipated 'risks' (adverse events, injury, discomfort) of the project. Efforts taken to minimize the 'risks'. For trials, proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.

12. Agreement to report all Serious Adverse Events (SAE) to AIIMS-P -IEC.
13. Other financial issues including those related to insurance.
14. An account of storage and maintenance of all data collected during the trial.
15. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)
16. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
17. Statement of conflicts of interest, if any.
18. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
19. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided
20. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
21. Curriculum vitae of all the investigators with relevant publications in last five years.
22. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
23. Any other information relevant to the study.
24. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal

Annexure 3B

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF AIIMS, PATNA

Submit six (6) hard copies of the Research Proposal along with Covering letter, a CD/DVD of the proposal and a 'soft copy' along with the following information to the Member Secretary, Institution Ethics Committee at the IEC office, AIIMS-P.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the IEC with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi/Concerned local Language, **in a simple layman's language, in a narrative form, directed to Participant/LAR, covering all the points given,** before it can be considered for placing before the IEC. Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all working days. Proposals received till 15th of preceding month will be processed in the coming Institution Ethics Committee meeting and those received after 15th will be processed in the next Institution Ethics Committee meeting. All meetings of Institution Ethics Committee will be held as far as possible on first Monday of Jan, March, May, July, September, and November. The frequency will change depending upon the number of proposals and will be updated on the website: **www.aiimspatna.org**.

While submitting replies to queries raised by the IEC, the candidates are advised to mention the IEC reference number/s and also attach a copy of the comments of the IEC Moreover if the approval is required in a particular format, the same may be submitted in a CD/DVD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC), AIIMS-P

(For attachment to each copy of the proposal)

Serial No of IEC Management Office:

Proposal Title:

	Name, Designation, Department & Qualifications	**Address Tel & Fax Nos. Email ID**	**No of projects already with Investigator**	**Signature**
PI				
Co-PI / Collaborators 1.				
2.				
3.				
4.				
5.				
6.				
	Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

Tick appropriately

Sponsor Information :							
1. Indian	a) Government	☐	Central ☐	State ☐	Institutional ☐		
	b) Private	☐					
2. International	Government	☐	Private ☐	UN agencies ☐			
3. Industry	National	☐	Multinational ☐				
Contact Address of Sponsor:							
Total Budget :							
Who will bear the cost of investigation / implants drugs / contrasts?		1.☐ Patient 2.☐ Project 3. ☐ Exempted 4. ☐ Other Agencies					

1.Type of Study :	Cross sectional ☐	case control ☐	cohort ☐	Clinical Trial ☐	Review ☐		
Participating Centre :	Single center ☐	Multi-centric ☐	Others (Specify) ☐				
2. Status of Review:	New ☐		Revised ☐				
3. Clinical Trials: **Drug /Vaccines/Device/Herbal Remedies :**							
i. Does the study involve use of:	Drug ☐	Devices ☐	V ☐				
	Indian Systems of Medicine/ Alternate System of Medicine ☐	Any other ☐	a ☐				
ii. Is it approved and marketed	In India ☐	UK & Europe ☐	USA ☐				
	Other countries, specify ☐						
iii. Does it involve a change in use, dosage, route of administration?					Yes	No	
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?					Yes	No	
If yes, Date of permission :							
iv. Is it an Investigational New Drug?					Yes	No	
If yes, IND No:							
a). Investigator's Brochure submitted					Yes	No	
b). *In vitro* studies data					Yes	No	
c). Preclinical Studies done					Yes	No	
d). Clinical Study is : Phase I ☐	Phase II ☐	Phase III ☐	Phase IV ☐				

e). Are you aware if this study/similar study is being done elswhere ? **If Yes**, attach details	Yes	No

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i. Number of Subjects :

ii. Duration of study :

iii.	Will subjects from both sexes be recruited	Yes	No
iv.	Inclusion / exclusion criteria given	Yes	No

v. Type of subjects Volunteers ☐ Patients ☐

vi. Vulnerable subjects Yes ☐ No ☐
(Tick the appropriate boxes)

pregnant women	☐	children	☐	elderly	☐
fetus	☐	illiterate	☐	handicapped	☐
terminally ill	☐	seriously ill	☐		
	☐		☐	me ntal	

vii. Special group subjects Yes ☐ No ☐
(Tick the appropriate boxes)

captives	☐	institutionalized	☐	employees	☐
students	☐	nurses/dependent	☐	armed	☐
any other	☐	staff	☐	forces	

6. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymised/ ☐

ii.	Confidential handling of data by staff	Yes	No
7. Use of biological/ hazardous materials		Yes	No
i.	Use of fetal tissue or abortus		
ii.	Use of organs or body fluids	Yes	No
iii.	Use of recombinant/gene therapy	Yes	No
	If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iv.	Use of pre-existing/stored/left over samples	Yes	No
v.	Collection for banking/future research	Yes	No

vi. Use of ionizing radiation/radioisotopes	Yes	No
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/bio hazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad? **If Yes, justify with details of collaborators**	Yes	No
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed. If so, reasons… ☐

8. Consent : *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language ☐	Alternatives to participation ☐
Statement that study involves research ☐	Confidentiality of records ☐
Sponsor of study ☐	Contact information ☐
Purpose and procedures ☐	Statement that consent is voluntary ☐
Risks & Discomforts ☐	Right to withdraw ☐
Benefits ☐	Consent for future use of biological material ☐
Compensation for participation ☐	Benefits if any on future commercialization ☐
Compensation for study related injury ☐	eg. genetic basis for drug development ☐

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐ Research staff ☐ Any other ☐

9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No
10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No

Iii.Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b) Benefit to society ☐		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long ?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	Yes	No
Conflict of interest for any other investigator(s) (if yes, please explain in brief	1_____Yes No 2_____Yes No	
15. Participant Information Sheet *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ Certified that Hindi version is a true translation of	
16. **Participant Informed Consent Form** *(mark √ if yes)*	☐ Attached English version ☐ Attached Hindi version ☐ Certified that Hindi version is a true translation of	
17. Whether any work on this project has started or not?	☐ *(mark √ if yes, X if no)* *(Please enclose a separate certificate to this effect).*	
18. In case of clinical trials CTRI status		

Checklist for attached documents:

Covering letter, through proper channel	☐
Project proposal – 06 Copies	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Patient information sheet	☐
Informed Consent form	☐
Investigator's brochure	☐
Copy of advertisements/Information brochures	☐
Copy of clinical trial protocol and/or questionnaire	☐
HMSC/DCGI/DBT/BARC clearance if required	☐
Undertaking that the study shall be done in accordance with ICMR and GCP guidelines	☐
In case of multi-centric study, IEC clearance of other centres must be provided	☐
Definite undertaking as to who will bear the expenditure of injury related to the project	☐
If an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)	☐
Permission to use copyrighted Questionnaire/proforma	☐
Investigator should provide undertaking what they will do with the leftover sample tissue	☐
Certificate/undertaking as mentioned in column 17	☐
Others	☐

All India Institute of Medical Sciences, Patna Institutional ethics committee

Ongoing Approved Research Review Submission Form

1. Reference number
2. Month / Year of approval
3. Number of ongoing review
4. Title of the research proposal
5. Name of the Principal Investigator (PI) with qualification and designation
6. Name of the Co-investigator(s) (Co-PI) with qualification and designation
7. Duration of the Project
8. Source of funding & financial allocation for the project / trial
9. Has subject recruitment begun?
10. If subject recruitment has not begin, give reasons and proceed to No:20
11. How many subjects have been screened?
12. How many subjects have been recruited?
13. How many more to be recruited
14. Is subject recruitment continuing?
15. Are there any 'drop outs'?
16. Are subjects still receiving active intervention?
17. Have there been any adverse events? If yes, give details
18. Have there been any Serious Adverse Events adverse events? If yes, give details.
19. Have there been any unanticipated study-related problems?
20. Is there any new risk or benefit information? If yes, give details.
21. Are there any interim changes to the protocol or consent form? If yes, give details including submission of revised protocol and consent form for approval
22. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?
23. List of attachments for review, if any
24. Remarks, if any
25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Annexure 4B

Institute Ethics Committee, AIIMS, Patna

Format for ***submission of revised/additional documents, protocols and information regarding already approved projects*** to be submitted by the Principal Investigator (PI) (Two copies of this form along with the revised documents to be submitted)

1. IEC Reference No:

2. Approval Date and Number:

3. Title:

4. Principal Investigator:

5. Purpose of this submission:

6. **New documents being submitted:** Please list the documents being submitted along with the differences from the previously approved documents in a tabular form as below:

S. No.	List of Documents being submitted	List the modifications/revisions made from previously approved proposal, wherever applicable

Place:
Date:

Signature PI/Collaborator _____
Name:

Annexure 4C

Six monthly progress of Project

Institute Ethics Committee Reference No._____

Study title:_____

Name of the Principal Investigator _____

Designation / Department _____

Duration of Study _____

Date of Starting of the Study _____

Period of Six monthly progress report: from_____to _____

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Progress:

Signature of Principal Investigator _____
Date:_____

Annexure 5

PARTICIPANT INFORMATION SHEET (PIS)

The project must be accompanied by the Participant information sheet addressed to the patient or participant or parent/ guardian, in case of minor. While formulating the participant information sheet, the investigator must provide the subjects with the following information in **English and Hindi, in a simple layman's language which can be understood by them, in a narrative form, directed to the participant/ LAR, covering all the points**:

1. Study Title
2. Aims and methods of the research study
3. Expected duration of participation
4. The benefits to be expected from the research to the participant or to others
5. Any risk or discomfort to the participant associated with the study
6. Maintenance of confidentiality of records
7. Provision of free treatment for research related injury
8. Compensation of subjects for disability or death resulting from such injury
9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise
10. Amount of blood sample (quantity in tea spoon full) to be taken
11. Costs and source of investigations, disposables, implants and drugs/ contrast media
12. Telephone number/ contact number of Principle investigator and Co-Investigator at the top of each page
13. In case of a drug trial:
    a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned
    b. Initial bioequivalence study of the drug/ references should be provided
14. Self-certification should be given that the translation to vernacular language is correct

Annexure 6

PARTICPANT INFORMED CONSENT FORM (PICF)

Protocol Study number: _____

Patient identification number for this study: _____

Title of the project: _____

_____

Name of Principal investigator: _____Tel. No (s). _____

The contents of the information sheet dated_____ that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

---------- Date:
(Signatures / Left Thumb Impression) Place:

Name of Participant: _____Son/Daughter/spouse of: _____

Complete postal address:_____

This is to certify that the above consent has been obtained in my presence.

---------- Date:
Signatures of the Principal Investigator Place:

1) Witness – 1

Signature

Name:

Address:

2) Witness – 2

Signature

Name:

Address:

NB: Three copies should be made, one each for (1) Patient (2) Researcher (3) Institution (Investigators are advised to prepare the translation in simple understandable Hindi on their own)

Annexure 7

सहभागी सुचित सहमति प्रपत्र

इस जाचं के लिए सहभागी पहचान नमबर_____

अनुसन्धान शीर्षक_____

मुख्य अन्वेषक का नाम _____ फोन नंबर: _____

मैंने दिनांक_____ के सूचना पत्र में दिये गए सभी तथ्यो को पड़ लिया हैं| मुझे समझ आने वालीं भाषा मैं विस्तारपूर्वक बत्ता दिया है और मैनें तथ्यो को भली भांति समझ लिया है| मैं पुष्टि करता हूँ कि मुझे प्रशन पुछने का अवसर दिया गया है|

मुझे अध्ययन की प्रकृति, उद्देश्य और इसके सम्भावित लाभ/जोखिमों और अध्ययन की सम्भावित अवधि अन्य प्रासंगिक जानकारी के बारे में विस्तार पुर्वक समझा दिया गया है | में समझाता हूँ कि इस अध्ययन में मेरी भागिधारी स्वेछिक है और इस अध्ययन से किसी भी समय बिना कोई कारण बताए, बिना मेरी चिकित्सा देखभाल या कानूनी अधिकारों के प्रभावित हए अपना नाम वापिस ले सकता/सकती हूँ |

मैं समझता हूँ कि इस अनुसन्धान में मेरी सहभागिता से मेरे बारे में एकत्र जानकारी और चिकित्सीय नोटों को एम्स अस्पताल के जिम्मेदार लोगो द्वारा देखा जायेगा| मैं इन व्यक्तियों को अपने रिकोर्ड देखने कि अनुमति प्रदान करता/करती हूँ |

मैं उपयुर्क्त अध्यन में भाग लेने के लिए अपनी सहमति प्रदान करता /करती हूँ |

सहभागी के हस्ताक्षर / बाएं अंगूठे का निशान दिनांक स्थान

सहभागी का नाम

पिता/पति का नाम

पूरा पता

यह प्रमाणित किया जाता हे कि उपयुर्क्त सहमति मेरी उपस्थति में ली गईं हैं |

मुख्य अन्वेषक के हस्ताक्षर दिनाक: स्थान:

१) गवाह के हस्ताक्षर
नाम
पता

२) गवाह के हस्ताक्षर
नाम
पता

Data Elements for reporting serious adverse events occurring in a clinical trial

1. Patient Details

Initials & other relevant identifier (hospital/OPD record number etc.)*
Gender
Age and/or date of birth
Weight
Height

2. Suspected Drug(s)

Generic name of the drug*
Indication(s) for which suspect drug was prescribed or tested
Dosage form and strength
Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)
Route of administration
Starting date and time of day
Stopping date and time, or duration of treatment

3. Other Treatment(s)

Provide the same information for concomitant drugs (including nonprescription/OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Suspected Adverse Drug Reaction(s)

Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.*

Start date (and time) of onset of reaction
Stop date (and time) or duration of reaction
Dechallenge and rechallenge information
Setting (e.g., hospital, out-patient clinic, home, nursing home)

5. Outcome

Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted

For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

*6. Details about the Investigator**

Name
Address
Telephone number
Profession (specialty)

Date of reporting the event to Licensing Authority:
Date of reporting the event to Ethics Committee overseeing the site:

Signature of the Investigator

*Note: Information marked * must be provided."*