INSTITUTIONAL ETHICS COMMITTEE (HUMAN)
STANDARD OPERATING PROCEDURE
Section - I, II, III and IV

JORHAT MEDICAL COLLEGE & HOSPITAL, JORHAT
Kushal Konwar Road, Borbhetta-785001

CONTENT

Section-I

Section-II

Section-III

Section-IV

Section-I

Standard Operating Procedure (SOP) for Institutional Ethics Committee for Human Research at Jorhat Medical College, Jorhat

1. ***Short Title:***

The following may be called as "Standard Operating Procedures for the Institutional Ethics Committee Human (IEC- H) of Jorhat Medical College and Hospital, Jorhat".

2. ***Objective***

The objective of Standard Operating Procedure (SOP) is to ensure quality and consistency in review of clinical research proposals and to follow the ICMR and national ethical guidelines for biomedical research on human subjects.

It is to ensure the protection of the rights and welfare of human participants in biomedical, experimental, and behavioural research conducted at JMCH, Jorhat.

3. ***Functions of Institutional Ethics Committee (IEC)***

IEC should provide independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies.

IEC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of research participants irrespective of the source of funding. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The IEC will ensure that all the cardinal principles of research ethics viz, autonomy, beneficence, non-malfeasance and justice are taken care of in planning, conduct and reporting of a proposed study. It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden/benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through periodic reports, final report and site visits etc. The committee will also ensure compliance with all regulatory requirements, applicable guidelines and laws.

4. ***Composition of IEC***

IECs shall be multidisciplinary and multisectorial in composition.

The number of members in the committee shall be kept small (7-12 members) as a large committee makes it difficult in reaching consensus and in having the presence of all the members. The external members shall be in majority to ensure the independence of the committee.

The Chairperson of the committee shall be from outside the Institution and not Head/former Head of Jorhat Medical College, Jorhat. The Member Secretary, drawn from Jorhat Medical College, Jorhat itself, shall conduct the business of the Committee. Other members will be a mix of medical and non-medical scientific and non-scientific persons including general public to reflect the differed viewpoints.

The composition may be as follows:-

1. ***Chairperson***
2. ***Basic medical scientists***
3. ***Clinicians***
4. ***Legal expert***
5. ***Social scientist/representative of non-governmental voluntary agency***

6. ***Lay person from the community***
7. ***Member-Secretary***

IEC shall have majority of its members from other institutions. They could be drawn from any public or private institute from anywhere in the country. There shall be adequate representation of age, gender, community etc. in the Committee to safeguard the interests and welfare of all sections of the society. The Committee can not consist entirely of men or entirely of women.

5. ***Constitution of IEC***

The Principal, Jorhat Medical College, Jorhat shall constitute the IEC, in consultation with the Academic Board in the following pattern:

1. ***Chairperson***
2. ***Member Secretary from Institute***
3. ***5-7 members from different specialties as specified above, some of them should be from the Faculty of the Institute.***

The committee will be normally reconstituted every 3 years

6. Authority under which IEC (Human),JMCH is constituted

The Principal cum Chief Superintendent will appoint the Chairman and all the committee members based on their competence, experience and integrity. He will request them by sending an official request letter (Annexure 1). Members will confirm their acceptance to the Principal by providing all required information (Annexure 2).

7. ***Membership requirements/Responsibilities***

1. The duration of the membership will be 3 years.
2. There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.
3. A member can be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall be with the Principal, Jorhat Medical College, Jorhat.
4. Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
5. Conflict of interest if any shall be declared by members of the IEC at the beginning of every meeting.

8. ***Quorum Requirements***

A minimum of 5 members including at least three outside members is required to compose a quorum for the meeting of which at least one member will be from outside the institution, and one member will be a non-scientific member.

This minimum 5 members list must include (a) Basic medical scientists (preferably one pharmacologist). (b) Clinicians (c) Legal expert (d) Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist or a similar person (e) Lay person from the community.

All decisions should be taken in meetings and not by circulation of project proposals.

9. ***Independent Consultants***

IEC may call upon subject experts as consultants for review of selected research protocols. 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 not take part in the decision making process.

10. ***Application Procedure***

1. All proposals should be submitted in the prescribed application form, copies of which will be available with the Member Secretary and in the office of the IEC(H).
2. All relevant documents should be enclosed with application.
3. The required number of copies of the proposal along with the application and documents in prescribed format duly signed by the PI and Co-investigators/Collaborators should be forwarded by the Head of the Department.
4. The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.
5. The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.
6. The decision of IEC 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.

11. ***Documentation***

All research proposals should be submitted with the following documents:

1. Title of the project
2. Names of the PI and Co-investigators with designation.
3. Name of any other Institute/Hospital/Field area where research will be conducted.
4. Approval of the Head of the Department.
5. Protocol of the proposed research.
6. Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant annexure like proforma, case report forms, questionnaires, follow-up cards, etc. to be used in the study.
8. Patient information sheet and informed consent form in English/Assamese and local language(s) should be enclosed. The patient information sheet should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them. The consent form should be as per schedule Y published in Gazette of India (2005).
9. For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available.
10. Any regulatory clearances required. Copy of clearances if obtained. This is necessary for new drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
11. Source of funding and Budget along with the supporting documents.
12. Indemnity issues including insurance for the compensation to the participants etc.
13. An undertaking to immediately report Serious Adverse Events (SAE) to IEC.
14. Statement of conflicts of interest, if any.

15. Plans for publication of results-positive or negative-while maintaining the privacy and confidentiality of the study participants.
16. Any other information relevant to the study.
17. Agreement to submit annual progress report and final report at the end of study.
18. The PI should provide the details of other ongoing research projects (Title of the project, Date of starting and duration, source and amount of funding).

12. ***Review Procedure***

1. Meetings of IEC shall be held on scheduled intervals as prescribed (once in 3 months, for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary.
2. The proposals will be sent to members at least 2 weeks in advance.
3. Decisions will be taken by consensus after discussions, and voting will be done if necessary.
4. PI should be available during the meeting and may be invited to offer clarifications.
5. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.
6. The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with signature of Chairperson at each page.

13. ***Element of Review***

1. Scientific design and conduct of the study.
2. Approval of scientific review committee and regulatory agencies.
3. Assessment of predictable risks/harms and potential benefits.
4. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
5. Management of research related injuries, adverse events and compensation provisions.
6. Justification for placebo in control arm, if any.
7. Availability of products to the trial subjects after the study, if applicable.
8. Patient information sheet and informed consent form in English/Assamese and local language.
9. Protection of privacy and confidentiality of subjects.
10. Involvement of the community, wherever necessary.
11. Protocol and proforma of the study including the consent form.
12. Plans for data analysis and reporting.
13. Adherence to all regulatory requirements and applicable guidelines.
14. Competence of investigators, research and supporting staff.
15. Facilities and infrastructure.

14. ***Expedited Review***

Proposals which are recommended for minor revisions will be reviewed by a sub committee appointed by the IEC for clearance and approved by the Chairperson. The approvals will be reported in the next IEC meeting by Member Secretary. The revised form of proposals requiring major changes will be reviewed at the next ethics committee meeting. Rejected proposals may be reconsidered only if a very strong background is there.

15. ***Decisions Making***

1. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
2. Only members will make the decision. The decisions shall be taken in the absence of

investigators, representatives of sponsors, consultants.

3. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
4. Revised proposals may be subjected to an expedited review.
5. All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the IEC.

   i) *PI should submit annual report of the ongoing project on format prescribed by the Institute, to the IEC.*
   ii) *The final report of the completed study should be submitted by PI.*
   iii) *The PI should highlight the changes in the protocols/brochures/informed consent form etc. being amended from the previous documents while submitting amended documents to IEC.*

16. *Communicating the Decision*

1. Decision will be communicated to PI by the Member Secretary in writing.
2. Suggestions for modifications and reasons for rejection shall be communicated to the PI.

17. *Memorandum of Understanding and Indemnity Agreement for Sponsored* Drug/Device/Collaborative Trials

After the approval from IEC, the sponsor/CRO will submit the clinical trial agreement/Memorandum of Understanding and Indemnity Agreement document on Rs. 100 stamp paper separately (two copies) to the Institute which will be signed by sponsor and the Principal, Jorhat Medical College, Jorhat with the counter signature of PI. As per existing policy of the Institute, there will be 25% overhead charges to the total cost of the trial/per patient cost.

The drug trial shall be started by the PI after the agreement is signed by both the parties as well as DCGI and required regulatory approvals are available for the concerned trial.

18. *Follow up Procedures*

1. Annual report should be submitted by the PI on prescribed format along with comments.
2. Final report should be submitted at the end of study on prescribed format including a copy of the report which has been sent to sponsoring agency.
3. All SAEs and the interventions undertaken should be intimated immediately to IEC. The PI should submit the SAEs reported by other centers from time to time to the Member Secretary for information to IEC along with comments if any action is required in the current study.
4. Protocol deviation, if any, should be informed with adequate justifications.
5. Any amendment to the protocol should be submitted for approval.
6. Any new information related to the study should be communicated to IEC.
7. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
8. Change of investigators should be done with the approval of IEC.

19. *Record Keeping and Archiving*

1. Curriculum Vitae (CV) of all members of IEC.
2. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies.
3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
4. All study related documents (study protocols with enclosed documents, progress reports, and

SAEs.) should be archived for minimum of five years after the completion of study. A copy of filled CRF shall remain with the PI for minimum of ten years.

5. Final report of the approved projects.

20. ***Updating IEC Members***

1. All relevant information on ethics will be brought to the attention of the members of IEC by the Member Secretary.
2. Institute Members will be encouraged to attend national and international training programs/ conferences/ seminars in the field of research ethics to help in improving the quality of research protocols/ ethics committee submissions and review.

21. Terms of reference

Terms of reference will be maintained in the office of AIIMS 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.

22. Management and Administration

A 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 and it has been decided by the authority to charge Rupees 500 for review of proposal of post graduate thesis and Rupees 1000 from faculty members for their research proposal. A Separate account will be opened in the bank for keeping and maintaining the accounts**.**

Letter Reference No. **Annexure – 1**

From
The Principal
Jorhat Medical College, Jorhat-785001
To
....
.....

Sub: Constitution of Institute Ethics Committee (Human) dated: .....

Dear Sir / Madam

On behalf of Jorhat Medical College and Hospital, Jorhat, I request your submission for possible appointment as a member of Institutional Ethics Committee of Jorhat Medical Colege and Hospital .
Kindly send your written acceptance in the enclosed format and provide short curriculam vitae along with the acceptance letter

Yours sincerely

Signature

Name

Annexure – 2

From, _____ _____
_____

To
The Principal
Jorhat Medical College, Jorhat-785001

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 JMCH,Jorhat.
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:

Annexure No- 3

JORHAT MEDICAL COLLEGE, JORHAT

Form to be filled by the Principal Investigator (PI) for submission to Institutional Ethics Committee (IEC)
(for attachment to each copy of the proposal)

***Code No. of IEC:**

** To be filled by IEC Member Secretary*

Proposal Title:

	Name, Designation & Qualifications	**Departmental Tel Nos. Email ID**	**Signature**
PI			
Co-PI/ Collaborators **1.**			
2.			
3.			

Please attach Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years). The investigators should sign their CV.

SPONSOR INFORMATION

1. Indian	a) Government ◯ Central ◯ State ◯ Institutional ◯	
	b) Private ◯	
2. International	Government ◯ Private ◯ UN Agencies ◯	
3. Industry	National ◯ Multinational ◯	
4. Contact address of sponsor		
5. Budget		

Study information

1. Type of study	Epidemiological	◯	Basic Sciences	◯	Behavioral	◯
	Clinical	◯	Single Centre	◯	Multicentric	◯
2. Status of review	New	◯	Revised	◯		
3. Clinical trials	***YES***	◯	***No***	◯		

If YES,

Drug/Vaccines/Device/Herbal Remedies ◯ ◯

I. Does the study involve use of

Drugs ◯ Devices ◯ Vaccines ◯

Indian Systems of Medicines/ Alternate systems of Medicine ◯ Any Other None

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, copy of permission attached	Yes ◯	No ◯

IV.	Is it an Investigational New Drug?	Yes ◯	No ◯
If yes			
a.	*Investigator's Brochure enclosed*	Yes ◯	No ◯
b.	*Preclinical studies data available (If yes, provide summary)*	Yes ◯	No ◯
c.	*Clinical studies data available (If yes, provide summary)*	Yes ◯	No ◯
d.	*Clinical study is Phase I ◯ Phase II ◯ Phase III ◯ Phase IV ◯ NA ◯*		
e.	*DCGI's permission obtained*	Yes ◯	No ◯
***If yes**, copy of letter enclosed*		Yes ◯	No ◯

4. Brief description of the proposal-aim(s) and objectives, justification for study, methodology describing the potential risks and 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 (a) Study:_____ (b) Subject participation_____

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 circle)

Pregnant Women	◯	Children	◯	Elderly	◯
Fetus	◯	Illiterate	◯	Handicapped	◯
Terminally ill	◯	Seriously ill	◯	Mentally Challenged	◯
Economically & socially backward	◯	Any other	◯		

VII. Special group subjects

(Tick the appropriate circle)

Captives	◯	Institutionalized	◯	Employees	◯
Students	◯	Nurses/Dependent	◯	Armed Forces	◯
Any Other	◯	Staff	◯		

6. Privacy and confidentiality

I. Study Involves
- Direct Identifiers ◯
- Identifiers/Coded ◯
- Completely Anonymised /Delinked ◯

II. Confidential handling of data by staff Yes ◯ No ◯

7. Use of biological/hazardous materials

I.	Use of fetal tissue or abortus. **If yes** provide details	Yes ◯ No ◯
II.	Use of organs or body fluids. **If yes** provide details	Yes ◯ No ◯
III.	Use of recombinant/gene therapy products **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 **If yes**, has Bhabha Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes ◯ No ◯
VII.	Use of Infectious/biohazardous specimens	Yes ◯ No ◯
VIII.	Proper disposal of material	Yes ◯ No ◯

ix. Will any sample collected from the patients be sent abroad? Yes◯ No ◯

If yes, give details and address of collaborators

a. Sample will be sent abroad because (Tick appropriate circle)

Facility not available in India ◯
Facility in India inaccessible ◯
Facility available but not being accessed ◯
If so, reasons _____

b. Has necessary clearance been obtained Yes ◯ No ◯

8. Consent *Written ◯ Oral◯ Audio-Visual◯

i.Patient Information Sheet attached : (Tick the included elements) Yes ◯ No◯

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 material biological	◯
Compensation for participation	◯	Benefits if any on future commercialization e.g.	◯
Compensation for study related injury	◯	Genetic basis for drug development	
Translation of information sheet in local Language	◯		

ii. If healthy volunteers will be included, information sheet for them attached Yes ◯ No ◯

iii. Consent form in English ◯ in local Languages ◯

iv. Who will obtain consent? PI-Co-PI ◯ Nurse/ Counsellor ◯
Research Staff ◯ Any Other ◯

**If written consent is not obtained, give reasons:*

9. Will any advertising be done for recruitment of Subjects? Yes◯ No ◯
(Posters, flyers, brochure, websites – if so attach a copy)

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? Yes ◯ No ◯

If yes, Minimal or no risk ◯
More than minimum risk ◯
High risk ◯

iii. Is there benefit a) to the subject? Yes ◯ No ◯
Direct ◯ Indirect ◯
b) to the society Yes ◯ No ◯

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? Yes ◯ No ◯

If yes, reporting will be done to

Sponsor ◯ IEC ◯ DSMB ◯

iii. Is there a plan for interim analysis of data? ? Yes ◯ No ◯

12. Is there compensation for injury?

If yes, by

Sponsor ◯ Investigator ◯

Insurance Company ◯ Any Other ◯

13. Do you have conflict of interest? Yes◯ No◯

(Financial/Non financial)

If yes, specify _____

Check list for attached documents:

1. Project proposal-**5 copies** ◯
2. Curriculum Vitae of all Investigators ◯
3. Brief description of proposal/summary ◯
4. Copy of the Protocol/Project and questionnaire (if any) ◯
5. Investigator's Brochure ◯
6. Copy of Patient information sheet & Consent form in local languages ◯
7. Copy of Advertisements/Information brochures ◯
8. DCGI/DBT/BARC clearance if obtained ◯
9. Copy of Insurance Policy ◯
10. Copy of Clinical trial agreement ◯
11. Copy of IEC proforma ◯
12. Copy of PI undertaking ◯
13. Copy of Case Report Form ◯

Signature of PI

Date

Signature of Head of the Department

Jorhat Medical College, Jorhat
UNDERTAKING BY THE PRINCIPAL INVESTIGATOR

1. **NAME AND CODE NUMBER OF THE PROJECT**

2. **NAME, DESIGNATION AND DEPARTMENT OF THE PRINCIPAL INVESTIGATOR**

3. **OTHER MEMBERS OF THE RESEARCH TEAM**

4. **NAME AND ADDRESS OF ANY OTHER MEDICAL COLLEGE, HOSPITAL OR INSTITUTION WHERE PARTS OF THE STUDY WILL BE DONE**

5. **NUMBER OF ONGOING PROJECTS/CLINICAL TRIALS IN WHICH YOU ARE PI.**

1. *I confirm that I will initiate the study only after obtaining all regulatory clearances.*
2. *I will not implement any deviation from the approved protocol without prior consent of the sponsor nature and it will be intimated to the IEC at the earliest.*
3. *I confirm that the CO PI and other members of the study team have been informed about their obligations and are qualified to meet them*
4. *I will personally supervise the study and ensure that requirements of obtaining informed consent and other ethical requirements under ICMR and National Regulatory Guidelines are adhered to.*
5. *I will maintain accurate and complete record of all cases in accordance with GCP provisions and make them available for audit/inspection by IEC, Regulatory authorities, Sponsors or their authorized representatives.*
6. *I will inform the IEC and the Sponsors of any unexpected or serious adverse event at the earliest and definitely within seven days of its occurrence.*
7. *I will maintain confidentiality of the identity of all participating subjects and assure security and confidentiality of study data.*
8. *I and my colleagues will comply with statutory obligations, requirements and guidelines applicable to such clinical studies.*
9. *I will inform IEC of the date of starting the study within 2 weeks of initiation of the trial and submit annual progress reports and final report to Member Secretary, IEC within 4 weeks of the due date.*

Signature of Principal Investigator

Date

ONE PAGE CV
(For Investigators)

Last Name	**First Name**	**Middle Initial**
Date of Birth (mm/dd/yy):		**Sex:**
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator)		
Professional Mailing Address (Include institution name)	**Study Sited Address (Include institution name)**	
Telephone (Office):	**Mobile Number:**	
Telephone (Residence):	**E-Mail:**	
Academic Qualifications (Most current qualification first)		
Degree/Certificate	**Year**	**Institution, Country**
Current and Previous 4 Relevant Positions Including Academic Appointments (Most current position first)		
Month and Year	**Title**	**Institution/Company, Country**
Brief Summary of Relevant Clinical Research Experience:		
Signature: **(Signature Required)**		**Date:**

Format for communication to the principal investigator by the member secretary, institutional ethics committee

INSTITUTIONAL ETHICS COMMITTEE (H)
JORHAT MEDICAL COLLEGE
JORHAT 785001

No/JMC/IEC(H)/20_____ / **Jorhat dated_____**

To,

Prof. /Dr. _____

_____

_____

Dear Prof. /Dr. _____

The Institutional Ethics Committee (H), Jorhat Medical College, Jorhat, in its meeting held on _____, has reviewed and discussed your application to conduct the clinical trial/project entitled "_____"

sponsored by	Code No.

The following documents were reviewed:

a) Trial Protocol (including protocol amendments)/project, dated _____Version no (s). _____
b) Patient Information Sheet and Informed Consent Form (including updates if any) in Assamese, English and/or vernacular language.
c) Investigator's Brochure, dated _____, Version no. _____
d) Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
e) Current CV of investigator from outside Jorhat Medical College, Jorhat.
f) Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.
g) Investigator's Agreement with the Sponsor.
h) Investigator's undertaking.
i) DCGI approval letter/submission letter.
j) Case Report Form
k) Any other/additional documents

Decision of Committee:	*Institutional Ethics Committee Member Secretary*

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The following members of the ethics committee were present at the meeting held on (dated_____ place_____)

_____
Chairman of the Ethics Committee

_____
Member Secretary of ethics committee

_____
Name of each member with designation

We approve the trail to be conducted in its presented form.

The institutional ethics committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient's information/ informed consent and asks to be provided a copy of the final report.

Yours sincerely

Member Secretary
Institutional Ethics Committee (H)
Jorhat Medical College
Jorhat

Annexure No - 7

JORHAT MEDICAL COLLEGE, JORHAT
INTIMATION OF START OF STUDY

1. Project/Trial Code Number	
2. Title of the drug/multicentric trial	
3. Principal Investigator (Name & Department)	
4. Sponsor	
5. Contract Research Organization (CRO) if any	
6. Date of sanction by IEC	
7. Date of start	

_____

(Signature of Principal Investigator)

Date _____

JORHAT MEDICAL COLLEGE, JORHAT
PROGRESS REPORT (ANNUAL)/FINAL REPORT

1. Project/Trial Code Number	
2. Title of the drug/multicentric trial	
3. Principal Investigator (Name & Department)	
4. Sponsor	
5. Contract Research Organization (CRO) if any	
6. Date of sanction by IEC	
7. Date of start	
8. Objectives of the study	
9. Progress report as per objectives (attach separate sheet)	
10. Serious Adverse Events if any with details (in summary form)	
11. Protocol deviation if any with reasons/justifications	
12. Report/publications/conference presentation	
13. Awards/recognition	

Date:

_____

(Signature of Principal Investigator)

_____

(Signature of Head of the Department)

Jorhat Medical College, Jorhat

GUIDELINES FOR PATIENT INFORMATION SHEET

Potential recruits to your research/trial study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate, and preferably in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

1. ***Study Title***

   Is the title self explanatory to a lay person? If not, an additional simplified title may also be included.

2. ***Invitation Paragraph***

   You should explain that the patient is being asked to take part in a research/trial study. The following is an example:

   "You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. ***What is the purpose of the study?***

   The background and aim of the study should be given here

4. ***Why have I been chosen?***

   You should explain how and why the patient was chosen and how many other patients will be studied.

5. ***Do I have to take part?***

   You should explain that taking part in the research/trial is entirely voluntary. You could use the following paragraph:-

   "It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

6. ***What will happen to me if I take part?***

You should say how long the patient will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or a clinic (if this is appropriate) and how long these visits will be. You should explain if the patient will need to visit the doctor (or clinic) more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc? Whenever possible you should draw a simple flow chart or plan indicating what will happen at each visit. What are the patient's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 8.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to use - the following simple definitions may help:-

Randomized Trial: Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual - i.e. by chance. Patients in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the patients what chance they have of getting the study drug/treatment: e.g. a one in four chance.

Blind Trial: In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you not your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect the results.

Cross-over Trial: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.

Placebo: A placebo is a dummy treatment such as a pill, which looks like the real thing but is not. It contains no active drug, chemical or ingredient.

7. ***What do I have to do?***

Are there any lifestyle restrictions? You should tell the patient if there are any dietary restrictions. Can the patient drive? Drink? Take part in sport? Can the patient continue to take his/her regular medication? Should the patient refrain from giving blood? What happens if the patient becomes pregnant? Explain (if appropriate) that the patient should take the medication regularly.

8. ***What is the drug or procedure that is being tested?***

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. Patients entered into drug trials should preferably be given a card (similar to an identity card) with details of the trial they are in. They should be asked to carry it at all times.

9. ***What are the alternatives for diagnosis or treatment?***

For therapeutic research/trial the patient should be told what other treatment options are available.

10. ***What are the side effects of taking part?***

For any new drug or procedure you should explain to the patients the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the patient will clearly understand (e.g. 'damage to the heart' rather than 'cardiotoxicity'; 'abnormalities of liver tests' rather than 'raised liver enzymes'). For any relatively new drug it should be explained that there may be unknown side effects.

11. ***What are the possible disadvantages and risks of taking part?***

For studies where there could be harm to an unborn child if the patient were pregnant or became pregnant during the study, the following (or similar) should be said:

"It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of foetal damage.

If future insurance status, e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the patients have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should clearly state what will happen if you detect or find a condition of which the patient was unaware. It is treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIV status)?

12. ***What are the possible benefits of taking part?***

Where there is no intended clinical benefit to the patient from taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the patient during the course of the study, e. g. saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to: "We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with (name of condition) better".

13. ***What if new information becomes available?***

If additional information becomes available during the course of the research/trial you will need to tell the patient about this. You could use the following:

"Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form.

Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue."

14. ***What happens when the research/trial study stops?***

If the treatment will not be available after the research/trial finishes this should be explained to the patient. You should also explain to them what treatment will be available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the patient.

15. ***What if something goes wrong?***

You should inform patients how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from patients as to their treatment by members of staff (doctors, nurses etc) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event.

16. ***Will my taking part in this study be kept confidential?***

You will need to obtain the patient's permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research/trial is:

"If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"

"All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized from it."

17. ***What will happen to the results of the research/trial study?***

You should be able to tell the patients what will happen to the results of the research/trial. You might add that they will not be identified in any report/publication.

18. ***Who is organizing and funding the research/trial?***

The answer should include the organization or company sponsoring or funding the research/trial (e.g. Govt. agency, pharmaceutical company, NGO, academic institution).

The patient should be told whether the doctor conducting the research/trial is being paid for including and looking after the patient in the study. This means payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the costs of a research nurse.

19. ***Who has reviewed the study?***

You may wish to mention that IEC has reviewed and approved the study (you should not however list the members of the Committee).

20. ***Contact for further information***

You should give the patient a contact address for further information. This can be your name or that of another doctor/nurse involved in the study. (Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers)

Remember to thank your patient for taking part in the study!

The patient information sheet should be dated and given a version number.

The Patient Information Sheet should state that the patient will be given a copy of the information sheet and the signed consent form.

Signature of PI

Date

JORHAT MEDICAL COLLEGE, JORHAT
INFORMED CONSENT FORM

❖ *Study Title:*		
❖ *Study Number:*		
❖ *Subject's Full Name:*		
❖ *Date of Birth:*		❖ *Age:*
❖ *Address:*		
❖ *Study Title:*		
❖ *Study Number:*		
❖ *Subject's Full Name:*		

1. I confirm that I have read and understood the information sheet dated_____ for the above study and have had the opportunity to ask questions.

   OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that the sponsor of the clinical trial/project, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)

5. I agree to take part in the above study

❖ *Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:*	*Date:*
❖ *Signatory's Name*	*Date:*
❖ *Signature of the Investigator*	*Date:*
❖ *Study Investigator's Name*	*Date:*
❖ *Signature of the Witness*	*Date:*
❖ *Name of the Witness*	

Jorhat Medical College, Jorhat
SECRECY UNDERTAKING BY MEMBER OF INSTITUTIONAL ETHICS COMMITTEE

❖ *Name:*	
❖ *Designation:*	
❖ *Address:*	

I understand that as a Member of the Institutional Ethics Committee I may receive documents containing confidential or privileged information about patients, volunteers or commercial products.

I agree not to disclose or discuss such information or minutes of the meeting with persons not entitled to have them. I also agree either to return all documents marked CONFIDENTIAL/PRIVILEGED to Member Secretary or destroy them after perusal.

Signature ***Date***

JORHAT MEDICAL COLLEGE, JORHAT
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Annexure No -13

JORHAT MEDICAL COLLEGE, JORHAT
LIST OF SUPPORTING STAFF OF ETHICS COMMITTEE

1. **Sunita Handoque Phukan** ➢ ***Ministerial Supervisor***
2. **Rubi Neog** ➢ ***Data Assistant***
3. **Basanta Baruah** ➢ ***Computer Operator***

SECTION: 2
Standard Operating Procedure (SOP)
Vulnerable Subjects
Institutional Ethics Committee (Human)
Jorhat Medical College, Jorhat

Purpose: This SOP describes who the vulnerable subjects are and the procedure as to how the care is taken while doing research on them to protect the wellbeing of the vulnerable subject.

2.0 Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding in ability to communicate or understand are in a situation that prevents them from doing so.

Individuals may be considered to be vulnerable if they are:

- Socially, economically or politically disadvantaged and therefore susceptible to being exploited
- Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled
- Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or
- Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

Following are some examples of vulnerable populations or groups:

1. Economically and socially disadvantaged (unemployed individuals, orphans, abandoned Individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.);

2. Children (up to 18 years);

3. Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);

4. Tribals and marginalized communities;

5. Refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;

6. Afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;

7. Terminally ill or are in search of new interventions having exhausted all therapies;

The key principle to be followed when research is planned on vulnerable persons is that others will be responsible for protecting their interests because they cannot do so or are in a compromised position to protect their interests on their own.

2.1 Principles of research among vulnerable populations

2.1.1 Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.

2.1.2 If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.

2.1.3 Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.

2.1.4 In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.

2.1.5 Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.

2.1.6 If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

2.2 Additional safeguards/protection mechanisms

When vulnerable individuals are to be recruited as research participants additional precaution should be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them. In the first case, they may be subjected to undue pressure, while in the second, they may be easily manipulated. If they perceive that their caregivers want them to participate in research, or if the caregiver stands to benefit from the dependant's participation, the feeling of being pressed to participate may be irresistible which will undermine the potential voluntariness of the consent to participate.

2.2.1 Researchers must justify the inclusion of a vulnerable population in the research.

2.2.2 ECs must satisfy themselves with the justification provided and record the same in the proceedings of the EC meeting.

2.2.3 Additional safety measures should be strictly reviewed and approved by the ECs.

2.2.4 The informed consent process should be well documented. Additional measures such as recording of assent and reconsent, when applicable, should be ensured.

2.2.5 ECs should also carefully determine the benefits and risks of the study and examine the risk minimization strategies.

2.2.6 As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period.

2.2.7 Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.

2.2.8 Research on sensitive issues such as mental health, sexual practices/preferences, HIV/ AIDS, substance abuse, etc. may present special risks to research participants.

2.2.9 Researchers should be cognizant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful.

2.2.10 Participants may be prone to stigma or discrimination, specifically when the participant is enrolled as a normal control or is recruited from the general population in certain types of research.

2.2.11 Efforts should be made to set up support systems to deal with associated medical and Social problems.

2.2.12 Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion.

2.2.13 Whenever possible, ancillary care may be provided such as setting up of a facility, school for unattended children of the participants or a hospital, or counseling centre.

2.3 Obligations/duties of stakeholders to protect vulnerable participants: All stakeholders have different responsibilities to protect vulnerable participants as follows:

2.3.1 Researchers:

Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. Justify inclusion/exclusion of vulnerable populations in the study. Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. Ensure that prospective participants are competent to give informed consent. Take consent of the LAR (legally acceptable/authorized representative) when a prospective participant lacks the capacity to consent. Respect dissent from the participant. Seek permission from the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc.

2.3.2 Ethics Committees:

During review, determine whether the prospective participants for a particular research are vulnerable. Examine whether inclusion/exclusion of the vulnerable population is justified. Ensure that COI do not increase harm or lessen benefits to the participants. Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible .Suggest additional safeguards, such as more frequent review and monitoring, including site visits. Only the full committee should do initial and continuing review of such proposals. ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD.

2.3.3 Sponsors :

The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety.

2. 4. Women in special situations

Women have equal rights to participate in research and should not be deprived arbitrarily of the opportunity to benefit from research. Informed consent process for some women can be challenging because of cultural reasons. Hence, the women may consider consulting their husbands or family members, if necessary. Although autonomyof the woman is important, the researcher must follow the requirements of local cultural practices so as not to disturb the harmony in the household/family/community.

2.4.1 Participation of a woman in clinical trials or intervention studies that may expose her to risk is elaborated as follows-

Researchers must provide the EC with proper justification for inclusion of pregnant and nursing women in clinical trials designed to address the health needs of such women or their fetuses or nursing infants. Some examples of justifiable inclusion are trials designed to test the safety and efficacy of a drug for reducing perinatal transmission of HIV infection from mother to child, trial of a device for detecting foetal abnormalities or trials of therapies for conditions associated with or aggravated by pregnancy, such as nausea, vomiting, hypertension or diabetes.

If women in the reproductive age are to be recruited, they should be informed of the potential risk to the foetus if they become pregnant. They should be asked to use an effective contraceptive method and be told about the options available in case of failure of contraception.A woman who becomes pregnant must not automatically be removed from the study when there is no evidence showing potential harm to the fetus. The matter should be carefully reviewed and she must be offered the option to withdraw or continue. In case the woman opts for continued participation, researchers and sponsors must adequately monitor and offer support to the woman for as long as necessary.

2.4.2 Prenatal diagnostic studies:

Research related to prenatal diagnostic techniques in pregnant women should be limited to detecting foetal abnormalities or genetic disorders as per the Pre-Conception and Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, amended in 2003 and not for sex determination of the fetus.

2.4.3 Research on sensitive topics:

When research is planned on sensitive topics, for instance, domestic violence, genetic disorders, rape, etc. confidentiality should be strictly maintained and privacy protected. In risk mitigation strategies, appropriate support systems such as counseling centers, police protection, etc. should be established.

2.5 Children

Children are individuals who have not attained the legal age of consent (up to 18 years). At younger ages, children are considered vulnerable because their autonomy is compromised as they do not have the cognitive ability to fully understand the minute details of the study and make decisions. At older ages, although they may attain the cognitive ability to understand the research, they still lack legal capacity to consent. Therefore, the decision regarding participation and withdrawal of a child in research must be taken by the parents/ LAR in the best interests of their child/ward. The EC should take into consideration the circumstances of the children to be enrolled in the study including their age, health status, and other factors and potential benefits to other children with the same disease or condition, or to society as a whole.

2.5.1 Children can be included in research if the situation, condition, disorder or disease fulfils one of the following conditions:

1. It is exclusively seen in childhood.

2. Both adults as well as children are involved in research, but the issues involved are likely to be significantly different in both these populations. Research is generally permitted in children if safety has been established in the adult population or if the information likely to be generated cannot be obtained by other means. The physiology of children is different from that of adults, and the pharmacokinetics of many drugs is age-dependent based on the maturation of the drug metabolism pathways. For example, children metabolize many drugs much more rapidly as compared to adults, hence the dose of the drug per kg of body weight that needs to be given, is much higher in children as compared to adults. The absorption of drugs also varies with age. Pharmacokinetics and toxicity profile varies with growth and maturation from infancy to adulthood.T he adverse effects of many drugs may also be different in children as compared to adults. For instance, tetracyclines cause

teeth discoloration in young children, aspirin use is associated with Reye's syndrome in children.

Age appropriate delivery vehicles and formulations (e.g. syrups) are needed for accurate, safe, and palatable administration of medicines to infants and children. The pathophysiology of many disorders is dependent on a child's growth, development and adaptive plasticity. Examples include adaptive changes in the motor system following a perinatel stroke

2.5.2 Consent

1. Consent from the parent(s) should be taken before prior to the study. The EC will decide whether the consent should be taken from both parents or single parent. Generally, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.

2. Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. In fact, their parents are also vulnerable and there is a high likelihood of therapeutic misconception. The potential benefits and risks must be carefully explained to parents so as to make them understand the proposed research.

3. Research involving institutionalized children would require consent of the child, consent of parents/LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal or management may be involved).

4. When the research involves sensitive issues related to neglect and abuse of a child, the EC may waive the requirement of obtaining parental/LAR consent and prescribe an appropriate mechanism to safeguard the interests of the child.

2.7 Research involving sexual minorities and sex workers

There are unique challenges associated with research on sexual minorities and sex workers such as privacy, confidentiality, possibility of stigma, discrimination and exploitation resulting in increased vulnerability.

2.7.1 Protection of their dignity and provision of quality healthcare should be well addressed in the research proposal, in consultation with the community before the proposal is finalized.

2.7.2 To have a representative of the sexual minority group/ Sex worker as a special invitee to participate in the meeting of the EC if there is a research proposal involving these participants.

2. 7.3 The EC can suggest setting up of a community advisory board to act as an interface between the researcher(s) and the community and the researcher can sensitize the participants of the community for better understanding about details of the research via the community advisory board.

2.8 Research among tribal population

2.8.1 **Research** on tribal populations in a community should be conducted only if that Particular research benefits the tribal population and /or reveals some novel information.

2.8.2 Whenever and wherever possible, the community leader such as Gauburha or with Equivalent portfolio should be informed about the research and a written consent can be taken prior to the ethical clearance.

2. 8.3 For hospital research, consent from the individual participant should be taken prior to Include them as research subject.

2.8.4 Informed consent should be taken in consultation with community elders and persons who know the local language/dialect of the tribal population and in the presence of appropriate witnesses

2.8.5 Benefit sharing with the tribal group should be ensured for any research done using tribal knowledge that may have potential for commercialization.

2.9 Patients who are terminally ill.20

Terminally ill patients or patients who are in search of new interventions having exhausted all available therapies are vulnerable as they are ready to give consent for any intervention that can give them a ray of hope. These studies are approved so that the scientific community or professional groups do not deny such patients the possible benefit of any new intervention that is not yet validated.

2.9.1 Since therapeutic misconception is high there should be appropriate consent procedures and the EC should carefully review such protocols and recruitment procedures.

2.9.2 Additional monitoring should be done to detect any adverse event at the earliest.

2.9.3 Benefit-risk assessment should be performed considering perception of benefits and risks by the potential participant.

2.9.4 The EC should carefully review post-trial access to the medication, especially if it is beneficial to the participant.

2.10 Other vulnerable groups

Other vulnerable groups include the economically and socially disadvantaged, homeless, refugees, migrants, persons or populations in conflict zones, riot areas or disaster situations. Additional precautions should be taken to avoid exploitation/retaliation/reward/credits and other inducements when such individuals are to be recruited as research participants.

2.10.1 Autonomy of such individuals is already compromised and researchers have to justify their inclusion.

2.10.2 ECs have to satisfy themselves with the justification provided to include these participants and record the same in the proceedings of the EC meeting.

2.10.3 Additional safety measures suggested earlier in the guidelines should be strictly followed by the ECs.

2.10.4 The informed consent process should be well documented. There should not be any undue coercion or incentive for participation. A person's refusal to participate should be respected and there should be no penalization.

2.10.5 The EC should also carefully determine the benefits and risks of the study and examine risk minimization strategies.

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SECTION-3
Standard Operating Procedure (SOP)
Conflict of Interest
Institutional Ethics Committee (Human)
Jorhat Medical College, Jorhat

1. Purpose:
SOP for conflict of interest (COI) describes the process/ procedure for declaring conflict of interest by researchers and reviewers

2. Definition of term COI
A discrepancy between personal interest and professional responsibility of a person in a position of trust.
Here, a professional judgment concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest ,financial or non financial (personal, academic, political). It can be at the level of researchers, EC members, institutions or sponsors.

3. Responsibilities of IEC(H) member

3.1. Member must disclose COI before every review meeting
3.2. A member who has declared COI shall excuse oneself from decision making on that protocol
3.3. The declaration of COI shall be minuted and properly recorded including the time of recusal and rejoining the meeting

4. Management of COI

4.1. Public disclosure of Financial COI
4.2. Disclosure to human subject
4.3. Requiring a non conflicted co investigator to obtain informed consent from human subject
4.4. Requiring that the data collection, data analysis, and interpretation be conducted in conjunction with a non conflicted co investigator capable and willing to take appropriate measures to protect the design, conduct and reporting of research against potential bias resulting from Financial Conflict of Interest (FCOI).
4.5. Modification of research plan may be an option
4.6. Change of personal responsibilities, disqualification of personnel from participation in all or a portion of the research
4.7. Disclosure of conflict of interest in any publication related to the research is advocated.
4.8. The ethics committee members will not show indulgence to any bias by the institutional authority or sponsoring organization.

SECTION- 4
STANDARD OPERATING PROCEDURE
RESIGNATION & REMOVAL OF ETHICS COMMITTEE MEMBERS

Purpose: To establish procedures for removal or resignation of EC members.
Responsibility: Chairman and Member Secretary are responsible for implementing this SOP.

Procedure for Resignation:

3.1: Submit an application addressing the Chairman stating the reason for resignation at three calendar days prior to the next meeting

Procedure for Termination:

3.1: Member may be terminated for unbecoming conduct from members of IEC(H).
3.2: Inability to participate in three consecutive IEC (H) meetings..
3.3: Members indulge in Conflict of Interest.
3.4: In all situations or circumstances member Secretary / Chairman will serve a letter as termination to the member.
3.5: Chairman/ Member Secretary would appoint a new member falling in the same category of membership.
3.6: Documentation of termination or resignation will be recorded in the minutes of the next scheduled meeting.