



**Standard operating procedures (SoP)
for
Institutional Ethics Committee (IEC)**

**Centre for Social Studies (CSS)
VNSG University Campus
Surat: 395007
Ph: 0261-2227173-74**

Content

Sr. No	Subject Title	Page No.
1	Establishing and Constituting the Institutional Ethics Committee (IEC)	01
2	Procedure for convening and conducting IEC meetings	02
3	Procedure for submission of research project for review by Ethics Committee	03
4	Procedure for initial scrutiny of proposals	05
5	Procedure for reviewing the research proposals	06
6	Procedure for expedited review of research project by Ethics Sub-Committee	07
7	Procedure for decision making regarding the research project	08
8	Procedure for decision making regarding the research project involving vulnerable population	09
9	Procedure for the non-funded & funded project budget	10
10	Procedure for communicating the decision of IEC to the Investigator	11
11	Procedure for follow-up of research projects by Ethics Committee	12
12	Procedure for documentation and archiving of documents and communications of IEC	13
13	Constitution of the IEC of the CSS	14
14	Form to be filled for submission to Institutional Ethics Committee (IEC)	15
15	Respondent Informed Consent Form (RICF)	21
16	Checklist for the submission of project proposal	22
17	Reviewer form	23

CSS-IEC

Standard Operating Procedure (SoP)

1. Title: Establishing and Constituting the Institutional Ethics Committee (IEC)

1. PURPOSE

To establish and constitute the Institutional Ethics Committee for CSS.

2. SCOPE

Applicable to CSS.

3. RESPONSIBILITY

Director is responsible for implementing this SOP.

4. PROCEDURE

- 4.1 Committee will be called CSS Institutional Ethics Committee (CSS-IEC)
- 4.2 Director (Head of the Institute) will select and nominate the Chairman and Member Secretary for CSS IEC.
- 4.3 The IEC will be constituted by the Director in consultation with the Chairman in accordance with the requirement specified in Appendix VIII of schedule Y, & Good research practices for social science research in India.
- 4.4 Director will invite the members to join ethics committee by sending the official request letter.
- 4.5 Members will confirm their acceptance to the Director by providing all the required information for membership.
- 4.6 The Director will ensure that the IEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of communities they serve.
- 4.7 Director will designate and instruct Chairman of IEC or his/her representative to conduct the regular proceedings of IEC for the institute
- 4.8 At regular intervals, Director will review the functioning of IEC.
- 4.9 Arrangement should be made for the documentation and maintenance of records of IEC

2. Title: Procedure for convening and conducting IEC meetings

1. PURPOSE

To hold regular Ethics Committee meetings.

2. SCOPE

Applicable to CSS.

3. RESPONSIBILITY

The Chairman and Member Secretary are responsible for implementing this SOP.

4. PROCEDURE

4.1 Meetings will be planned in accordance with the need of the work load & the Member Secretary in consultation with chairman may convene the IEC meeting

4.2 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.

4.3 All the IEC meetings will be held regularly on scheduled dates that are announced and notified in advance.

4.4 All the proposals will be received at least three weeks before the meeting, checked for completeness as per the check list initially by the office superintendent (**IEC-04**), subsequently by the member secretary (through a nominated person) using the evaluation form (**IEC-05**)

4.5 Members will be given not less than 10 days time in advance to review study proposals and the relevant documents.

4.6 Minutes of the IEC meetings, all the proceedings and deliberation will be documented.

4.7 Signatures of the Chairman and the Member Secretary & Director will be obtained on the minutes of the meeting document.

4.8 Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues.

4.9 Independent experts may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement. They will not have a role in decision making

3. Title: Procedure for submission of research project for review by Ethics Committee

1. PURPOSE

To submit a research proposal for review by IEC.

2. SCOPE

Applicable to Principal Investigators (PIs) from CSS and PIs from CSS Collaborating Institutions where CSS faculty is Co-Investigators (CoIs)

3. RESPONSIBILITY

All investigators are responsible for implementing this SoP. Every protocol or amendment submitted for review to IEC must contain number, version and date. All the research proposals must be submitted in the prescribed application form, duly filled, along with all necessary documents for the review.

4. PROCEDURE

4.1 The Project Investigator has to submit an application in a prescribed format along with study protocol and other study related documents necessary for review of the IEC (Form No: IEC-01, 02,03A & B, 04).

4.2 Application can be submitted to the office of the IEC, CSS, on any working day.

4.3 All the proposals and documents must be submitted at least three weeks in advance from the scheduled date of IEC meeting

4.4 Five copies (soft copies will be accepted) of study proposal must be submitted for Ethic Committee review along with application form duly signed and dated by the investigator(s) to info@css.ac.in

4.5 Receipt of the application will be acknowledged by the IEC office.

4.6 Every application will be allotted an IEC registration number to be used for all future correspondence and reference.

4.7 **Submission of Study Related Documents for review:** If required, apart from a research proposal, IEC may ask PIs to submit other study related documents like a copy of proposed interview schedule, interview guide etc.

- 4.8 **All amendments/ changes (if any) to the approved research proposal** must be submitted to the IEC immediately for its review. No changes in the protocol, and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the subject, or when the change(s) involve only logistical or administrative aspects of the study. A covering letter should be submitted mentioning reason/s for amendments and summary of changes and the amended text must be highlighted in the revised Protocol and Protocol Related Documents.
- 4.9 **Submission of Report of Serious Adverse Events (SAEs):** In case of studies involving medical intervention (e.g. blood samples etc.) all Serious Adverse Events (SAEs) at field site occurring during the study should be submitted to the IEC within seven working days of their occurrence. **If the SAE is 'death', it should be reported to the IEC within 24 hours of its occurrence.**

4. Title: Procedure for initial scrutiny of proposals

1. PURPOSE

To check the research proposals submitted by the investigators for completeness.

2. SCOPE

Applicable to CSS.

3. RESPONSIBILITY

The office of Member Secretary is responsible for implementing this SoP.

4. PROCEDURE

- 4.1 Every proposal will be collected and compiled by the Institute Ethics Committee office.
- 4.2 An office staff/ member nominated by the Member Secretary/Director will verify the proposals for completeness
- 4.3 In case of incomplete data, the investigators will be informed by the office after consulting the Member Secretary to make the necessary corrections and to resubmit.

5. Title: Procedure for reviewing the research proposals

1. PURPOSE

To review the research proposals submitted by the investigators both scientifically and ethically.

2. SCOPE

Applicable to CSS.

3. RESPONSIBILITY

All members of IEC are responsible for implementing this SOP.

4. PROCEDURE

- 4.1 Every proposal will be sent not less than 10 days before the meeting to all members of IEC. They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC review.
- 4.2 All the members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
- 4.3 Generally, the IEC review will be done through formal meetings but if required IEC can also decide through electronic circulation of proposal.
- 4.4 Expert opinion of additional members would be obtained if necessary. Every proposal will be collected and compiled by the Institute Ethics Committee office.

6. Title: Procedure for expedited review of research project by Ethics Sub-Committee

1. PURPOSE

To provide expedited review and approval of a research proposal.

2. SCOPE

Applicable to the members of IEC CSS.

3. RESPONSIBILITY

All members of Sub-committee are responsible for the implementing this SOP.

4. PROCEDURE

4.1 IEC will receive and consider the proposals for expedited review and approval for the studies having/involving:

- i. No or minimum risk to the study participants.
- ii. Re examination of a proposal already examined by the IEC.
- iii. Study based only on secondary data involving no fieldwork.
- iv. Similar study proposal for which IEC had already given approvals earlier.
- v. When urgent studies are required.
- vi. All ICSSR PhD students and post doctoral fellow proposals.

All other proposals which do not comply with the above criteria will be reviewed in the Regular Ethics Committee meeting.

4.2 All expedited approvals will be given in a meeting of the Sub-Committee of three members **(nominated by the Chairman and Director)**. All three members including the Member Secretary should be present for the meeting.

4.3 Decision taken by the Sub-Committee on expedited approval will be brought to the notice of the main committee members at the next regular meeting of the IEC.

7. Title: Procedure for decision making regarding the research project

1. PURPOSE

To make a decision regarding approval of the submitted research proposal.

2. SCOPE

Applicable to of IEC CSS.

3. RESPONSIBILITY

All members of are responsible for the implementing this SoP.

4. PROCEDURE

4.1. In making decision on application for the ethical review of any research proposal, IEC will consider the following:

- 4.1 Member having a conflict of interest will indicate to the Chairman prior to the review of application and same will be recorded in the minutes.
- 4.2 Where there is a conflict of interest, member will withdraw from the decision making procedure.
- 4.3 A decision will only be taken when sufficient time has been allowed for the review and discussion of an application in the absence of non members (e.g. Investigator) from the meeting.
- 4.4 Decision will only be taken at meetings where a quorum is complete.
- 4.5 Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal.
- 4.6 Only IEC members who participated in review and discussion will participate in decision making.
- 4.7 Wherever possible, the decision will be arrived through consensus and not by vote, but when a consensus appears unlikely voting can be resorted to.
- 4.8 Decision will specify the conditional decision if any, with clear suggestions and re-review procedure.
- 4.9 Rejection of proposal will be supported by clearly stated reasons.

8. Title: Procedure for decision making regarding the research project involving vulnerable population *

1. PURPOSE

To make a decision regarding approval of the submitted research proposal.

2. SCOPE

Applicable to of IEC CSS.

3. RESPONSIBILITY

All members of are responsible for the implementing this SoP.

4. PROCEDURE

In making decision on application for the ethical review of research proposal involving Vulnerable population, IEC will consider the following:

- 4.1 A decision will only be taken when sufficient time has been allowed for the review and discussion of an application in the absence of non members (e.g. PI and CoIs) from the meeting.
- 4.2 Decision will only be taken at meetings where a quorum is complete.
- 4.3 Decision will be taken only after reviewing a complete application with all the required documents necessary
- 4.4 Decision will specify the conditional decision if any, with clear suggestions and re-review procedure.
- 4.5 Rejection of proposal will be supported by clearly stated reasons.

* **Pregnant women / children / elderly / Foetus / illiterate/ handicapped/ Terminally ill / seriously ill/mentally Challenged / Scheduled Castes (SCs) subjects/ Scheduled Tribe (STs) subjects/ economically & socially backward (OBCs) subjects etc.**

9. Title: Procedure for the non-funded & funded project budget

1. PURPOSE

To harmonize fund utilization and strengthening of the infrastructure for research.

2. SCOPE

Applicable to CSS.

3. RESPONSIBILITY

Director & Project PI are responsible for implementing this SOP.

4. PROCEDURE

- 4.1 There would not be any processing fees or any other fees for consideration of dissertation/thesis, non-funded/ self funded project by the faculty of CSS.
- 4.2 All externally funded projects should have budget provision of IEC processing fee of 5000/-. IEC processing fee will be utilized for organising IEC meetings and related incidental expenses.

10. Title: Procedure for communicating the decision of IEC to the Investigator

1. PURPOSE

To communicate the decision of IEC to the applicant.

2. SCOPE

Applicable to of IEC CSS.

3. RESPONSIBILITY

Member Secretary is responsible for implementing this SOP.

4. PROCEDURE

- 4.1. A decision of the IEC will be communicated to the applicant in writing, within 14 days of the meeting at which the decision was taken. The minutes **(IEC- 06)** will be circulated to all the guides/supervisors in case of student proposals. All the approvals **(IEC-07)** will be valid for only five years or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after five years if necessary.
- 4.2. An investigator is expected to submit **reply** to the letter of recommended modifications / queries sent by the IEC, within 30 days of date of receipt of the letter. If the investigator fails to reply within this period, the file will be considered closed by the IEC and ethics clearance certificate will not be issued by IEC. The investigator will have to re-apply for the ethics committee approval.
- 4.3. Applicant need to collect a certificate of approval from the IEC office/IEC Member Secretary.
- 4.4. The communication of the decision will include:
 - 4.4.1. Name and address of IEC.
 - 4.4.2. The date and place of decision.
 - 4.4.3. The name and designation of the applicant.
 - 4.4.4. Title of the research proposal reviewed.
 - 4.4.5. The clear identification of proposal no., version no., date, amendment no., date.
 - 4.4.6. A clear statement of decision reached.
 - 4.4.7. Any advice by the IEC to the applicant.
 - 4.4.8. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re reviewed.
 - 4.4.9. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated. Signature of the member secretary with date

11. Title: Procedure for follow-up of research projects by Ethics Committee

1. PURPOSE

To carry out follow-up of the research proposals.

2. SCOPE

Applicable to IEC CSS.

3. RESPONSIBILITY

All members of the IEC and the investigators are responsible for implementing this SOP.

4. PROCEDURE

- 4.1 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.
- 4.2 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.
- 4.3 Following instances and events will require the follow-up review:
 - 4.4.1. Any protocol amendment likely to affect rights, safety or well being of research subject of conduct of study.
 - 4.4.2. Serious or unexpected adverse effect, action taken by Investigator, Sponsor and Regulatory Authority.
 - 4.4.3. Any event or information that may affect the benefit/risk ratio of the study.
- 4.5. A decision of a follow up review will be issued and communicated to the applicant indicating modification/suspension/termination /continuation of the project.
- 4.6. In case of premature suspension /termination, the applicant must notify the IEC of the reasons for suspension/termination with a summary of results.
- 4.7. Applicant (non-thesis project) 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.

12. Title: Procedure for documentation and archiving of documents and communications of IEC

1. PURPOSE

To archive the study related documents, proceedings and communications.

2. SCOPE

Applicable to IEC CSS.

3. RESPONSIBILITY

The Member Secretary is responsible for implementing this SoP.

4. PROCEDURE

- 4.1 All the documents and communications of IEC will be dated, filed and archived in IEC office.
- 4.2 Only persons, who are authorized by the Chairman of IEC, will have the access to the various documents.
- 4.3 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.
- 4.4 No document (except agenda) will be retained by any IEC member.
- 4.5 At the end of each meeting, every member must return 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.
- 4.6 Following documents will be filed and archived with proper label in on the top of file
 - 4.6.1 The constitution, written standard operating procedures of the IEC, and regular (annual) reports.
 - 4.6.2 The curriculum vitae of all IEC members.
 - 4.6.3 A record of all income and expenses if any, of the IEC, including allowances and reimbursements made to the secretariat and IEC members.
 - 4.6.4 The published guidelines for submission established by the IEC.
- 4.7 Following documents will be files and archived for easy identification of proposal.
 - 4.7.1 The agenda of the IEC meetings.
 - 4.7.2 The minutes of the IEC meetings.
 - 4.7.3 One copy of all material submitted by an applicant.
 - 4.7.4 A copy of the decision and any advice or requirements sent to an applicant.
 - 4.7.5 All written documentation received during the follow-up.
 - 4.7.6 The notification of completion, premature suspension, or premature termination of study.

13. Title: Constitution of the IEC of the CSS

The following experts will constitute the Institutional Ethics Committee.

- | | |
|--|------------------------------|
| (1) CSS Director; | (2) Member (Subject Expert); |
| (3) Member (Medical Expert); | (4) Member (Legal Expert); |
| (5) Member (Psychologist); | (6) Member (Theologist); |
| (7) Member Secretary Faculty (Member of the CSS) | |

From the year 2015, the following is the composition of the CSS IEC Committee.

No.	Designation	Name & organizational title, telephone No., Fax No., e-mail, mailing address	Qualification
1	CSS Director	Professor Satyakam Joshi satyakamjoshi@gmail.com	PhD (Sociology)
2	Member (Subject Expert)	Professor Harish Doshi doshiharish@yahoo.com	PhD (Sociology)
3	Member (Medical Expert)	Dr. Vikas Desai psmvikas@hotmail.com	MBBS, MD (PSM)
4	Member (Legal Expert)	Principal Jagruti Patel jagrutikpatel@hotmail.com	PhD (Law)
5	Member (Psychologist)	Dr. Dipti Joshi dedipti@msn.com	PhD (Psychology)
6	Member (Theologist)	Fr. Issac isrumao@gmail.com	B.Com
7	Member Secretary	Dr. Akash Acharya akash.acharya@gmail.com	PhD (Economics)

14. Title: Form to be filled for submission to Institutional Ethics Committee (IEC) one copy

Proposal Title:

	Name, Designation & Qualifications	Address, Tel & Fax Nos. Email ID	Signature
Principal Investigator (Includes PhD students and Post Docs)			
Co Investigator (Includes Guide/Supervisor)			
1.			
2.			

Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years). Email it to info@css.acin

Tick appropriately

Sponsor Information :			
1. Indian			
a) Research Councils	ICSSR <input type="checkbox"/>	UGC <input type="checkbox"/>	Other <input type="checkbox"/> _____
a) Government	Central <input type="checkbox"/>	State <input type="checkbox"/>	Local (ULBs) <input type="checkbox"/>
b) Private	Foundation <input type="checkbox"/>	Corporate <input type="checkbox"/>	
2. International	Government <input type="checkbox"/>	Private <input type="checkbox"/>	UN agencies <input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	
Contact Address of Sponsor:			
Total Budget :			

1. Type of Study :	Field based <input type="checkbox"/>	Secondary Data based <input type="checkbox"/>	Both <input type="checkbox"/>
	Involved Clinical text (e.g. blood test) <input type="checkbox"/>		
2. Status of Review:	New <input type="checkbox"/>	Revised <input type="checkbox"/>	

3. Clinical Trials:		
Drug /Vaccines/Device/Herbal Remedies :		
Does the study involve use of :		
Drug <input type="checkbox"/>	Devices <input type="checkbox"/>	Vaccines <input type="checkbox"/>
Indian Systems of Medicine/ Alternate System of Medicine <input type="checkbox"/>	Any other <input type="checkbox"/>	NA <input type="checkbox"/>
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 rationale (Attach sheet with maximum 500 words):		
5. Subject selection: (Sample Size)		
Number of Subjects :		
Duration of study :		
iii. Will subjects from both sexes be recruited	Yes	No
Inclusion / exclusion criteria given	Yes	No
Vulnerable subjects Yes <input type="checkbox"/> No <input type="checkbox"/> (Tick the appropriate boxes)		
Pregnant women <input type="checkbox"/>	children <input type="checkbox"/>	elderly <input type="checkbox"/>
Fetus <input type="checkbox"/>	illiterate <input type="checkbox"/>	handicapped <input type="checkbox"/>
Terminally ill seriously ill <input type="checkbox"/>	mentally Challenged <input type="checkbox"/>	STs <input type="checkbox"/>
economically & socially backward (OBCs) <input type="checkbox"/>	SCs <input type="checkbox"/>	

ii. Is there physical / social / psychological risk / discomfort? If Yes, Minimal or no risk <input type="checkbox"/> More than minimum risk <input type="checkbox"/> High risk <input type="checkbox"/>	Yes	No
iii. Is there a benefit a) to the subject? Direct <input type="checkbox"/> Indirect <input type="checkbox"/> b) Benefit to society <input type="checkbox"/>		
11. Data Monitoring		
ii. Is there a plan for reporting of adverse events? If Yes, reporting is done to : Sponsor <input type="checkbox"/> Ethics Committee <input type="checkbox"/>	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of study database? If Yes, for how long ?	Yes	No
12. Is there compensation for participation? If Yes, Monetary <input type="checkbox"/> In kind <input type="checkbox"/> Specify amount and type:	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	Yes	No
Checklist for attached documents:		
Project proposal	<input type="checkbox"/>	
Curriculum Vitae of Investigators	<input type="checkbox"/>	
Brief description of proposal	<input type="checkbox"/>	
Respondent information sheet	<input type="checkbox"/>	
Informed Consent form	<input type="checkbox"/>	
Copy of advertisements/Information brochures	<input type="checkbox"/>	

Place:

Signature of PI/PG Student &

CO-PI/PG Guide

Date:

Protocol for research proposal

Prepare the proposal using MS world, Times New Roman 12 font size, with 1.0 line spacing for A4 size paper with 1 inch margin on all side. Submit the proposal to Gen. Secretary IEC, CSS.

1. **Title of the Project** : Indicate the appropriate title for the proposed study
2. **PhD Student /Principal Investigator** : Bold letters only
3. **PhD Guide / Co-investigator/s** : Bold letters only
4. **Subject key words** : 3-5 words, JEL classification if applicable
5. **Introduction** : Explain the scientific background and rationale for the investigation being proposed (100-300 words)
Mention justification for study
6. **Research question** : Mention Study problem & Need of the study.
Usefulness of the project. Will the study lead to improvements in human wellbeing and/or increase knowledge?
7. **Aims & Objective** : Mention Aims & Objectives (State specific objectives, including any pre-specified hypotheses)
8. **Sponsor details** : Source of funding & financial allocation for the project
9. **Study type** : Field based/Secondary data etc.
10. **Methodology** : Mention details methodology describing the duration of the project, setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection, potential risks & benefits, method of subject/patient accrual for study, provide Performa/questionnaire. Also provide inclusion & exclusion criteria
11. **Ethical issues** : Mention Plan / Process of obtaining informed consent / confidentiality of information/ risks involved-minimal? More than minimal?-high risk? [Explain all anticipated 'risks' (adverse events, injury, discomfort...) of the project & efforts taken to minimize the 'risks']/ Report of adverse event/ Policy regarding treatment of study related injury/ compensation for study related injury and compensation for participation. Policy regarding dissemination of data, presentation of data, publication
12. **Statistical methods to be applied** : Use of SPSS, statistical methods etc.
13. **Expected results & Conclusion** : Brief about results of similar studies, benefits of study, analysis and whether it is of national significance with rationale
14. **Reference** : Provide as per standard journal requirement

RESPONDENT INFORMATION SHEET (RIS)

Investigator must provide the subjects/respondents with the following information in simple **understandable layman's language in English/Hindi/Gujarati/Other regional language** which can be understood by them:

1. Title of the study/project.
2. Aims and methods of the research.
3. Expected duration of the subject participation.
4. The benefits to be expected from the research to the subject or to others.
5. Any risk to the subject associated with the study.
6. Maintenance of confidentiality of records.
7. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
8. Where applicable, amount of blood sample to be taken should be mentioned.
9. Telephone number/contact number of the candidate and one of the investigators must be mentioned.
10. Self certification should be given that translation to vernacular is accurate.

15. Title: Respondent Informed Consent Form (RICF)

Title of project: _____

Name of Principal Investigator: _____ Tel.No(s). _____

The contents of the respondent information sheet (RIS) 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 at any time, without giving any reason.

I understand that the information collected about me from my participation in this research may be looked at by responsible individuals from the institute. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

(Signatures / Left Thumb Impression)

Date:
Place:

Name of the Respondent: _____

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

Witness:

Date:
Place:

Signature

NB Two copies should be made, for (1) respondent, (2) researcher

16. Title: Checklist for the submission of project proposal

Title of Project	
Principle Investigator	
Date of Submission	

Sr. No	Document	Yes/ No/ NA	Submission date
1	Project submission application form duly filled IEC-01		
2	Protocol as per the format IEC-02		
3	IEC-01, 02, duly signed by the PhD-student/ investigator(s), guides, co-guides and Head of concerned departments, with date?		
4	Information sheet & consent in English IEC-03/A&B		
5	Information sheet & consent in Regional language- Gujarati, Hindi		
6	Consent form appropriately worded for adults and children (less than 18 years) e.g. Instead of 'my participation', 'my child's/ward's participation' to be replaced.		
7	Complete address and phone number of the investigator/guide provided in the appropriate place in consent form		
8	Case record form/ Questionnaire/ Performa		
9	Others as per requirement of project <ul style="list-style-type: none"> • Administrative sanction from the Head of the Institution should be sought by investigators for studies involving collaboration with other Indian or foreign institution/University. 		

17. Title: Reviewer form

Title of Project	
Principle Investigator / PhD student	
IEC/In/ No. & Date	

Details	Yes	No	NA
Is all the documentation provided?			
Scientific importance and validity			
1. Will the study lead to improvements in human health and wellbeing or increase knowledge?			
2. If the study is a replication of a previous study, is it justified?			
3. Can the intervention studied be practically implemented?			
4. Are the objectives stated clearly?			
5. Is the study design appropriate in relation to the objectives?			
Assessment of Risks/Benefits			
1. Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?			
2. Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?			
3. Have adequate provisions been made for dealing with and reporting adverse effects?			
4. Have adequate provisions been made for safety monitoring and termination of the research project?			
Respect for the dignity of the research participants			
<i>Informed consent</i>			
1. Is the process for obtaining informed consent appropriate?			
2. Are the participants competent to give consent?			
3. Is the justification adequate for the intention to include individuals who cannot consent?			
4. Will dissent be respected?			
5. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?			
6. Is the consent given voluntarily and not due to deception, intimidation or inducement			

(**Deception:** dishonesty/trick/fraud, **Intimidation:** pressure, **Inducement:** incentive/encouragement)

Confidentiality			
1. Will the researcher collect only the minimum information/samples required to fulfil the study objectives?			
2. Is the privacy of the research participant safeguarded?			
3. Are data/sample storage and disposal procedures adequate?			
Rights of the participants			
1. Is the participant's right to unconditionally withdraw from the research at anytime safeguarded?			
2. Is there provision for participants to be informed about newly discovered risks or benefits during the study?			
3. Is there provision for the subjects to be informed of results of clinical research?			
Fair participant selection			
1. Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?			
2. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?			
3. Is the research conducted on vulnerable individuals or groups?			
4. Is the research a community research?			
5. Is the research a clinical trial?			
Responsibilities of the researcher			
1. Has the researcher obtained permission from the relevant authorities?			
2. Are there any conflicts of interest, including payments and other rewards?			
3. Are there any other ethical / legal/ social /financial issues in the study?			
4. Budget: Acceptable?			

Additional Comments:

.....
.....
.....

Recommendation: **Approve** [] **Reject** [] **Conditional Approval** (please state the conditions)

.....
.....
.....

Name of Reviewer:

Signature:

Date: