Gokhale Institute of Politics and Economics
(Deemed to be University)

Constitution of the Ethics Committee

- Certificate of Ethics Committee IEC

- SOP of Ethics Committee 2023

- SOP of Ethics Committee 2018

GOKHALE INSTITUTE OF POLITICS AND ECONOMICS DEEMED TO BE UNIVERSITY II PUNE-4.

File No. - EC/NEW/INST/2023/3421

सत्यमेव जयते

Government of India
Ministry of Health & Family Welfare
Department of Health Research

2nd Floor, IRCS Building,
New Delhi - 110001
Dated : 04-Aug-2023

Provisional Certificate

Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter IV of the New Drugs and Clinical Trials Rules, 2019.

Name :	**Gokhale Institute Internal Ethics Committee**
Address :	**Gokhale Institute of Politics and Economics, Gokhale Institute of Politics and Economics, Pune , Pune, Maharashtra - 411004**
Contact No:	**2025683355**
Fax :	**2025652579**

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

Note: EC registration number provided by DHR should be displayed on every certificate of approval issued by the Ethics committee

ANU NAGAR
(Anu Nagar)
Joint Secretary
Department of Health Research
Designated Authority

Approved SOP by the IEC

Standard Operating Procedures (SOP)

GOKHALE INSTITUTE OF POLITICS AND ECONOMICS

INSTITUTIONAL ETHICS COMMITTEE

Version 3: January 2023

Email: gipeiec@gipe.ac.in

Table of Contents

1. Introduction

The Gokhale Institute of Politics and Economics, Pune, was established in 1930 by the Servants of India Society. It is the oldest research and training institute in Economics in the country. It is dedicated to research into the socio-economic dimensions of Indian society.

Research in human subjects is now guided by principles laid down by committees at National and International levels. It is essential to follow Good Clinical Practices (GCP) adopted internationally. The Indian Council of Medical Research (ICMR) in 2017 has issued National Ethical Guidelines for Biomedical and Health Research involving Human Participants. All these principles are put into practice through formulation of an Institutional Ethics Committee (IEC).

2. Authority under which IEC is constituted:

Authorities of Gokhale Institute of Politics and Economics constituted the Institutional Ethics Committee under the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, in order to ensure that Health and Allied Institutes shall conduct research on human subjects, using research methodology that meets international and local regulations, ethical standards and is consistent with principles of GCP.

3. Objectives of GIPE Institutional Ethics Committee

Research in public health, social and behavioral sciences is expanding rapidly and human participation and/ or use of previous data in such studies is largely inevitable. Adherence to research ethics is an integral part of scientific endeavors. In view of this, the objectives of the GIPE Institutional Ethics Committee are as follows:

A. To review and scrutinize research proposals involving human participants

B. To provide ethical clearance to research proposals or ongoing research projects

C. To protect individual participants rights

D. To ensure privacy and confidentiality of participants' data

E. To provide guidelines or suggestions to researchers in case of ethical violation of human participants

F. To ensure that an independent, competent and consistent ethical review mechanism, in an objective manner, is put in place for all health and biomedical research proposals dealt by the committee in accordance with National regulations, Indian Council of Medical Research (ICMR) guidelines for Biomedical Research on Human Participants and Good Clinical Practices.

4. Applicable Regulations and Guidelines:

- Ethical Guidelines for Biomedical Research on Human Participants by ICMR, New Delhi 2017.
- International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines
- Good Clinical Practices Guidelines issued by the Central Drug Standard Control Organization (CDSCO), Directorate General of Health Services, Government of India.
- ICMR Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research.

5. Preparing and amendment of Standard Operating Procedures (SOPs)-

The current SOP is valid for a period of three years from the effective date, and it will be reviewed, discussed and revised every three yearly or earlier, as and when required for effective functioning of the IEC.

Any member of the IEC, faculty members, or investigators can make a request for revision or amendment to remove inconsistency/discrepancy in the existing SOPs. If IEC members agree to the request, the Chairperson/Co-Chairperson in consultation with the Member

Secretary/Co-Secretary will appoint the SOP team. This team will revise/formulate the SOP. If IEC members do not agree to the request, no further action will be taken.

The Chairperson/Co-Chairperson of the IEC will appoint a team to formulate the SOP, which will consist of Member Secretary/Co-Secretary and 1-2 IEC members. The SOP preparation team would draft a SOP, get it reviewed and approved by all the IEC members. All IEC members will review the SOP and the final version will be forwarded to the Chairperson/Co-Chairperson for review and approval. Once approved, a revised version of SOP will be distributed. A copy of newly formulated SOPs along with the copy of the old version will be archived.

The Previous version of the SOP is valid till the effective date of the next version. Approved SOPs will be implemented from the effective date.

The Footer Information of the SOP should include:

- Page Numbering (format page x)
- SOP Version Number (1,2,3….) dated (dd/mm/yyyy)
- Amendment Number and Date (Amendment 1,2,3 ….Dated dd/mm/yyyy), if any
- The word 'CONFIDENTIAL'

6. Role of IEC:

- ❖ IEC will review all research proposals involving human participants to be conducted at the Gokhale Institute of Politics and Economics to evaluate the possible risks to the subjects and expected benefits.
- ❖ To assess the adequacy of documentation for ensuring privacy, confidentiality of the subjects and ensure justice to the subjects.
- ❖ IEC will ensure the protection of subject's rights, safety, dignity and wellbeing.
- ❖ IEC provides a multidisciplinary forum for the analysis and discussion of guidelines, regulatory laws and cardinal principles of research ethics viz. autonomy, beneficence, non-malfeasance and justice and ensures that these are adhered to in planning, conducting and reporting of proposed research,

management of the collected data through the Committee's advisory, educational, policy development, and service functions.

- ❖ To ensure that the research projects carried out are sound in design, have statistical validity and are conducted according to the Indian Council of Medical Research and International council on Harmonization/Good Clinical Practice guidelines.

7. Responsibilities of IEC members:

The GIPE-IEC will review proposals related to human participants in the field of public health, behavioral and other social sciences.

The IEC will uphold principles of Beneficence and Nonmaleficence, Fidelity and Responsibility, Integrity, Justice, Respect for People's Rights and Dignity. In doing so, the goals of the research will not override the overall well-being of the actual or potential participants.

The IEC will look into planning, conduction, and reporting of the research protocols. The committee shall look into aspects of informed consent procedures, risk-benefit ratio, ethicality of methods in order to safeguard all involved participants.

It will not only review proposals before the start of the study but also monitor the approved studies through follow up procedures like annual reports, final reports, etc.

The duties of every member of the GIPE-IEC are outlined in the table below and have been aligned with the ICMR National Ethical Guidelines 2017.

Members of EC	Role and Responsibilities
Chairperson	Conduct GIPE-IEC meetings and be responsible for independent and efficient functioning of the GIPE-IEC * Ensure active participation of members (particularly non-affiliated, non medical/ non- technical) in discussions and deliberations of GIPE-IEC * Ratify minutes of the previous meetings * In case of anticipated absence of Chairperson at a planned meeting/ or recluse due to conflict of interest, the Chairperson should make sure that nominated committee member as Acting Chairperson is present or the members present may elect an Acting Chairperson on the day of the meeting in case of absence of nominee. The Acting Chairperson should be a non-member of the GIPE and will have all the powers of the Chairperson for that meeting/proposal. * Seek COI declaration from members and ensure quorum and fair decision making. * Handle complaints against researchers, IEC members, conflict of interest issues, and requests for use of IEC data, etc. Decisions need to be ratified by the GIPE-IEC for confirmation in this regard.
Member secretary	* Organize a system for receiving, preparing, circulating, and maintaining every proposal received for review * Schedule GIPE-IEC meetings, prepare the agenda and minutes * Maintain GIPE-IEC documentation, communication and archiving * Take efforts for training of GIPE-IEC officers and GIPE-IEC members * Update SOPs as and when required * Ensure adherence of GIPE-IEC functioning to the SOPs * Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. * Evaluate the need for expedited review/ exemption from review or full review. * Evaluate the need to obtain prior scientific review, invite independent consultants/ experts, patient or community representatives.

Basic Medical Scientist	* Scientific and ethical review with special emphasis on the intervention, benefit risk analysis, research design, methodology and statistics, continuing review process, serious adverse events (SAE), protocol deviation, progress and completion report with clinical problems or paramedical issues. * For clinical trials, pharmacologists review the drug safety and pharmacodynamics.
Clinician/	* Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics * Ongoing review of the protocol * Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation. * Thorough review of protocol, investigator's brochure (if applicable) and all other protocol details and submitted documents.
Legal Expert	* Ethical review of the proposal, informed consent document along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site/ field approvals, researcher's undertaking, protocol specific other permissions, permissions for adolescent/ children research and any other matters of human rights violation. * Interpret and inform GIPE-IEC members about new regulations if any * Pointing out any legal violations in research
Social Scientist /representative of NGO/ Philosopher/ ethicist/ theologian	* Ethical review of the proposal, informed consent document along with the translations. * Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any * Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

Lay person	* Ethical review of the proposal, informed consent document along with translation(s). * Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. * Serve as a patient/participant/ community representative and bring in ethical and societal concerns. * Assess on societal and ethical aspects if any.

8. Composition

In accordance with the ICMR National Ethical Guidelines and New Drugs and Clinical Trials Rules 2019, the committee shall constitute of experts from the following categories:

1. Chairperson / Co-Chairperson
2. Basic medical scientist
3. Clinician
4. Legal Expert
5. Social Scientist /representative of NGO/Philosopher/ethicist/theologian
6. Lay person from the community
7. Member Secretary / Co-Secretary
8. A member other than the above representation can be co-opted if necessary

The committee will have at least 7 members and at least one member will be a female. The medical scientist and clinician should have recognised medical qualification, expertise and training. The Chairperson will not be affiliated to GIPE and the member secretary will be affiliated to GIPE. At least 50% of the members will not be affiliated with GIPE.

a. Membership requirement

Every member of GIPE-IEC must:

1. Provide an updated curriculum vitae
2. Provide full name, qualifications, designation, and organizational title for access in public domain.
3. Agree to undergo training or update their skills during their tenure
4. Declare Conflict of Interest, if applicable, at the appropriate time

5. Agree to maintain confidentiality and professional ethics of all the research project related information

b. Membership appointment

1. All appointments, including member, member-secretary and independent consultants, will be made by the Chairperson, GIPE. The Chairperson, GIPE shall inform the EC and General Body of the GIPE about the appointments at their scheduled meetings.
2. In the absence or conflict of interest of the Chairperson or member-secretary, the concerned individual will nominate another member of the Ethics Committee as the acting Chairperson or acting member-secretary.
3. The committee will be appointed for a period of 3 years. After 3 years, at least 50% of the members must be replaced.
4. A member can be replaced in the event of resignation, removal, or death.
5. The Chairperson, GIPE, shall suggest the nominee for Chairperson GIPE-IEC and Member Secretary GIPE-IEC in case they recluse to attend a particular meeting/s; or evaluate a particular proposal submitted to the GIPE-IEC on the ground of conflict of interest/ any other valid ground.

c. Honorarium / Consultancy to the Members/ Invited Experts etc:

1. An honorarium of Rs. 2000 (Rupees Two Thousands) and Rs.500 as conveyance allowance for attending the meeting in-person will be paid to each of the IEC members or the experts who attend the meeting.
2. If there is any change in the honorarium, then it will be recorded in the minutes of the meeting in which it is changed.
3. Transport of Rs.500/- (Rupees Five Hundred only) may be provided to the IEC members for attending the meetings, if required.

d. Quorum

The quorum requirements will be as follows:

1) A minimum of five members excluding their Chairperson and member secretary (or their nominee) must be present.

2) Minimum one non-affiliated member will be part of the quorum

3) The quorum should include at least one medical scientist, one clinician, one legal expert, one

social scientist, and one lay person.

4) No decision can be made in absence of the quorum.

e. Training

The IEC members shall be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted or professional body(ies), so that they become aware of their role and responsibilities.

All new members will be trained on the Standard Operating Procedures of the Ethics Committee by Member Secretary/Co-Secretary. The new member will be given training and a copy of Schedule Y, ICMR Guidelines on Biomedical Research on Human Participants, Good Clinical Practices- ICH and Indian guidelines. Any change in the regulatory requirements shall be brought to their attention.

They should be aware of local, social and cultural norms, as this is the most important social control mechanism.

All the IEC members shall be periodically trained on Regulatory requirements, Ethics and Good Clinical Practices.

IEC may organize Clinical Research and Ethics related training programs for the IEC members or for the faculty or students of the constituent units of Gokhale Institute of Politics and Economics or may provide financial assistance for conduct of such programs.

IEC may provide financial assistance to the IEC members or other external faculty who would take such training from a professional body (ies).

f. Independent Consultants

Independent consultants or experts can be invited by the Chairperson of the IEC for their opinion in case of selected research proposals that the committee does not have particular expertise in. Such independent consultants or experts can give their specialized opinions but do not become a part of the decision-making procedure of the GIPE-IEC.

g. Resignation, removal, and reconstitution

Any member who wishes to resign may submit a written letter to the Chairperson, GIPE-IEC at least 30 days prior to the next scheduled meeting. A member will be considered

for termination from his/ her duties in case of:

1. Regular defaulter
2. Inability to be part of meetings on any grounds
3. Failure to attend meetings without prior notice for more than three consecutive times

GIPE chairperson will replace the resigned/ removed member with a new member of the same category. New appointments can be made in consultation with the member-secretary and/ or Chairperson of GIPE-IEC.

h. Conflict of Interest

A member will declare their conflict of interest, if any, in writing to the Chairperson of the IEC, at least two weeks before the meeting. The conflict is declared in the application form. Members will not take part in the decision making process of research proposals in which they are PI or co-PI. The Chairperson, GIPE, shall suggest the nominee for Chairperson GIPE-IEC and Member Secretary GIPE-IEC in case they recluse to attend a particular meeting/s; or evaluate a particular proposal submitted to the GIPE-IEC on the ground of conflict of interest. Members (including Chairperson GIPE-IEC and Member Secretary, GIPE-IEC) shall recluse for the proposal for which they have declared conflict of interest. In such cases, acting Chairperson, and/or acting Member Secretary nominated by the Chairperson GIPE shall act as Acting-Chairperson and Acting Member secretary for those proposals.

9. Application Procedure

a. Documentation

For a proposal to be considered for review, the following documents must be submitted to the IEC, at least 1 month before the next scheduled meeting. All submissions will be made as a soft copy on email.

1) Cover letter to the member-secretary

2) Duly filled Application form to GIPE-IEC (Annexure I)

3) Updated curriculum vitae of PI and Co-PI

4) List of ongoing research projects and published and presented papers, books, etc. of PI and Co-PI

5) Complete research protocol (details given in next section)

6) Application form for Exemption from review (if applicable; Annexure II)

7) Informed consent form to be given to participant or consenting authority (if applicable)

8) Participant information sheet (if applicable, refer Annexure III) 9) Statement of conflict of interests (if applicable)

10) Undertaking by PI and Co-PI (Annexure IV)

11) Receipt of Payment

12) Any other relevant documents

b. Research Protocol

The research protocol should include the following:

All forms to be uploaded to the link in PDF format/Word Format.

1. Title page with signatures of all investigators
2. Brief summary of the project
3. Background and rationale of study
4. Research objective and aims
5. Detailed description of method: sample, design, phases of study (if any), data collection procedures and participant recruitment methods, tools and scales to be used, procedure of study, data analysis plan, details of invasive procedure (if any)
6. Complete intervention plan and relevant ethical considerations (if any)
7. Adequate permission of using copyrighted material/ scales/ tools/ tests/ experiments, etc.
8. Estimated duration and timeline of project
9. Justification of method used, used of experimental conditions, plan to withdraw study/ intervention for any particular participant
10. Benefit-risk assessment
11. A statement on storage and maintenance of data collected
12. Plan to maintain the privacy and confidentiality of the study participants
13. Ethical considerations and safeguards for protection of participants

c. Submission of Research Proposal

The research proposal for approval by the committee shall be submitted to the Secretariat Office at the following address:

Institutional Ethics Committee Office

Gokhale Institute of Politics and Economics

Pune-411004

Phone No- 02025650287, Ext - 204

Email ID- gipeiec@gipe.ac.in

1. The administrative staff will be provided by Gokhale Institute of Politics and Economics.
2. The list of documents to be submitted for IEC review and approval is attached as Annexure I to IV
3. The documents shall be submitted a minimum two weeks prior to the scheduled IEC meeting.
4. A Clinical Trial Agreement (CTA) should be a tri-party document, signed by the Principal Investigator (PI), the Head of the Institute and the Sponsor. If a draft of the CTA is submitted for IEC review, the executed copy of the same shall be notified to the IEC.
5. Prior to submission to the IEC, all the research projects should have received approval from the Scientific Review/Advisory Committee.

d. Payment

As GIPE-IEC is exclusively for institutional research submissions from GIPE researchers, the IEC will not be charging any fees for submission of research proposals.

e. Communicating the Decision

The communication of the decision, duly signed by the Chairperson and member secretary, will include:

1. Name and address of the IEC

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2. Name and designation of the applicant
3. Title of the study along with the unique reference number
4. Name of details of members present during the said review meeting
5. Statement of decision reached
6. Complete application and protocol as received from the applicant
7. Suggestions/ modifications asked for by the committee (if applicable)
8. Clear reason for rejection (if applicable)
9. Validity of the IEC clearance

f. Follow-up procedures

The following procedures for follow up will be implemented:

1. For all projects, yearly updates will be submitted to the committee (Annexure VI).
2. A reminder will be sent to those who fail to send the yearly update report. If the update report is not received for 3 months after the reminder, the clearance provided will be revoked with immediate effect.
3. Any change in PI or Co-PI must be communicated to the IEC
4. Any deviation from the protocol should be re-submitted for approval to the IEC with adequate justifications (Annexure VII)

g. Record keeping

The following documents will be kept and filed by the IEC:

1. Curriculum vitae of all GIPE-IEC members and independent consultants
2. Standard Operating Procedure of the IEC
3. Invitation, acceptance, and appointment letters of members of the IEC
4. Copy of all study protocols, application documents, decision letter, and progress reports
5. Copy of correspondence with all members, researchers and regulatory bodies
6. Minutes of all meetings signed by the Chairperson and Member Secretary.
7. National and international guidelines followed by the IEC

h. Validity of approval

A clearance provided to a proposal will be valid for a period of 5 years. After 5 years, the

approval will lapse. The researcher can make a fresh application in order to seek approval for the study.

In case of specific research that involves intervention, clinical trials the approval can be for a shorter duration for two years. The IEC can set a requirement of timely reports for the continuation of the approval.

10. Review Procedure

The general rules for review meetings of GIPE-IEC will be as follows:

1. The meetings for review of proposals will be held once every 2 months. A calendar of meeting dates will be released in January every year/ beginning of every academic year. In case there are no proposals or any other re-submissions, the meeting can be canceled by the member-secretary through written notification to all members and the chairperson. Additional meetings can be scheduled as per the workload.
2. The proposals should be sent to members at least 1 week in advance by the member-secretary.
3. Every proposal will be allotted a unique reference number by the member secretary for all future correspondence.
4. Decisions will depend on consensus between members. If needed, voting will be employed.
5. The Principal Investigator (PI) will be invited to make a presentation before the committee in case of expedited and full committee review. In case of exempted review, if need be, the PI can be asked for clarifications through written communication or a brief presentation by the principal investigator. If the PI is unavailable, the co-PI can do the needful. If there is no PI, or co-PI, the proposal will be considered in the next meeting or whenever the PI is next available.
6. Independent consultants can be invited when required but they will not be part of the final decision-making process.
7. Proceedings of every meeting will be minuted.
8. Meetings can be conducted in online/ offline mode, depending on the convenience of all the members.

a. Decision-making

1. The member-secretary will screen all submissions for their completeness and categorize

them into three categories: exemption from review, expedited review and full committee review.

2. All eligible proposals will be discussed by the committee before arriving at a consensus.
3. Decisions can be to approve, revise, or reject the proposal.
4. Decisions can be made only when the quorum is met.
5. Decisions can be made by the members only. Independent consultants/ experts can only give an opinion on the relevant subject-matter.
6. If the GIPE-IEC is unable to reach a consensus or majority, the final decision will be made by the Chairperson.

b. Classification of Risk

Proposals will be classified into exemption from review, expedited review and full committee review on the basis of the risk involved. The risk will be evaluated by the member-secretary on the basis of the following criteria:

Kind of Risk	Description	Examples
Less than minimal risk	Probability of harm or discomfort anticipated in the research is NIL or not expected.	Meta analysis, re-analysis of existing datasets; basic surveys where data is kept strictly anonymous and non-identifiable; survey data collection on non sensitive topics
Minimal risk	The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and that confidentiality is	Personal interviews; group activities; non-interventional studies; non-invasive imaging in healthy subjects; participant observation; experimental design with non-sensitive topics and non vulnerable groups.

	adequately protected.	
Medium risk	The probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk, but not significantly greater.	Research on healthy children and adolescents; interventional studies, minimal invasive techniques; studies that may cause physical or psychological harm and distress; surveys on controversial/ sensitive topics; research involving use of personal/ identifiable data
High risk	The probability of harm or discomfort is serious, prolonged and/or permanent or there is significant uncertainty about the nature or likelihood of adverse events.	Studies with highly vulnerable groups like victims, handicapped children or adults ; studies on criminals or prisoners; studies on very sensitive topics like pornography, suicide; bereavement and grief studies; manipulation of IV in experiments; interventional or clinical trials

c. Type of Review

There are 3 types of review: 1) Exempted review, 2) Expedited review, 3) Full committee review.

1) Exempted Review

Proposals that fall under 'less than minimal' risk will be exempted from review. Exempt reviews are carried out independently by the chairperson. Researchers who wish to apply for exempted review will submit an additional form (Annexure II) for the same. However, the proposal will be scrutinized for level of risk by the member secretary and

will be sent for appropriate review.

2) Expedited Review

Proposals presenting 'less than minimal risk' or 'minimal risk' can be presented for an expedited review to Chairperson and member-secretary or a sub committee. Proposals that may qualify for expedited review include:

a. Research in emergency situation

b. Research on disaster management

c. Nationally relevant proposals

d. Research projects that may be time bound and need to be launched immediately

e. Revised proposal previously approved through full review by the GIPE-IEC

Additional meetings can be called in between the 2 months for expedited reviews, if deemed necessary by the member-secretary and/ or chairperson.

3) Full Committee Review

All other proposals that present "minimal risk", "medium risk", or "high risk" will be put through full committee review by all members. Proposals that have already begun their work and are classified as "less than minimal risk" or "minimal risk" will mandatorily go ahead for full committee review. "Medium risk" or "high risk" proposals that have already begun their work, will not be accepted for review by the IEC.

Annexures

11. Annexure

I. Application form to GIPE-IEC (Part A: Investigators' Information, Part B: Research Information and Part C: Participant Related Information Form)

II. Application form for Exemption from review

III. Contents of participant information sheet (PIS)

IV. Undertakings to be submitted by PI and Co-PI

V. Study Completion/ Final Report Format

VI. Yearly Update to GIPE-IEC Format

VII. Changes in Ongoing Project Format

VIII. Invitation letter to a member (For Office Use)

IX. Acceptance letter from a member (For Office Use)

X. Appointment letter to a member (For Office Use)

XI. Sample approval letter from GIPE-IEC (For Office Use)

Annexure I

Application form to GIPE-IEC (Part A: Basic Information, Part B: Research Information and Part C: Participant Related Information Form)

Part A: Basic Information	
Title of the study	
Name of Principal Investigator	
Institute of PI/Affiliation of PI	
Date of submission	
Type of review requested	• Exempted review (if yes, submit Annexure II) • Expedited review • Full committee review
Duration of the study (in months)	
Funding for the study	• Self-funded • Institution funded • Funding agency (if yes, specify):
Tick all documents that have been attached	• Cover letter to the member-secretary • Duly filled Application form to GIPE-IEC (Annexure I)

	• Updated curriculum vitae of PI and Co-PI • List of ongoing research projects and published papers in the last 5 years of PI and Co-PI • Complete research protocol (details given in next section) • Application form for Exemption from review (if applicable) • Informed consent form to be given to participant or consenting authority (if applicable) • Participant information sheet (if applicable, refer Annexure III) • Statement of conflict of interests (if applicable) • Undertaking by PI and Co-PI (Annexure IV) • Receipt of Payment • Any other document (specify):
Has any work on the project started already?	• Yes • No

Details of Researchers (Add more rows below if more researchers are part of the proposal)

	Name	Designation and Qualification	Department and Institution	Address and email address	Conflict of Interest
Principal Investigator					• Yes • No
Co-Investigator 1					• Yes

					• No
Co-Investigator 2					• Yes • No
Co-Investigator 3					• Yes • No
Co-Investigator 4					• Yes • No

Part B: Research Information	
Type of study design (Tick all applicable)	• Survey • Personal interviews • Participant observation • Group discussions • Experiments

	• Single-case designs/ Small n design • Case study • Quasi experimental • Longitudinal • Psychological scale development study • Intervention study • Meta-analysis • Use of secondary data • Clinical trial • Other (specify):
Estimated sample size (if applicable)	
Site for data collection (Tick all applicable)	• Online mode • Institute laboratory • Data collection in community • Classrooms/ colleges/ schools/ similar educational site • At workplace • Other (specify):
Language in which study will be conducted (if applicable)	
Dissemination of findings/ study (Tick all applicable)	• Scientific article • Book publication • Report submission to government or private authority • No dissemination • Other (specify)
Storage of **identifier data** if individual data is	• Coded (linkage file is maintained with a Participant ID and personal information which is not included in the main data file)

involved	• De-identified (identifiers of individual are completely destroyed) • Completely anonymous (personal information and identifiers are never collected) • Identifiable (all identifiers of participants are retained) • Not applicable to present study • Other (specify):

Benefit Risk Ratio

Anticipated physical/ social/ psychological/ economic risk to the participants	• Yes • No
Categorize level of risk	• Less than minimal risk • Minimal risk • Medium risk • High risk
Describe risk management strategy	

What are the potential benefits from the study? (Tick all applicable)

	Yes, direct benefit	Yes, indirect benefit	No benefit
For the participant	•	•	•
For the society/ community	•	•	•
For scientific progress	•	•	•

Explain all benefits that have been marked as "yes" (direct or indirect):

Part C: Participant Related Information	
Type of participants in the study	• Healthy Volunteers • Vulnerable/ Special groups • Other (specify):
If Vulnerable groups, specify type of vulnerable/ special group	• Children under 18 years • Elderly • Differently abled (Mental/ Physical) • Terminally ill/ People with specific illness or disease • Refugees/ Migrants/ Homeless • Economically and socially disadvantaged • Armed forces/ any frontline workers • Specific caste • Other (specify):
Incentive provided to participants	• No incentives • Monetary (provide details): • Non-monetary (provide details):
Type of consent	• Self-consent (signed) • Self-consent (verbal) • Self-consent (online) • Parental/ guardian consent (explain procedure): • School consent (explain procedure):

Principal Investigator

Name:

Designation:

Institute:

Date:

Sign:

Annexure II

Application form for Exemption from review

Title of the study:

Principal Investigator (Name, designation and affiliation):

Choose reasons why exempted review is requested:

- Use of secondary/ previously existing data
- Study of harmless/ non sensitive issues
- No physical/ psychological/ social/ economic harm
- Any other reason (please specify):

Principal Investigator

Name:

Designation:

Institute:

Date:

Sign:

Decision and signature of member-secretary with date:

Annexure III

Contents of participant information sheet (PIS)

Before a participant begins the study, a participant information sheet must be provided to them or the parent/ guardian. The following information must be provided to them in the language they can understand (English or the local language). The language should be lucid and simple. A copy of the participant information sheet should be attached along with the application form.

1. Title of the project
2. Aims and objectives
3. Brief description of what is expected of them
4. Expected duration of the research
5. Potential benefits to the participants/ society/ scientific community
6. Potential risks of the study to the participant
7. Voluntary participation and freedom to drop from the study without any penalty or cost
8. Policy for maintenance of data and records
9. Contact details of the principal investigator
10. Statement (in case of any experimental manipulation/ deception/ interventions, etc) that the study will not have any adverse impact on the participants

Annexure IV

Undertakings to be submitted by PI and Co-PI

The Principal Investigators and Co-Principal Investigators agree to the following:

•	I/ We declare that the information provided in this application is complete and correct.
•	I/ We declare that all involved investigators have approved the research proposal/ documents that have been submitted.
•	I/ We declare that the same/ similar research protocol has not been submitted to another ethics committee/ institutional review board or similar committee simultaneously or previously. If it has been previously reviewed or rejected by another such committee, the documents have been duly attached.
•	I/ We confirm that the study will be conducted in accordance with the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, New drugs and Clinical Trial Rules 2019 GCP guidelines and other applicable regulations and guidelines.
•	I/ We will comply with the policies and guidelines of the institute where this study will be conducted.
•	I/ We will ensure that all personnel conducting the study will be qualified and trained and will adhere to the research protocol.
•	I/ We agree to submit yearly reports, completion/ final report, amendment reports as and when applicable.
•	I/ We will provide any additional information asked for by the GIPE-IEC with regards to the project or investigator(s).
•	I/ We will ensure that all data and records are maintained accurately.

•	I/ We will ensure privacy, confidentiality, and safety of all participants in the study.
•	I/ We will obtain any additional government/ institutional approvals, as required, before conducting the study.
•	I/ We declare that no prior work has happened as part of this proposal. If work has started, it has taken place in the exact same manner as stated in the proposal.

	Name	Designation and Qualification	Department and Institution	Signature with date
Principal Investigator				
Co-Investigator 1				
Co-Investigator 2				

Co-Investigator 3				
Co-Investigator 4				

Annexure V

Study Completion/ Final Report Format

Title of the study	
Principal Investigator (Name, designation and affiliation)	
Unique Reference number	
Date of IEC approval (DD/MM/YYYY)	
IEC approval valid upto (DD/MM/YYYY)	
Was the study completed?	• Yes, it has been completed • No, it was prematurely terminated
Date of completion of project (DD/MM/YYYY)	
Provide a summary of findings (attach additional page if required) or Provide reason for premature termination of study	

Were there any deviations from the original proposal?	• No • Yes (give details):
Describe plan for publication	

Principal Investigator

Name:

Designation:

Institute:

Date:

Sign:

Annexure VI

Yearly Update to GIPE-IEC Format

Title of the study	
Principal Investigator (Name, designation and affiliation)	
Unique Reference number	
Date of IEC approval (DD/MM/YYYY)	
IEC approval valid upto (DD/MM/YYYY)	
Period of report	From _____(DD/MM/YYYY) To _____(DD/MM/YYYY)
Description of completed work (since last update/ since approval, whichever is later)	
Description of pending work	

Have there been any ethical concerns so far?	• No • Yes (give details)
Give details of data collection (if there is data collection involved) **Sample refers to individual participants, observations, personal interviews, groups discussion, etc*	• Total sample expected: • Total sample collected: • Total sample pending:
Give details of studies/ phases completed (if project has multiple phases/ studies)	• Total studies planned: • Total studies completed: • Total studies: pending:
Have there been any publications/ presentations/ conferences regarding this	• No • Yes (give details)

project so far?	

Principal Investigator

Name:

Designation:

Institute:

Date:

Sign:

Annexure VII

Amendments in Ongoing Project Format

Title of the study	
Principal Investigator (Name, designation and affiliation)	
Unique Reference number	
Date of IEC approval (DD/MM/YYYY)	
IEC approval valid upto (DD/MM/YYYY)	
Impact on benefit and risk ratio?	• No • Yes (give details)
Type of review requested for amendment	• Exempted review (if original review was exempted) • Expedited review (No alteration in risk to participants) • Full review (There is an alteration in risk to participants)

Brief details of Amendments (should be supplemented with a complete protocol):

Sr No	Existing Provision	Proposed Amendment	Reason/ Justification	Section of protocol

Principal Investigator

Name:

Designation:

Institute:

Date:

Sign:

Annexure VIII

Invitation letter to a member (For Office Use)

Reference number:

Date: _____

From,

Chairperson,

Gokhale Institute of Politics and Economics.

To,

[Name]

[Designation]

[Institute]

Subject: Invitation to be a member of Gokhale Institute of Politics and Economics's Institutional Ethics Committee (GIPE-IEC)

Dear _____,

Based on your expertise in the field of _____, I am pleased to invite you to be a _____ of Gokhale Institute of Politics and Economics's Institutional Ethics Committee (GIPE-IEC) for a period of 3 years. I request you to kindly confirm your willingness to be a member at the earliest.

With Regards,

Chairperson,

Gokhale Institute of Politics and Economics

GOKHALE INSTITUTE OF POLITICS AND ECONOMICS DEEMED TO BE UNIVERSITY PUNE-4.

Annexure IX

Acceptance letter from a member (For Office Use)

Date: _____

From,

To,

Chairperson,

Gokhale Institute of Politics and Economics

Subject: Consent to be a member of GIPE-IEC (letter dated: , ref number:)

Dear Sir/ Madam,

With reference to your letter, I am willing to become a _____ of GIPE-IEC. I will regularly attend meetings for review and give my opinions regarding ethical aspects in an unbiased manner.

I agree to making my name, qualifications, designation, and organizational title public as a member of GIPE-IEC.

I agree to declare conflict of interest and not participate in quorum in such cases. I agree to keep all research related information completely confidential.

Thank you.

Yours sincerely,

[Name]

[Designation]

[Institute]

Enclosed:

1) A copy of updated curriculum vitae

Annexure X

Appointment letter to a member (For Office Use)

APPOINTMENT ORDER

I am pleased to appoint you as the Chairperson/ Member Secretary/ Member of the Gokhale Institute of Politics and Economics's Institutional Ethics Committee (GIPE-IEC) as a _____ expert following the receipt of your acceptance letter. The appointment shall be effective from ____ for a period of 3 years or till further notice provided the following conditions are satisfied:

1. You should be willing to publicize your name, qualifications, designation, and organizational title.
2. You declare conflict of interest and not participate in quorum in such cases
3. You consent to sign confidentiality agreement between you & the GIPE-IEC with regards to all research-related information.

Further, the renewal of your appointment will be by agreement between you and GIPE-IEC & one month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & conditions regarding the resignation procedure, disqualification procedures, replacement procedures, etc. may be found in the Standard Operating Procedures of Gokhale Institute of Politics and Economics's Institutional Ethics Committee (GIPE-IEC).

You will be paid a sum of INR/...../- per sitting as Honorarium for your services rendered towards attending the Gokhale Institute of Politics and Economics's Institutional Ethics Committee (GIPE-IEC).

We sincerely hope your association with Gokhale Institute of Politics and Economics's Institutional Ethics Committee (GIPE-IEC) will be scientifically productive and beneficial to the Association & the community at large.

GOKHALE INSTITUTE OF POLITICS AND ECONOMICS DEEMED TO BE UNIVERSITY II PUNE-4.

Annexure XI

Sample approval letter from GIPE-IEC (For Office Use)

Date:

To: [Name of Principal Investigator]

[Institute of Principal Investigator]

Unique Reference Number of Protocol:

Project Title: [Project Title]

Notice of Institutional Ethics Committee Review

This is to state that the above-mentioned protocol has been reviewed by the Gokhale Institute of Politics and Economics's Institutional Ethics Committee (GIPE-IEC). The members of the committee who were present during the review of the said protocol as follows:

1. [Full name, affiliation, and designation in the committee]
2.
3.
4.
5.

The protocol was exempted from review/ subjected to full review/ subjected to expedited review. The research involved less than minimal/ minimal/ medium/ high risk because [state brief reason, refer to table of classification of risks]. The GIPE-IEC deems the study as ethical and fit to be conducted on human participants/ does not deem the study as ethical and fit to be conducted on human participants/ suggests modifications for the study, after which the protocol can be re submitted. The following modifications are being suggested for the following reasons/ The protocol was deemed not ethical for the following reasons (if applicable):

1.
2.

The review clearance will expire on [DD/MM/YYYY]. If your project continues beyond this date, you will be required to re-submit the research protocol to the committee for a fresh review.

Your responsibility as a principal investigator also include:

1. Submit yearly update of project progress (refer Annexure VI)
2. Submit final/ completion report (refer Annexure V) when the project is completed or unduly terminated
3. Submit an amendment report (refer Annexure VII) if a deviation is being made from the research protocol.
4. Inform the GIPE-IEC about change in investigator(s).

If you have any questions regarding your research protocol or the review process, you may contact the Gokhale Institute of Politics and Economics's Institutional Ethics Committee (GIPE-IEC) on _____ [email].

With Best Regards,

_____

Member Secretary

Gokhale Institute of Politics and Economics's Institutional Ethics Committee (GIPE-IEC)

Document Name	**Standard Operating Procedures** **Institutional Ethics Committee**
Document Version No	**Version No. 01 (One) dated 18/01/2023**
No of Pages	**48**
Date Created	**17/01/2023**
Date of Implementation	**18/01/2023**
Prepared By	**Designation : Research Officer /Medical Officer** **Name : Vishal Gaikwad / Dr. Kaustubh Bondre** **Signatures:**
Reviewed By	**Designation : Member Secretary** **Name : Prof. Anjali Radkar** **Signature :**
Approved By	**Designation : Chairperson** **Name : Prof. Prakash Doke** **Signature**

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Document Name	Standard Operating Procedures Institutional Ethics Committee
Document Version No	Version No. 01 (One) dated 18/01/2023
No of Pages	48
Date Created	17/01/2023
Date of Implementation	18/01/2023
Prepared By	Designation : Research Officer /Medical Officer Name : Vishal Gaikwad / Dr. Kaustubh Bondre Signatures:
Reviewed By	Designation : Member Secretary Name : Prof. Anjali Radkar Signature : Anjali Radkar
Approved By	Designation : Chairperson Name : Prof. Prakash Doke Signature :

Gokhale Institute of Politics and Economics
(Deemed to be University)
Pune – 411 004

Institutional Ethics Committee

Sr. No.	Name	Qualifications	Affiliation	Role in the IEC
1	Dr. P.P. Doke	M.D., D.N.B., Ph.D.	Bharati Vidyapeeth University, Medical College	Chairperson
2	Dr. Sanjeevanee Mulay	M.Sc. (Statistics), Ph.D. (Economics)	Senior Demographer and Statistician, retired faculty of GIPE	Co-Chairperson
3	Dr. Anjali Radkar	M.Sc.(Statistics), Ph.D. (Population Studies)	Professor, GIPE	Member Secretary
4	Dr. Savita Kulkarni	M.A. and Ph.D.(Economics)	Assistant Professor, GIPE	Co-Secretary
5	Ms. Vaishali Deshpande	M.Sc. (Anthropology)	Consultant (Clinical Research and body composition)	Social Scientist
6	Dr. Ujjwala Barve	Ph.D. (Communication and Journalism)	Head, Department of Communication and Journalism, Savitribai Phule Pune University	Social Scientist
7	Dr. Medha Deshpande	Ph.D. (Economics)	Retired professor of Economics from S.N. D.T University	Social Scientist
8	Dr. Sharad Deshpande	Ph.D. (Philosophy)	Retired professor of Philosophy from Savitribai Phule Pune University	Social Scientist
9	Adv. Sayali Ganu	B S L L.L,M.(Business Laws), L.L.M. (Constitutional Law), PGDIPRL, M.B.L.	Practising Lawyers Visiting Faculty, GIPE	Legal Expert
10	Ms. Ashwini Jogalekar	M.Com, Diploma in Financial Management, computer application, Tally 4 & 9, HR & Admin	Finance and Accounts Officer, GIPE	Member
11	Dr. Angeline Jeyakumar	Ph.D. in Food Science and Nutrition	Assistant Professor, Savitribai Phule Pune University, Interdisciplinary School of Health Sciences	Basic Scientist

12	Dr. Minal Naravane	Ph.D. (Education)	Director, STPEA and Center for Human Development, Yashwantarao Chavan Academy of Development Administration	Lay Person
13	Dr. Deepa Pandit Agarwal	Ph.D. (Biometry and Nutrition)	Data Coordinator, Centre for Mental Health Law and Policy (CMHLP), Indian Law Society, Pune	Member
14	Dr. Shailesh Deshpande	M.D. (Preventive and Social Medicine)	Head-Education, Chellaram Diabetes Institution, Pune	Clinician
15	Mr. Abhay Tilak	M.A. & M. Phil. (Economics)	Director, Indian School of Political Economy	Member

GIPE Ethics Committee <gipeiec@gipe.ac.in>

Minutes of the meeting held on 25th July 2023 for approval

5 messages

GIPE Ethics Committee <gipeiec@gipe.ac.in> Mon, Aug 21, 2023 at 1:58 PM
To: Prakash Doke <prakash.doke@gmail.com>, Sharad Deshpande <sharad.unipune@gmail.com>, Medha Deshpande <deshpande.medha@gmail.com>, angejp@unipune.ac.in, Kaustubh Bondre <kaustubh.bondre@gipe.ac.in>, SUNIL BEDEKAR <advocatebedekar@gmail.com>, Anjali Radkar <anjali.radkar@gipe.ac.in>, Shailesh Deshpande <proshade2002@gmail.com>, vaishali deshpande <vaishalideshpande@hotmail.com>

Dear Members,

Trust that you are well.

Kindly find the attached minutes of the meeting held on 25th July 2023.

Request you to review and edit/approve.

Thanks and regards
Savita

Minutes_25_July_2023.docx
11K

Shailesh Deshpande <proshade2002@gmail.com> Tue, Aug 22, 2023 at 10:51 AM
To: GIPE Ethics Committee <gipeiec@gipe.ac.in>
Cc: Prakash Doke <prakash.doke@gmail.com>, Sharad Deshpande <sharad.unipune@gmail.com>, Medha Deshpande <deshpande.medha@gmail.com>, angejp@unipune.ac.in, Kaustubh Bondre <kaustubh.bondre@gipe.ac.in>, SUNIL BEDEKAR <advocatebedekar@gmail.com>, Anjali Radkar <anjali.radkar@gipe.ac.in>, vaishali deshpande <vaishalideshpande@hotmail.com>

Dear Madam,
Thanks for sharing the MoM.
You may add a paragraph regarding the discussion on the second research proposal (anemia and IFA supplementation).
Rest looks good to me.
Best regards,
- Shailesh.

On Mon, 21 Aug 2023 at 13:59, GIPE Ethics Committee <gipeiec@gipe.ac.in> wrote:

> Dear Members,
>
> Trust that you are well.
>
> Kindly find the attached minutes of the meeting held on 25th July 2023.
>
> Request you to review and edit/approve.
>
> Thanks and regards
> Savita

GOKHALE INSTITUTE OF POLITICS AND ECONOMICS DEEMED TO BE UNIVERSITY PUNE-4

vaishali deshpande <vaishalideshpande@hotmail.com> Tue, Aug 22, 2023 at 2:28 PM

To: GIPE Ethics Committee <gipeiec@gipe.ac.in>, Prakash Doke <prakash.doke@gmail.com>, Sharad Deshpande <sharad.unipune@gmail.com>, Medha Deshpande <deshpande.medha@gmail.com>, "angejp@unipune.ac.in" <angejp@unipune.ac.in>, Kaustubh Bondre <kaustubh.bondre@gipe.ac.in>, SUNIL BEDEKAR <advocatebedekar@gmail.com>, Anjali Radkar <anjali.radkar@gipe.ac.in>, Shailesh Deshpande <proshade2002@gmail.com>

MOM are fine with me.

Vaishali Deshpande

Get Outlook for Android

From: GIPE Ethics Committee <gipeiec@gipe.ac.in>
Sent: Monday, August 21, 2023 1:58:59 PM
To: Prakash Doke <prakash.doke@gmail.com>; Sharad Deshpande <sharad.unipune@gmail.com>; Medha Deshpande <deshpande.medha@gmail.com>; angejp@unipune.ac.in <angejp@unipune.ac.in>; Kaustubh Bondre <kaustubh.bondre@gipe.ac.in>; SUNIL BEDEKAR <advocatebedekar@gmail.com>; Anjali Radkar <anjali.radkar@gipe.ac.in>; Shailesh Deshpande <proshade2002@gmail.com>; vaishali deshpande <vaishalideshpande@hotmail.com>
Subject: Minutes of the meeting held on 25th July 2023 for approval

Dear Members,

Trust that you are well.

Kindly find the attached minutes of the meeting held on 25th July 2023.

Request you to review and edit/approve.

Thanks and regards
Savita

SUNIL BEDEKAR <advocatebedekar@gmail.com> Tue, Aug 22, 2023 at 4:47 PM
To: GIPE Ethics Committee <gipeiec@gipe.ac.in>

Confirming the MoM.

On Mon, 21 Aug, 2023, 1:59 pm GIPE Ethics Committee, <gipeiec@gipe.ac.in> wrote:

> Dear Members,
>
> Trust that you are well.
>
> Kindly find the attached minutes of the meeting held on 25th July 2023.
>
> Request you to review and edit/approve.
>
> Thanks and regards
> Savita

Kaustubh Bondre <kaustubh.bondre@gipe.ac.in> Wed, Aug 23, 2023 at 12:17 PM
To: GIPE Ethics Committee <gipeiec@gipe.ac.in>

MoM are fine with me.

On Mon, Aug 21, 2023 at 13:59 GIPE Ethics Committee <gipeiec@gipe.ac.in> wrote:

Dear Members,

Trust that you are well.

Kindly find the attached minutes of the meeting held on 25th July 2023.

Request you to review and edit/approve.

Thanks and regards
Savita

Gokhale Institute of Politics and Economics
(Founded by Rao Bahadur R.R. Kale, Satara)
(Deemed to be University u/s 3 of the UGC Act, 1956)
846, Shivajinagar, B.M.C.C. Road
PUNE - 411 004 (INDIA)

Standard Operating Procedures

Institutional Ethics Committee

Gokhale Institute of Politics and Economics

Version 2

Date effective from 20 June 2018

Reviewed & approved by

Fax No. : (020) 25652579
Website : www.gipe.ac.in
E-mail : gokhaleinstitute@gipe.ac.in

Telephone : (020) 25650287, 25654288/89, 25675008
25661367, 25661369/70

Table of Contents		
Sr. No	**Title**	**Page No.**

Standard Operating Procedures

Gokhale Institute of Politics and Economics

1.0 Introduction:

Research in human subjects is now guided by principles laid down by committees at National and International levels. It is essential to follow Good Clinical Practices (GCP) adopted internationally. The Indian Council of Medical Research (ICMR) has also issued ethical guidelines for research on human subjects. All these principles are put into practice through formulation of an Institutional Ethics Committee (IEC).

1.1 Authority under which IEC is constituted:

Authorities of Gokhale Institute of Politics and Economics constituted the Institutional Ethics Committee in order to ensure that Health and Allied Institutes shall conduct research on human subjects, using research methodology that meets international and local regulations, ethical standards and is consistent with principles of GCP.

2.0 Purpose:

The purpose of this SOP is to contribute to the effective functioning of the Institutional Ethics Committee (IEC) at Gokhale Institute of Politics and Economics, Pune, India. So that an independent competent and consistent ethical review mechanism, in an objective manner, is put in place for all health and biomedical research proposals dealt by the committee in accordance with National regulations, Indian Council of Medical Research (ICMR) guidelines for Biomedical Research on Human Participants and Good Clinical Practices.

3.0 Scope:

- IEC will review all research proposals involving human participants to be conducted at the Gokhale Institute of Politics and Economics to evaluate the possible risks to the subjects and expected benefits.
- To assess the adequacy of documentation for ensuring privacy, confidentiality of the subjects and ensure justice to the subjects.

- IEC will ensure the protection of subject's rights, safety and wellbeing.
- IEC provides a multidisciplinary forum for the analysis and discussion of guidelines, regulatory laws and cardinal principles of research ethics viz. autonomy, beneficence, non-malfeasance and justice and ensures that these are adhered to in planning, conducting and reporting of proposed research through the Committee's advisory, educational, policy development, and service functions.
- To ensure that the research projects carried out are sound in design, have statistical validity and are conducted according to the Indian Council of Medical Research and International council on Harmonization/Good Clinical Practice guidelines.

Preparing and amendment of Standard Operating Procedures (SOPs)-

The current SOP is valid for period of three years from the effective date, and it will be reviewed, discussed and revised every three yearly or earlier as and when required for effective functioning of the IEC.

Any member of the IEC, faculty members, or investigators can make a request for revision or amendment to remove inconsistency / discrepancy in the existing SOPs. If IEC members agree to the request, the Chairperson in consultation with Member Secretary will appoint SOP team. This team will revise / formulate the SOP. If IEC members do not agree to the request, no further action will be taken.

The Chairperson of the IEC will appoint a team to formulate the SOP, which will consist of Member secretary and 1-2 IEC members. SOP preparation team would draft a SOP, get it reviewed and approved by all the IEC members. All IEC members will review the SOP and the final version will be forwarded to the Chairperson for review and approval. Once approved, revised version of SOP will be distributed. Copy of current SOPs along with the copy of the old version will be archived.
The Previous version of the SOP is valid till the effective date of next version.
Approved SOPs will be implemented from the effective date.

The Footer Information of the SOP should include:

- Page Numbering (format page x)
- SOP Version Number (1,2,3….) dated (dd/mmm/yyyy)

- Amendment Number and Date (Amendment 1, 2,3 ….Dated dd/mmm/yyyy) if any
- The word 'CONFIDENTIAL'

4.0 Responsibilities of IEC:

1. To safeguard the dignity, rights, safety and well-being of all actual and potential research participants.
2. To ensure that the research projects carried out are sound in design, have statistical validity and are conducted according to the Indian Council of Medical Research and International Conference on Harmonization/Good Clinical Practice guidelines.
3. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
4. To assist in the development and the education of a research community responsive to local health care requirements and to allot appropriate funds for the same.
5. IEC would conduct Periodic self-assessments and corrective and preventive actions (as required) would be implemented.

Applicable Regulations and Guidelines:

- Ethical Guidelines for Biomedical Research on Human Participants by ICMR, New Delhi 2017.
- International Council on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practices
- Good Clinical Practices Guidelines issued by the Central Drug Standard Control Organization (CDSCO), Directorate General of Health Services, Government of India.
- ICMR Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research.

6.0 Composition of IEC:

The composition of the IEC will be multidisciplinary and multi-sartorial. It shall be compatible with the requirements of Schedule Y and its amendments, ICH GCP guidelines and ICMR guidelines to ensure its independence and competence. The composition may be as follows:

1	Chairperson	1
2	Basic medical scientists	1-2
3	Clinicians	1-2
4	Legal expert	1-2
5	Social scientist/ representative of non-governmental voluntary agency	1-2
6	Lay person/community representative	1-2
7	Member Secretary	1
8	A member other than the above representation can be co-opted if necessary	

The Chairperson shall be preferably from the health field but should not belong to the institution Gokhale Institute of Politics and Economics.

The Member Secretary shall be from Gokhale Institute of Politics and Economics for administrative convenience.

IEC shall include at least one member whose primary area of interest or specialization is non-scientific and at least one member who is independent of the institute.

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

IEC shall have appropriate gender representation.

The IEC members from the institution from where the research project is submitted for review and approval will be considered as internal members. The other IEC members will be considered external members.

Ad hoc substitutions for regular IEC members are permitted to fulfil the regulatory requirements of quorum if the regular member from that field is not available for the meeting. This will be documented in the minutes.

The Ad hoc member shall have an equal standing as of other members in the committee. Committee may have a list of pre-identified members from different specializations.

The current member list is attached as an Annexure I.

7.0 Terms of Reference:

7.1 Membership Requirements:

A member of the IEC will have tenure of three years. The members will be continued and there will be no limit on the number of times the membership is extended.

- All members shall sign the 'Confidentiality Agreement' and the 'Agreement for Declaration of Conflict of Interest'.

7.2 Appointments:

Institute authorities had appointed the IEC members at the inception of the IEC from varied backgrounds as per the regulatory and ICMR guidelines.

Institute authorities or its nominee will appoint the new IEC members as and when required.

The newly appointed member shall give his/her acceptance by signing the 'Consent Letter'.

7.3 Replacement, Resignation and Removal Procedure:

- If a member completes his or her tenure or does not wish to continue and opts to leave before the completion of his/her tenure or dies during the tenure, the Secretary, in consultation with the Chairperson and the Committee members shall appoint a new member with a similar background in his or her place.
- The member shall communicate his or her resignation preferably in writing to the IEC.
- If a member is found to be unable to discharge his or her responsibilities or unable to attend at least seventy five per cent of the meetings in any one calendar year, he or she will cease to be a member.

7.4 Honorarium / Consultancy to the Members/ Invited Experts etc:

- An honorarium of Rs. 1000 (Rupees One Thousand only) will be paid to each of the IEC member or the experts who attend the meeting.
- If there is any change in the honorarium then it will be recorded in the minutes of the meeting in which it is changed.
- Transport may be provided to the IEC members for attending the meetings, if required.

8.0 Training:

The IEC members shall be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted or professional body(ies), so that they become aware of their role and responsibilities.

All new members will be trained on the Standard Operating Procedures of the Ethics Committee by Member Secretary. The new member will be given training and a copy of Schedule Y, ICMR Guidelines on Biomedical Research on Human Participants, Good Clinical Practices- ICH and Indian guidelines. Any change in the regulatory requirements shall be brought to their attention.

They should be aware of local, social and cultural norms, as this is the most important social control mechanism.

All the IEC members shall be periodically trained on Regulatory requirements, Ethics and Good Clinical Practices.

IEC may organize Clinical Research and Ethics related training programs for the IEC members or for the faculty or students of the constituent units of Gokhale Institute of Politics and Economics or may provide financial assistance for conduct of such programs.

IEC may provide financial assistance to the IEC members or other external faculty of who would take such training from a professional body (ies).

9.0 Functions:

9.1 Primary Functions of IEC:

- Reviewing the project proposals and other relevant documents submitted for review and approval.
- Maintaining records of the activities such as Agenda, minutes of the meeting etc.
- Adhering to the applicable regulatory requirements.
- Complying with the ICMR and GCP guidelines.
- Keep updated on regulations and guidelines for the review of Research studies.
- Review progress reports and Monitoring of the sites to which IEC accords approval.

9.2 Responsibilities of the Chairperson:

- The Chairperson will head the Committee, preside over its meetings and conduct the meetings according to the ICMR and GCP guidelines.
- If he/she is unable to attend the meeting, he will nominate an IEC member to preside over the meeting and conduct it. In case of long absence of the chairman, the Chairman in consultation with member secretary nominate alternate member for performing his functions during his absence.
- Chairperson is the concluding authority in IEC voting or final decisions, he/she will sign the minutes.
- If Member Secretary has a conflict of interest as a Principal Investigator, in any research project then documents communicating IEC decisions like approval letter shall be signed by the Chairperson.

9.3 Responsibilities of the Member Secretary:

Member Secretary is responsible for all the administrative work of the committee. In consultation with the Chairperson, Member Secretary shall discharge the following functions-

- Receive all correspondence related to research proposals.
- Check the new proposal documents for their completeness.
- Convene the meetings in consultation with the Chairperson.
- Preparing and communicating the agenda for the meetings.
- Forward the proposals/ matters for review to the IEC members.
- Invite the Principal Investigator for the scheduled meeting whenever necessary.
- Decide and invite the experts for the meeting whenever required.

- Prepare minutes of the meeting and place the minutes of the previous meeting for the confirmation by the IEC members in the current meeting.
- Respond to the queries or provide clarifications to the observations submitted to the IEC by the Investigators.
- Take 'Confidentiality agreement' (Annexure III) and 'Agreement for the Declaration of the Conflict of Interest' from the IEC members.
- He/ She will train the IEC members on the Standard Operating Procedures of the Ethics Committee.
- To ensure that complaints and concerns of study subjects are addressed and managed appropriately.
- Member Secretary is the custodian of all the documents pertaining to the IEC.

9.4 Responsibilities of the IEC Members:

- Attending meetings on a regular basis.
- Maintaining strict confidentiality regarding protocol information, reviews and decisions and all matters discussed at committee meetings.
- Disclosing conflict of interests, respecting each other's views and the deliberative process.
- Deciding independently if the design and conduct of proposed studies will protect participants' safety, rights and welfare.
- Will evaluate the possible risks to the study participants with proper justifications, expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice.
- Remaining impartial and objective when reviewing protocols Serving as main reviewers for research in their areas of expertise.
- Keeping up-to-date with national and international research ethics and regulatory guidelines.
- Taking part in research ethics-related continuing education.
- To carry out work delegated by Chairperson and Member Secretary

9.5 Role of Expert Advisors:

- The IEC will maintain a list of Expert Advisors in various specialties, who may be invited to attend the meeting and advise the Committee on a subject related to their specialty and thus help the Committee in making the decision.
- Their opinion or advice will be recorded, but they will not take part in the decision making process.

9.6 Site Monitoring by IEC:

- It is responsibility of the IEC to monitor the sites to which they have accorded approvals for the conduct of the study. A committee appointed by the Chairperson shall conduct the monitoring, if required.
- The committee shall submit the monitoring report to the secretariat within 14 days.
- In the next IEC meeting, the findings of the monitoring will be discussed in detail
- The PI may be called for the meeting to seek clarification when the monitoring report is to be discussed.
- Appropriate action shall be decided by the committee, which may include:
  - Continuation of the project with or without changes
  - Recommendation for additional training
  - Recommendation for recruiting additional members in the study team
  - Suspension of the study
  - Any other
  - Opportunities for improvement are identified and appropriate actions are initiated
- The secretariat will convey the decision to the Principal Investigator (PI) within 14 days of the meeting

9.7 Policy to Monitor or Prevent the Conflict of Interest:

A set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain is termed as Conflict of Interest (COI).

A conflicting interest of an Ethics Committee member generally includes the following:

- Participation in a study where Ethics Committee member is listed as an investigator or is a member of the research team at the same institution or at other site where the same study shall be conducted

- Financial interest where the Ethics Committee member holds significant equity or stock options, receives or expects to receive compensation with a value that may be affected by the outcome of the study, has an ownership interest (including patent, trademark or copyright interest) in the drug, product or technology that is the subject of the research, or receives a significant amount annually as a salary, consulting income or other compensation from the sponsor.

- Non-financial (personal, academic or political) interest that he or she believes conflicts with the member's ability to review a project objectively.

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Procedure for handling an IEC member's conflicting interest:

- No IEC member shall participate in the review, comment or approval of the projects in which he/she has a conflict of interest.
- All the IEC members shall sign the agreement of 'Declaration of the Conflict of Interest' (Annexure III) at the time of joining the committee.
- The member who has a conflict of interest shall declare the same in the beginning of meeting in writing to the Chairman of the IEC.
- The member who discloses a conflict of interest may attend the presentation done by the investigator team, but shall not participate in the deliberative discussion or vote on the protocol.
- This shall be documented in the minutes of the meeting.
- This policy applies to all research proposals reviewed by the Committee, including initial and continuing reviews where approval for the study or other study related documents are accorded.

10.0 Operating Procedures:

10.1Submission of Research Proposal:

The research proposal for approval by the committee shall be submitted to the **Secretariat Office** at the following address:

Institutional Ethics Committee Office
Gokhale Institute of Politics and Economics
Pune-411004
Phone No- 02025650287, Ext - 204
Email ID- gipeiec@gipe.ac.in

- The administrative staff will be provided by Gokhale Institute of Politics and Economics.
- The list of documents to be submitted for IEC review and approval is attached as Annexure IV
- The documents shall be submitted minimum two weeks prior to the scheduled IEC meeting.
- A Clinical Trial Agreement (CTA) should be a tri-party document, signed by the Principal Investigator (PI), the Head of the Institute and the Sponsor. If draft of the CTA is submitted for IEC review, the executed copy of the same shall be notified to the IEC.
- Prior to submission to the IEC, all the research projects should have received approval from the Scientific Review/Advisory Committee.

10.2 Processing of Proposal:

All the documents submitted to the IEC shall be acknowledged by the Member Secretary.

The Member Secretary shall assign a unique number to each proposal and check it for its completeness. If any critical item is missing, the Member Secretary shall inform the PI and request for it in writing. If it is done on phone, fax or e-mail, the same shall be documented.

The Member Secretary shall make copies of the relevant documents and circulate them to the members along with a covering letter.

If the Member Secretary is an investigator for any project, then any other IEC member including the Chairperson will acknowledge the receipt of documents submitted to IEC for that project.

10.3 Frequency of Meetings:

Secretary in consultation with the Chairperson shall convene the meeting in the following conditions:

- Has at least two projects for discussion
- IEC fee of Rs. 20000/- will be charged for an urgent meeting for a single project, if required.

10.4 Review Procedure:

The primary task of the IEC is review of research proposals and their supporting documents with special attention given to the Informed Consent process, documentation, and the suitability and feasibility of the protocol. IEC will take into account the requirements of applicable laws and regulations.

The Member Secretary shall convene the meeting of the Committee in consultation with the Chairperson

a. If a proposal/ documents require urgent review, a special meeting may be convened in consultation with the Chairperson.
b. The meeting shall be scheduled after ascertaining the availability of the members for the proper quorum.
c. The **quorum** shall consist of at least 7 members who shall include at least one independent member, one non-medical person, member from legal community and one lady.
d. A member can play more than one role in the Ethics Committee depending upon his expertise, but during the meeting he/ she can play only one role at a time.
e. The Member Secretary shall maintain the attendance log of each meeting.
f. The Member Secretary shall inform the PIs, whose proposal is being discussed, of the date, time and the venue of the meeting and request them to be available for project presentation and for clarification, if any.
g. The Chairperson shall preside over the meeting and conduct the proceedings. If he/she is unable to attend, he/she shall nominate any other member to act on his behalf.

h. Only those members, who attend the meeting and take part in the deliberations, shall vote on the proposal.

i. If a member is not able to attend the meeting for some genuine reason and remains absent for the meeting with the prior consent of the Chairperson, the written comments/observations communicated by him should be considered for discussion.

j. PI or his / her representative shall make a presentation of the study to the IEC

k. IEC shall discuss the study in detail. Informed Consent Document, assent form (as applicable) and translations are reviewed for appropriateness of language, accuracy and completeness of information. IEC will also review it for implications of its contents, safety, compensation of research participant and other ethical considerations.

l. Decisions regarding a project submitted to the IEC will be taken by consensus or by voting if required. The open voting system will be followed and all members shall have equal voting rights. More than 50% votes are required to approve a project. In case of an equal number of votes (a tie), the Chairperson will cast the deciding vote. If an IEC member is the principal investigator for a particular research project, he/she will not vote for that project.

m. The decision on each proposal shall be minuted, including all the dissents regarding rejection of proposal.

n. The Chairperson shall approve the minutes of the meeting and letters to the respective principal investigators shall be issued by the Secretary. In case the Secretary is part of the Principal Investigator's team, the letters shall be issued by the Chairperson.

o. Decisions regarding the research proposal shall be communicated to the PI in writing within 10working days after the meeting.

p. Approval for the research projects will be given for the period of one year and it will be renewed on submission of yearly study progress report.

IEC will review the project in detail:-Suitability of the investigators' qualifications and experience for the proposed study.

- Rights and responsibility of subject are documented. Subject's confidentiality and privacy is protected.
- The appropriateness of the study design in relation to the objectives of the study.
- Recruitment strategies

- The statistical methodology (including sample size calculation),
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
- Subject's participation and withdrawal from the trial is voluntary.
- The adequacy of provisions made for monitoring and auditing the conduct of the research
- The manner in which the results of the research will be reported and published.

- Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.
- Contract and budget for indemnity, compensation etc.

10.4.1 Documentation of Minutes:

Minutes shall be documented with enough detail to reconstruct its decisions at a later date, additionally; comprehensive minutes show concern for participants' rights, safety and well-being. The minutes may include the following:

- Meeting logistics: date, time of start and venue.
- Review and approval of minutes of previous meeting.
- The minutes will identify all members attending the meeting
- The minutes will reflect when an ad hoc member substitutes for a regular member and for whom the ad hoc is substituting.
- The minutes will document when a member is rescued from discussion and voting due to a conflict of interest.
- The minutes will reflect the agenda of the meeting
- The minutes will include a summary of the discussion of the projects mentioned in the agenda and the resolutions.
- The minutes will include the discussion on the other relevant points which were not included in the agenda.
- The minutes will include a summary of expedited approvals given by the IEC since last IEC meeting.

- Minutes will be made available to the regulatory personnel during inspection of IEC or the site.

10.5 Expedited Approval:

The Chairperson in consultation with Member Secretary or another member nominated by him/her may approve a proposal without holding a formal meeting only under following conditions:

1. The proposal involves little or no risk to the participants. Minimal risk would be defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests.
2. The proposal involves minor modifications to a proposal already reviewed within proceedings, and concerns either an administrative matter or a change that does not affect the safety of the participant.
3. The protocol reviewed in an earlier meeting has been considered approvable with suggested amendments, and has now been amended accordingly.
4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

A subcommittee may be appointed by the Chairperson for expedited approval. This subcommittee shall submit its report to the chairperson who would take the final decision.

All proposals considered for expedited approval will be presented in subsequent full IEC meeting for ratifying the decision.

10.6 Appeal on Rejection:

1. If the proposal is rejected by the IEC, the PI may appeal for reconsideration within 12 weeks after providing the justification of such reconsideration.
2. If major modifications are required in the study documents, the PI may place a fresh proposal to IEC within 12 weeks.

10.7 On-going Review:

The Committee shall review the progress of the approved research projects at regular intervals.

For all projects, a study status report should be submitted every six months.

11.0 Institutional Ethics Committee Fee:

a. If an urgent meeting of IEC is called for, Rs. 20,000/-(Rupees Twenty Thousand only) will be charged.
b. A fee of Rs. 5000/- (Rupees Five Thousand only) will be charged for review of Amended projects.
c. Fee waiver may be considered for in house, non-sponsored projects.

The IEC fee should be paid by Cheque /Demand Draft in favour of 'Gokhale Institute of Politics and Economics'

12.0 Responsibilities of the Principal Investigator (PI):

The Principal Investigator or Co-investigator of a new research project is required to attend the IEC meeting wherein his/her project is being reviewed, to answer any queries pertaining to the project.

The committee expects the following from the PI after his / her research proposal is approved:

1. The PI should initiate the project, only after written approval from IEC and from regulatory authorities (if applicable).
2. The PI should submit the study status report as per the IEC recommendation.
3. To inform the IEC of study completion or discontinuation with reasons.
4. To submit justification for approval to restart studies discontinued earlier by the IEC and not to restart it before such approval has been accorded.
5. To submit the final study report, on its completion/closure or termination.
6. To inform about any changes in the protocol and /or patient information informed consent.
7. The PI should ensure that the sponsor registers the study in 'Clinical Trial Registry India', as applicable

13.0 Record keeping and Archival :

The Member Secretary will supervise the day-to-day activities and will maintain the correspondence pertaining to the IEC. The office will maintain all the records pertaining to the functioning of the IEC such as:

- The current list of the IEC members and their CVs, consent documents, Confidentiality Agreement, Declaration of the Conflict of Interest, GCP and other relevant training certificates etc.
- The current version of the SOP
- The agenda and minutes of the IEC meetings.
- Reference documents that are regularly required by the IEC for its deliberations- Declarations of Helsinki, Schedule Y and its Amendments, ICMR Bioethical Guidelines on Human Participants, GCP guidelines etc.
- Correspondence between the IEC and the PI /study team and other relevant records will be retained for a minimum period of five years after completion / termination of the study or no communication from the PI for three consecutive years about study status.
- Correspondence between the IEC and the regulatory bodies will be retained for a minimum period of five years after completion / termination of the study or no communication from the PI for three consecutive years about study status.
- The copies returned by the IEC members will be destroyed periodically.
- The torn pages may be given to an external agency for shredding and the same will be documented.

All the documents and communications of IEC should be labelled, filed and archived in a secure place.

Only persons, who are authorized by the IEC Chairperson, will have access.

14.0 Revision History:

This SOP is an SOP Version 2 dated 20 June 2018

This SOP is effective from 20 June 2018 Its duration is three years from the effective date or till the next amendment, whichever is earlier.

The SOP of the IEC may be made available to any member from Gokhale Institute of Politics and Economics upon a written/oral request for the same to the IEC.

Annexure I

Institutional Ethics Committee Members as on 20 June 2018:

Sr. No.	Name	Qualifications	Affiliation	Role in the IEC
1				Chairperson
2				Basic Scientist
3				Clinician
4				Social Scientist
5				Social Scientist
6				Legal Expert
7				Legal Expert
8				Lay Person
9				Member Secretary

Annexure II

Appointment Letter

Date:

To,

Dear,

I am pleased to appoint you as ---------- of the Institutional Ethics Committee (EC) at Gokhale Institute of Politics and Economics, Punew.e.f. ---------- for a term of three year / months provided following conditions of appointment are met.

1. You should be willing to publicize your full name, profession and affiliation.

2. You are willing to record all reimbursement for work and expenses, if any, within or related to an IEC and make it available to the public upon request.

3. You consent to sign confidentiality agreement between you and the IEC regarding meeting deliberations, applications, information on research participants, and related matters.

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

You will be paid Honorarium for your services rendered and as per the SOP.

Signature

Director

Gokhale Institute of Politics and Economics, Pune

Annexure III

GOKHALE INSTITUTE OF POLITICS AND ECONOMICS DEEMED TO BE UNIVERSITY II PUNE-4.

Date:

To,

The Member
Institutional Ethics Committee
Gokhale Institute of Politics and Economics

CONFIDENTIALITY AGREEMENT

The Institutional Ethics Committee (IEC), Gokhale Institute of Politics and Economics is honoured to have you as a member of the Committee.

The IEC receives from investigators, clinical research documents for review and approval. As an esteemed member of the IEC, these documents will be shared with you. The documents and the discussions that occur during the meetings are highly confidential. You are requested to comply with this code of confidence of the IEC.

If you agree to the foregoing, kindly indicate your acceptance thereof by signing this document.

Yours sincerely,

Member Secretary
Institutional Ethics Committee

Agreed and Accepted

Name: _____

Title:

_____

Signature: _____ Date:

_____

Annexure IV

Date:

To,
The Member
Institutional Ethics Committee
Gokhale Institute of Politics and Economics

Agreement for declaration of Conflict of Interest

The Institutional Ethics Committee (IEC), Gokhale Institute of Politics and Economics is honoured to have you as a member of the Committee.

The IEC receives from investigators, clinical research documents for review and approval. The professional judgment concerning a primary interest like participant's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain is termed as Conflict of Interest (COI).

You are requested to declare the conflict of interest if any in the projects submitted to you for review. This conflict of interest shall be declared in writing to the chairman of the IEC before the review of the project. You are requested to comply with this code of Conflict of Interest of the IEC.

If you agree to the foregoing, kindly indicate your acceptance thereof by signing this document. A copy of the same will be given to you for your records.

Yours sincerely,

Member Secretary
Institutional Ethics Committee

Agreed and Accepted

Name: _____

Title:

_____

Signature: _____ Date:

_____

Annexure V

List of documents to be submitted for IEC review and approval is as follows:

Sr. No.	Documents
1	A covering letter addressed to the Chairperson
2	Protocol or Study Plan a) Synopsis b) Full version
3	Data collection tools
4	Participant Information Sheet and Informed consent form in English and vernacular language. • including updates, if any • back translations, if any • translation certificates, if applicable
5	Permission from competent Regulatory Authority, if applicable.
6	CV of the Principal Investigator (PI)
7	Details of the research grant to support the project/ Investigator's Agreement with the Sponsor (Clinical Trials Agreement - Draft/Executive)

Documents should be submitted both in hard and soft copy.

Annexure VI

(Format for Approval of Ethics Committee)

To,

Dr.

Dear Dr._____

The Gokhale Institute of Politics and Economics Institutional Ethics Committee reviewed and discussed your application to conduct the clinical trial entitled "..." on..... (Date).

The following documents were reviewed:

a. Trial Protocol (including protocol amendments), dated_____ Version no. (s) _____

b. Patient Information Sheet and Informed Consent Form (including updates if in any) in English and/ or vernacular language.

c. Proposed methods for patient accrual including advertisement (s) etc.

Proposed to be used for the purpose.

d. Principal Investigator's current CV.

e. Investigator's Agreement with the Sponsor.

f. Investigator's Undertaking (Appendix VII).

The following members of the ethics committee were present at the meeting held on (date, time, and place)

_____ Chairman of the Ethics Committee

_____ Member Secretary of the Ethics Committee

_____ Name of each member with designation

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

The Institutional Ethics Committee expects to be informed about the progress of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report.

Yours sincerely,

Member Secretary/ Chairperson

Institutional Ethics Committee

Gokhale Institute of Politics and Economics

Gokhale Institute of Politics and Economics

Minutes of Institutional Ethics Committee Meeting

Meeting of the Institutional Ethics Committee of the institute was held on Monday, 27 August 2018at 10:30 am at Conference Hall, UGC Building of the institute.

Following members attended the meeting

1. Dr. P.R. Deke
2. Dr. Anjali Radkar
3. Dr. Savita Kulkarni
4. Adv. Sayali Gandu
5. Dr. Shailesh Deshpande
6. Ms. Vaishali Deshpande
7. Ms. Ashwini Joglekar
8. Dr. Sanjeevanee Mulay
9. Dr. Angeline Jayakumar
10. Dr. Ujwala Barve
11. Dr. Medha Deshpande
12. Dr. Sharad Deshpande
13. Dr. Deepa Purohit

Dr. Milind Narvane, Ms. Neelam Mahapatra and Mr. Abhay Tilak could not attend the meeting.

Dr. Bhushana Karandikar presented the proposal 'Snack Food Consumption Pattern Study in Pune', along with data collection tools and consent form. IEC discussed the ethical concerns included in the study.

IEC suggested some changes in the sampling method and asked to circulate the consent form and the questionnaire for the approval.

Dr. Savita Kulkarni presented the proposal 'Evaluation Study of Opening and maintenance of Government Hostels for Scheduled Caste Boys and Girls in Maharashtra' along with data collection tools for different categories of respondents and consent forms. The study involves interviews of the boys and girls, below 18 years of age so assent forms (Consent of responsible person) also were prepared. IEC discussed the ethical concerns involved in the study.

IEC discussed the issues related to sampling technique and the draft questionnaires. The draft questionnaires were approved.

Dr. Anjali Radkar is Principal Investigator for this study. Being Secretary, IEC she did attend the meeting but did not participate in the discussion of the project proposal in view of conflict of interest.

After the IEC meeting was over training of the committee members was conducted, who could not attend the earlier training on 20 June 2018.

Dr. P.P. Doke

Dr. Anjali Radkar

Dr. Savita Kulkarni

Adv. Sayali Ganu - Dabake

Dr. Shailesh Deshpande

Ms. Vaishali Deshpande

Ms. Ashwini Jogalekar

Dr. Sanjeevanee Mulay

Dr. Angeline Jeyakumar

Dr. Ujjwala Barve

~~Mr. Abhay Tilak~~

Dr. Medha Deshpande

Dr. Sharad Deshpande

~~Ms. Neelam Mahaparale~~

Dr. Deepa Pandit

GOKHALE INSTITUTE OF POLITICS AND ECONOMICS
DEEMED TO BE UNIVERSITY
PUNE-4.

Institutional Ethics Committee Members as on 20 June 2018:

Sr. No.	Name	Qualifications	Affiliation
1	Dr. P.P. Doke	M.D., D.V.D., Ph.D.	Bharati Vidyapeeth University Medical College
2	D. Anjali Radkar	DSC (Statistics) Ph.D. (Bop) Studies	Professor G.C.J.P.E.
3	Dr. Shailesh Deshpande	M.D. (Preventive & Social Medicine)	Head Education Cultureen Parkar Institute, Pune
4	Dr. Ujjwala Barve	Ph.D. (Communication & Journalism)	Hindi Dept. (Communication & Journalism) PPU.
5	Mr. Abhay Tilak		
6	Adv. Sayali Ciarii	B.Sc., LL.M. (Business Law) LL.M. (Constitutional Law) PGDIPRL, M.PL	Practising Lawyer, Visiting Faculty, GJPE

7	Ms. Vaishali Deshapande	M.Sc. Anthropology Di clinical resea.	Consultant clinical reseach & body composition.
8	Dr. Savita Kulkarni	Ph.D. (Economics)	Assistant Professor. G.I.P.E.
9	Ms. Ashwini Jogalekar	Ad-Com / Diploma in Financial Management / Diploma in Computer Application / Tally 4.5 / ERP Diploma in HR & Admin	Finance & Accounts officer Gokhale Institute of Politics & Economics, Pune-411004.

10 Neelam Mahaparale — B.Pharm, PG. Diploma Clinical Research — Freelancer - Clinical Research Project manager - Dr. DY Patil. Medical college.

7.1.10: The Institution has a prescribed code of conduct for students, teachers, administrators and other staff and conducts periodic programmes in this regard.

https://gipe.ac.in/governance/planning-monitoring-board/