Institutional Ethics Committee
Guru Gobind Singh Indraprastha University
Sector 16-C, Dwarka, Delhi-110078

Dated : 15.02.2024

Notice

A meeting of the Institutional Ethics Committee will be held tentatively in last week of February ,2024. All the faculty members who wish to submit their research proposals for ethical clearance are requested to fill the prescribed format(s) attached with the notice uploaded on the website. You are requested to submit the soft as well as hard copy of the filled format along with the proposal and cover letter to the USBT office latest by 22nd February, 2023. Kindly attach all the mandatory documents as per the format. The checklist for the same is given in the point No. 12 of the format. The complete ICMR National Ethical Guidelines are available at the ICMR website.

Faculty members whose proposals were approved in the last IEC meeting are requested to submit the soft as well as hard copy six monthly progress report in the format attached with this notice uploaded on the university website.

Dr. Rinu Sharma
Member Secretary, IEC
GGSIPU

Copy to:
Deans, all USS
Head, UITS. Kindly upload the notice on University website

Six monthly progress of Project

Institute Ethics Committee Reference No.:

Study title:_

Name of the Principal Investigator :

Designation / Department

Duration of Study:
Date of Starting of the Study:

Period of Six monthly progress report: from to

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Progress:

Signature of Principal Investigator _____

Date:_____

(Annexure 1)
Application Form for Expedited Review

Logo of the Institute

(Name of the Institution)

EC Ref. No. *(*for office use):*

Title of study:
Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why expedited review from EC is requested[12]?
   i. Involve non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples ☐
   ii. Involve clinical documentation materials that are non-identifiable (data, documents, records). ☐
   iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)) ☐
   iv. Revised proposals previously approved through expedited review, full review or continuing review of approved proposals ☐
   v. Minor deviations from originally approved research causing no risk or minimal risk ☐
   vi. Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
   vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modification in the study proposal through full committee meeting/ expedited review depending on the importance of local consent related issues involved specific to the centre. ☐
   viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
   ix. Any other (please specify) ☐
2. Is waiver of consent being requested ? Yes ☐ No ☐
3. Does the research involve vulnerable person[13]? Yes ☐ No ☐
   If Yes give details:

Signature of PI: Click here to enter a date.

Comments of EC Secretariat:

Signature of Member Secretary: Click here to enter a date.

[12] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*
[13] *For details, refer to application for initial review, Section-C, 5(b)*
* *In case this is first submission, leave it blank*

(Annexure 2)
Application Form for Exemption from Review

Logo of the Institute

(Name of the Institution)

EC Ref. No.*(for office use):*

Title of study: Principal Investigator (Name, Designation and Affiliation)

1. Choose reasons why exemption from ethics review is requested [14]?
   - i. Research on data in the public domain/ systematic reviews or meta-analyses; ☐
   - ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person ☐
   - iii. Quality control and quality assurance audits in the institution ☐
   - iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
   - v. Consumer acceptance studies related to taste and food quality ☐
   - vi. Public health programmes by government agencies[15] ☐
   - vii. Any other (please specify in 100 words): ☐

Signature of PI: Click here to enter a date.

Comments of EC Secretariat:

Signature of Member Secretary: Click here to enter a date.

[14] *Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

[15] *Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)*

(Annexure 3)
Continuing Review/ Annual report format

Logo of the Institute

(Name of the Institution)

EC Ref. No.*(for office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval: Click here to enter a date. Validity of approval: Click here to enter a date.

2. Date of Start of study: Click here to enter a date. Proposed date of Completion: Click here to enter a date.

   Period of Continuing Report Click here to enter a date. ---- to ------ Click here to enter a date.

3. Does the study involve recruitment of participants? Yes ☐ No ☐
   (a) If yes, Total number expected No. Screened: No. Enrolled:

   Number Completed: No. on followup: .

   (b) Enrolment status – ongoing / completed/ stopped

   (c) Report of DSMB[16] Yes ☐ No ☐ NA ☐

   (d) Any other remark

   (e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA ☐
   If yes, total number withdrawn and reasons:

4. Is the study likely to extend beyond the stated period[17]? Yes ☐ No ☐
   If yes, please provide reasons for the extension

5. Have there been any amendments in the research protocol/informed consent document (ICD) during the past approval period?
   If No, skip to item no.6 Yes ☐ No ☐
   (a) If yes, date of approval for protocol and ICD : Click here to enter a date.

   (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants?
   If yes, when / how: Yes ☐ No ☐

[16] *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*
[17] *Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

6. Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes ☐ No ☐
   If yes, discuss in detail:

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐
   If yes, give details

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

   Describe in brief:

   (b) Have any SAE's occurred since last review? Yes ☐ No ☐
   If yes, number of SAE's : Type of SAE's:

   (c) Is the SAE related to the study? Yes ☐ No ☐

   Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

9. Has there been any protocol deviations/violations that occurred during this period?
   If yes, number of deviations
   Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

10. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC
    Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

Any other comments:

Signature of PI:

Click here to enter a date.

(Annexure 4)
Application/ Notification form for Amendments

Logo of the Institute

(Name of the Institution)

EC Ref. No.*(for office use):*

Title of study:
Principal Investigator (Name, Designation and Affiliation)

Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.

1. Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.

2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD[18]

3. Impact on benefit-risk analysis Yes ☐ No ☐
   If yes, describe in brief:

4. Is any re-consent necessary? Yes ☐ No ☐
   If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. Type of review requested for amendment:
   Expedited review (No alteration in risk to participants) ☐
   Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure/ICD:

Signature of PI:

Click here to enter a date.

[18]*Location implies page number in the ICD/protocol where the amendment is proposed.*

Title of study:
Principal Investigator (Name, Designation and Affiliation)

ICMR-Central Ethics Committee on Human Research (CECHR)

(Annexure 13)

Format for Curriculum Vitae for Investigators

EC Ref. No.*(for office use):*

Name:	
Present affiliation*(Job title, department, and organisation)***:**	
Address*(Full work address)***:**	
Telephone number:	**Email address:**
Qualifications:	
Professional registration *(Name of body, registration number and date of registration)***:**	
Previous and other affiliations*(Include previous affiliations in the last 5 years and other current affiliations)***:**	
Projects undertaken in the last 5 years:	

Relevant research training/experience in the area[25]:	
Relevant publications *(Give references to all relevant publications in the last five years)***:**	
Signature	**Date:** Click here to enter a date.

[25] *Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*