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

Dated : 22.02.2023

**Notice**

A meeting of the Institutional Ethics Committee will be held (online) on 1st March ,2023 at 2:00 p.m. All the faculty members who wish to submit their research proposals for ethical clearance are requested to fill the prescribed format attached herewith. 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 28th 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.

Rinu Sharma 22/2/23
Dr. Rinu Sharma
Member Secretary, IEC
GGSIPU

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

# Application Form for Initial Review

***(Name of the Institution)***

**Logo of the Institute** **EC Ref. No.***(for office use):*

**General Instructions: a) Tick one or more as applicable. Mark NA if not applicable**
**b) Attach additional sheets if required**

## SECTION A - BASIC INFORMATION

### 1. ADMINISTRATIVE DETAILS

(a) Name of Organization: Guru Gobind Singh Indraprastha University

(b) Name of the Ethics Committee: Institutional Ethics Committee, GGSIP University

(c) Name of Principal Investigator: Dr. Rinu Sharma

(d) Department/Division: Biotechnology (e) Date of Submission: 10-07-2021

(f) Type of review requested[1]:

Exemption from Review ☐ Expedited Review ☐ Full Committee Review √

(g) Title of the study: **Investigating the Expression and Role of FGFRs in Esophageal Cancer: Potential Targets for Therapy**
Acronym/ Short title, (If any): No

(h) Protocol number(If any): Version number:

(i) Details of Investigators:

| Name | Designation and Qualification | Department and Institution | Address for communication[2] |
|---|---|---|---|
| Principal Investigator/Guide | | | |
| Dr. Rinu Sharma | Assistant Professor Ph.D. | University School of Biotechnology, GGSIP University | AFR-202, University School of Biotechnology, GGSIP University, Sector 16C, Dwarka, New Delhi-110048 Email: rinusharma@gmail.com;9899011197 |
| Co-investigator/student/fellow | | | |
| Dr. Anoop Saraya | Professor & Head MBBS,MD,DNB,DM | Department of Gastroenterology, All India Institute of Medical Sciences, New Delhi | Department of Gastroenterology, All India Institute of Medical Sciences, Ansari Nagar,New Delhi-110029 Email: ansaraya@yahoo.co.in; 011-26593294 |

[1] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017on Page 36 Table 4.2. for the types of review*

[2] *Include telephone/mobile, fax numbers and email id*

| | | | |
|---|---|---|---|
| Dr. Nihar Ranjan Dash | Professor | Department of Gastrointestinal Surgery, AIIMS,New Delhi | Department of Gastrointestinal Surgery<br>All India Institute of Medical Sciences<br>Ansari Nagar<br>New Delhi-110029<br>E-mail: nagranjan@gmail.com |

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission: ***02***

ii) Co-Investigator at time of submission: ***01***

(k) Duration of the study: 3 years

## 2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: **Rs. 49.35778 lakhs**

At site In India √ Globally

(b) Self-funding ☐ Institutional funding ☐ Funding agency √

*(Specify): Project Submitted to SERB,DST*

## SECTION B - RESEARCH RELATED INFORMATION

## 3. OVERVIEW OF RESEARCH

(a)

Esophageal cancer (EC) is a morbid disease with a grim prognosis. The overall ratio of mortality to incidence is 0.88 worldwide and 0.9 in India. The standard management approach for esophageal cancer is neoadjuvant chemoradiotherapy followed by surgical resection of the tumor, but disease recurrence often ensues after curative resection and the 5-year survival rate (~20%) has not changed significantly for several decades. Moreover, heterogeneous response of neo adjuvant CRT among esophageal cancer patients as well as therapy-induced side effects represent major limiting factors of current treatment strategies. Therefore, identifying new targets for therapy or exploring those which are being currently used for other cancers is imperative.

Fibroblast growth factor receptors (FGFRs) are high affinity cell surface tyrosine kinase receptors, exerting their roles in embryogenesis, tissue homeostasis and development of cancer. Several studies report that mutations and aberrant expression of FGFRs is involved in the initiation and progression of cancers. Accumulating evidence suggests that dysregulation of the FGF signaling axis supplements oncogenesis, tumor progression, as well as the development of resistance to integral chemotherapy. Use of tyrosine kinase inhibitors (TKIs) for blocking the FGF/FGFR signaling axis has proved to be a successful therapeutic strategy in numerous tumor types. Limited number of studies carried out previously reveal that aberrations in FGFRs, especially gene amplification, occur in EC patients and have also been correlated to their poor prognosis. However, a comprehensive study to evaluate aberrant expression of FGFRs in esophageal cancer is lacking. Preliminary study carried out in our lab

suggest aberrant expression and oncogenic role of FGFRL1 in esophageal cancer. Therefore, keeping in view i)the emerging role of FGFRs in cancers ii) their potential as therapeutic target iii) lack of comprehensive data regarding their expression and role in esophageal cancer, we herein propose to investigate potential of FGFRs as markers for diagnosis/prognosis and target for therapy in EC. In order to fulfil our aim we will perform immunohistochemistry to analyse the expression of all FGFRs in EC tissues and correlate its expression to various clinicopathological parameters as well as response to therapy. We also aim to delineate the role of FGFRL1, new member of FGFR family, in esophageal cancer cells using RNAi approach. The effect of FGFR inhibitors/FGFRL1 siRNA on sensitivity/resistance to chemotherapeutic agents will also be investigated in chemoresistant versions of esophageal cancer cell lines.

Applicability: The present study will shed light on the clinical and functional significance of FGFRs in EC and may lead to establishment of FGFRs as a therapeutic targets for esophageal cancer treatment. Increasing use and success of FGFR inhibitors in other cancers further makes it important to investigate aberrant expression of FGFRs in EC. The results obtained after completion of the study will in future help in exploring the possible use of already approved FGFR inhibitors for targeted therapy in EC patients as well.

(b) Type of study:

| | | | | | |
|---|---|---|---|---|---|
| Basic Sciences | √ | Clinical | ☐ | Cross Sectional | ☐ |
| Retrospective | ☐ | Epidemiological/ Public Health | ☐ | Case Control | ☐ |
| Prospective | √ | Socio-behavioural | ☐ | Cohort | ☐ |
| Qualitative | ☐ | | | Systematic Review | ☐ |
| Quantitative | ☐ | Biological samples/Data | √ | | |
| Mixed Method | ☐ | Any others *(Specify)* | ☐ | | |

## 4. METHODOLOGY

(a) Sample size/ No. of Participants (*as applicable)*

At site In India **100** Globally

Control group **100** Study Group

Justification for the sample size chosen (*100 words*); In case of qualitative study, mention the criteria used for saturation

Esophageal cancer (N=100) and distant matched non-malignant tissue (5 cm apart from tumor) biopsies/surgery tissues will be collected from patients with ESCC who will undergo endoscopy/surgery at Department of Gastroenterology and Department of Gastrointestinal surgery, AIIMS.

(b) Is there an external laboratory/ outsourcing involved for investigations?[3] Yes ☐ No √ NA ☐

(c) How was the scientific quality of the study assessed?:

[3] *If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA/ MoU etc.*

| | | | | | |
|---|---|---|---|---|---|
| Independent external review | ☐ | Review by Sponsor/Funder | √ | Review within PI's institution | ☐ |
| Review within multi-centre research group | ☐ | No Review | ☐ | | |

Date of review:Project submitted toSERB Click here to enter a date.

Comments of Scientific Committee, if any(100 words)

## SECTION C - PARTICIPANT RELATED INFORMATION

### 5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Healthy volunteer | ☐ | Patient | √ | Vulnerable person/ Special groups | ☐ | Others *(Specify)* | ☐ |

Who will do the recruitment?

Participant recruitment methods used:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Posters/ leaflets/Letters | ☐ | TV/Radio ads/Social media/Institution website | ☐ | Patients / Family/Friends visiting hospitals | ☐ | Telephone | ☐ |

Others*(Specify)* √ *Patients visiting department of Gastroenterology and GI surgery will be recruited*

(b)

i. Will there be vulnerable person/special groups involved? Yes ☐ No √ NA ☐

ii. If yes, type of vulnerable person /special groups

| | | | |
|---|---|---|---|
| Children under 18 yrs | ☐ | Pregnant or lactating women | ☐ |
| Differently abled (Mental/Physical) | ☐ | Employees/Students/Nurses/ Staff | ☐ |
| Elderly | ☐ | Institutionalized | ☐ |
| Economically and socially disadvantaged | ☐ | Refugees/Migrants/Homeless | ☐ |
| Terminally Ill (stigmatized or rare diseases) | ☐ | | |
| Any other *(Specify)*: | ☐ | | |

iii. Provide justification for inclusion/exclusion

**Inclusion criteria**

a) Tissues histopathologically confirmed to have squamous cell carcinoma of esophagus and showing evidence of preneoplastic lesions will be included in the study.

**Exclusion criteria**

a) Tissues showing no evidence of esophageal carcinoma will be excluded from the study.

**Control(s):** Histopathologically confirmed matched distant normal esophageal tissues. In

addition, normal esophageal epithelial samples from patients who received surgery for treatment of any other non cancerous disease (eg. bariatric surgery) will be collected to be used as controls.

iv. Are there any additional safeguards to protect research participants?
NA

(c) Is there any reimbursement to the participant? Yes ☐ No √

If yes, Monetary ☐ Non-monetary ☐ Provide details

(d) Are there any incentives to the participant? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ Provide details

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI/ Institution?

If yes, Monetary ☐ Non-monetary ☐ Provide details Yes ☐ No √

## 6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants?

Yes ☐ No √

If yes, categorize the level of risk[4]:

| | | | |
|---|---|---|---|
| Less than Minimal risk | ☐ | Minimal risk | ☐ |
| Minor increase over minimal risk or Low Risk | ☐ | More than Minimal Risk or High Risk | ☐ |

ii. Describe the risk management strategy:

| (b) What are the potential benefits from the study? | Yes | No | If yes, Direct | Indirect |
|---|---|---|---|---|
| For the participant | ☐ | ☐ | ☐ | √ |
| For the society/community | √ | ☐ | ☐ | √ |
| For improvement in science | √ | ☐ | √ | ☐ |

Please describe how the benefits justify the risks

(c) Are Adverse Events expected in the study[5]? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify

## 7. INFORMED CONSENT

[4] *For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017. Page 6 in Table 2.1*

[5] *The term adverse events in this regard encompass both serious and non-serious adverse events.*

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to question 8. Yes ☐ No ☐

(b) Version number and date of Participant Information Sheet (PIS):
Version number and date of Informed Consent Form (ICF):

(c) Type of consent planned for :

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Signed consent | ☐ | Verbal/ oral consent | ☐ | Witnessed consent | ☐ | Audio-Video (A/V) consent | ☐ |
| Consent from LAR (If so, specify from whom) | ☐ | For children<7 yrs parental/LAR consent | ☐ | Verbal assent from minor (7-12 yrs) along with parental consent | ☐ | Written Assent from Minor (13-18 yrs) along with parental consent | ☐ |
| Other *(specify)* | ☐ | | | | | | |

(d) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐ Other*(Specify)* ☐

Any tools to be used

(e) Participant Information Sheet(PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ other ☐ (*specify*)

List the languages in which translations were done

If translation has not been done, please justify

(f) Provide details of Consent requirement for previously stored samples if used in the study[7]

(g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

| | | | | | |
|---|---|---|---|---|---|
| Simple language | ☐ | Data/ Sample sharing | ☐ | Compensation for study related injury | ☐ |
| Risks and discomforts | ☐ | Need to recontact | | Statement that consent is voluntary | |
| Alternatives to participation | ☐ | Confidentiality | ☐ | Commercialization/benefit sharing | ☐ |
| Right to withdraw | ☐ | Storage of samples | ☐ | Statement that study involves research | ☐ |
| Benefits | ☐ | return of research results | ☐ | Use of photographs/ identifying data | ☐ |
| Purpose and procedure | ☐ | Payment for participation | ☐ | Contact information of PI and Member Secretary of EC | ☐ |
| Others*(Specify)* ☐ | | | | | |

## 8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[8]?

PI ☐ Institution ☐ Sponsor ☐ Other agencies*(specify)* ☐

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ NA ☐

If yes, then who will provide the treatment?

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐ NA ☐

Sponsor ☐ Institution/ Corpus funds ☐ Project grants ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐ NA ☐

(e ) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify. Yes ☐ No ☐ NA ☐

[7] *Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017,Page 54 in Section 5.8*

[8] *Enclose undertaking from PI confirming the same*

## 9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. If Yes, Specify Yes ☐ No ☐ NA ☐

Anonymous/unidentified ☐ Anonymized: reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited / data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)

(b) Who will be maintaining the data pertaining to the study?

(c) Where will the data be analyzed[9] and by whom?

(d) For how long will the data be stored?

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

If yes, explain how you might use stored material/data in the future?

# SECTION D: OTHER ISSUES

## 10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐ NA ☐

(b) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief *(Max 50 words)* Yes ☐ No ☐ NA ☐

(d) Is there any plan for post research benefit sharing with participants? If yes, specify
Yes ☐ No ☐ NA ☐

(e) Is there is any commercial value or a plan to patent/IPR issues. If yes, Please provide details
Yes ☐ No ☐ NA ☐

(f) Do you have any additional information to add in support of theapplication, which is not included elsewhere in the form? If yes, provide the details. Yes ☐ No ☐

[9] *For example, a data entry room, a protected computer etc.*

## SECTION E: DECLARATION AND CHECKLIST[10]

| 11. DECLARATION (Please tick as applicable) | |
|---|---|
| ☐ | I/We certify that the information provided in this application is complete and correct. |
| ☐ | I/We confirm that all investigators have approved the submitted version of proposal/related documents. |
| ☐ | I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible. |
| ☐ | I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines. |
| ☐ | I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted. |
| ☐ | I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol. |
| ☐ | I/We declare that the expenditure in case of injury related to the study will be taken care of. |
| ☐ | If applicable, I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable. |
| ☐ | I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in |

| | |
|---|---|
| | any audit of the study if needed. |
| ☐ | I/We confirm that we will maintain accurate and complete records of all aspects of the study. |
| ☐ | I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples. |
| ☐ | I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study. |
| ☐ | I/We have the following conflict of interest (PI/Co-PI):<br><br>1.<br>2. |
| ☐ | I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable. |

Name of PI: Signature: Click here to enter a date.

Name of Co-PI: Signature: Click here to enter a date.

Name of Guide: Signature: Click here to enter a date.

Name of HOD: Signature: Click here to enter a date.

**12. CHECKLIST**

| S.No | Items | Yes | No | NA | Enclosure No. | EC Remarks(If applicable) |
|---|---|---|---|---|---|---|
| **ADMINISTRATIVE REQUIREMENTS** | | | | | | |
| 1. | Cover letter | ☐ | ☐ | ☐ | | |
| 2. | Brief CV of all Investigators | ☐ | ☐ | ☐ | | |
| 3. | Good Clinical Practice (GCP) training of investigators in last 3 years | ☐ | ☐ | ☐ | | |
| 4. | Approval of Scientific Committee | ☐ | ☐ | ☐ | | |
| 5. | EC clearance of other centers* | ☐ | ☐ | ☐ | | |
| 6. | Agreement between collaborating partners* | ☐ | ☐ | ☐ | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 7. | MTA between collaborating partners* | ☐ | ☐ | ☐ | | |
| 8. | Insurance policy/certificate | ☐ | ☐ | ☐ | | |
| 9. | Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification | ☐ | ☐ | ☐ | | |
| 10. | Copy of contract or agreement signed with the sponsor or donor agency | ☐ | ☐ | ☐ | | |
| 11. | Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol | ☐ | ☐ | ☐ | | |
| **PROPOSAL RELATED** | | | | | | |
| 12. | Copy of the detailed protocol[11] | ☐ | ☐ | ☐ | | |
| 13. | Investigators Brochure (If applicable for drug/biologicals/device trials) | ☐ | ☐ | ☐ | | |
| 14. | Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated) | ☐ | ☐ | ☐ | | |
| 15. | Assent form for minors (12-18 years) (English and Translated) | ☐ | ☐ | ☐ | | |
| 16. | Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated) | ☐ | ☐ | ☐ | | |
| 17. | Advertisement/material to recruit participants (fliers, posters etc) | ☐ | ☐ | ☐ | | |

| **PERMISSION FROM GOVERNING AUTHORITIES** | | | | | | |
|---|---|---|---|---|---|---|
| | **Other Registration/ permissions** | **Required** | **Not required** | **Received** | **Applied dd/mm/yy** | **EC Remarks** |
| 18. | CTRI | ☐ | ☐ | ☐ | Enter date | |
| 19. | DCGI | ☐ | ☐ | ☐ | Enter date | |
| 20. | HMSC | ☐ | ☐ | ☐ | Enter date | |
| 21. | NAC-SCRT | ☐ | ☐ | ☐ | Enter date | |
| 22. | ICSCR | ☐ | ☐ | ☐ | Enter date | |
| 23. | RCGM | ☐ | ☐ | ☐ | Enter date | |
| 24. | GEAC | ☐ | ☐ | ☐ | Enter date | |
| 25. | BARC | ☐ | ☐ | ☐ | Enter date | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 26. | Tribal Board | ☐ | ☐ | ☐ | Enter date | |
| 27. | Others (Specify) | ☐ | ☐ | ☐ | Enter date | |

| **ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY** | | | | | | |
|---|---|---|---|---|---|---|
| | **Item** | **YES** | **NO** | **NA** | **Enclosure no.** | **EC remarks** |
| 28. | | ☐ | ☐ | ☐ | | |
| 29. | | ☐ | ☐ | ☐ | | |

*[10]These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements Acknowledgement for Receipt of Application (Copy to be provided to PI)*

***For multicentric research. MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India;HMSC-Health Ministry's Screening Committee;NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy;IC-SCR-Institutional committee for Stem Cell Research;RCGM- Review Committee on Genetic Manipulation;GEAC- Genetic Engineering Approval Committee;BARC- Bhabha Atomic Research Centre*

*[11]Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 page no. 35Box 4.4(b)*

# 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*

**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 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.