COMMON FORMS for Ethical Committee Review

Logo of the Institute

Application Form for Initial Review

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

……

(Name of the Institution) **EC Ref. No.** *(For office use):*

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization: KRISHNADEVARAYA COLLEGE OF DENTAL SCIENCES AND HOSPITAL

(b) Name of Ethics Committee: KRISHNADEVARAYA COLLEGE OF DENTAL SCIENCES AND HOSPITAL – ETHICAL COMMITTEE [KCDSH - EC]

(c) Name of Principal Investigator: ……

(d) Department/Division: ……**(e) Date of submission:** dd mm yy

(f) Type of review requested[1] **:**

i). Exemption from review ☐ **ii) Expedited review ☐** **iii) Full committee review ☐**

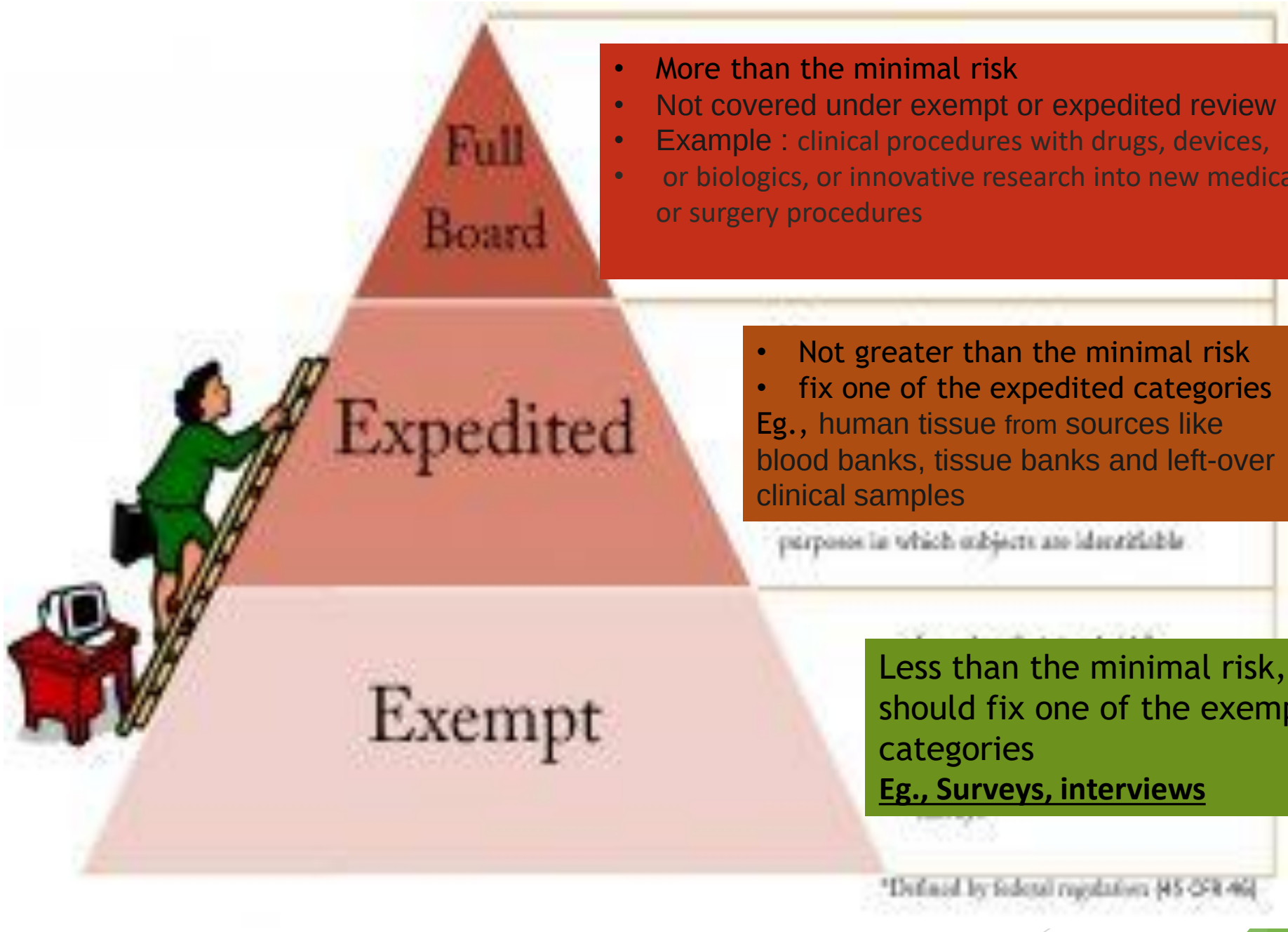
(g) Title of the study: ……

……

……

Acronym/ Short title, (If any): ……

:



- More than the minimal risk
- Not covered under exempt or expedited review
- Example : clinical procedures with drugs, devices,
- or biologics, or innovative research into new medical or surgery procedures

- Not greater than the minimal risk
- fix one of the expedited categories

Eg., human tissue from sources like blood banks, tissue banks and left-over clinical samples

Less than the minimal risk, should fix one of the exempt categories

Eg., Surveys, interviews

i) EXEMPTION FROM REVIEW

- Proposals with less than minimal risk where there are no linked identifiers, for example;

1. **Education research**- Testing or comparing a curriculum or lesson
2. **Surveys, interviews, educational tests, public observations (that do not involve children)**

   Example ; Surveying teachers, nurses, or doctors about a technique or an outcome

3. **Benign behavioral interventions**- through verbal, written responses, (including data entry or audiovisual recording) from adult subjects who prospectively agrees Eg., Performing cognitive tasks
4. **Federal research/demonstration projects** - to study, public benefit or service programs.
5. **Taste and food evaluation studies** Taste and food quality evaluation and consumer acceptance studies

(Annexure 2)

Logo of the Institute

Application Form for Exemption from Review

.....

(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[*]?

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[**] ☐

vii. Any other (please specify in 100 words): .....

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[*]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.

[**]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)

Version 2.0

EXPEDITED REVIEW

- Proposals that pose no more than minimal risk to the research participants may subject to this review
- Example;
  - Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;
  - Research involving clinical documentation materials that are non-identifiable (data, documents, records);
  - Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);
  - Minor deviations from originally approved research causing no risk or minimal risk.
  - Continuing review of research previously approved - Progression/ Annual Reports.

EXPEDITED REVIEW

- Prospective collection of biological specimens for research purposes by noninvasive means
  - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  - permanent teeth if routine patient care indicates a need for extraction;
- For multi-centre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.

(Annexure 1)

Logo of the Institute

Application Form for Expedited Review

..... *(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[#] ?
   - i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
   - ii. Involves 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 proposal previously approved through expedited review, full review or continuing review of approved proposal. ☐
   - v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
   - vi. Progress/annual report 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 modifications 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 persons[$] ? Yes ☐ No ☐

   If Yes give details: .....

   .....

   .....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[#] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*

[$] *For details, refer to application for initial review; Section-C, 5(b)*

* *In case this is first submission, leave it blank*

Version 2.0

Examples of Full Board Research

- All research proposals **involving MORE than minimal risk procedures**
- **EXAMPLES :**
  - Clinical procedures with drugs, devices, or biologics, or innovative research into new medical or surgery procedures.
- Disclosure of information that could require mandatory legal reporting (e.g., child/elder abuse, etc.)
- Studies involving deception of participants .
- Projects that involve vulnerable population (*Children, prisoner, pregnant women and neonates, per federal regulation)*

(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			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission

ii) Co-Investigator at time of submission:

…….. ……..

(k) Duration of the study: ……..

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

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

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: .....

At site..... In India..... Globally .....

(b) Self-funding ☐ Institutional funding ☐ Funding agency *(Specify)* ☐

.....

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words): .....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

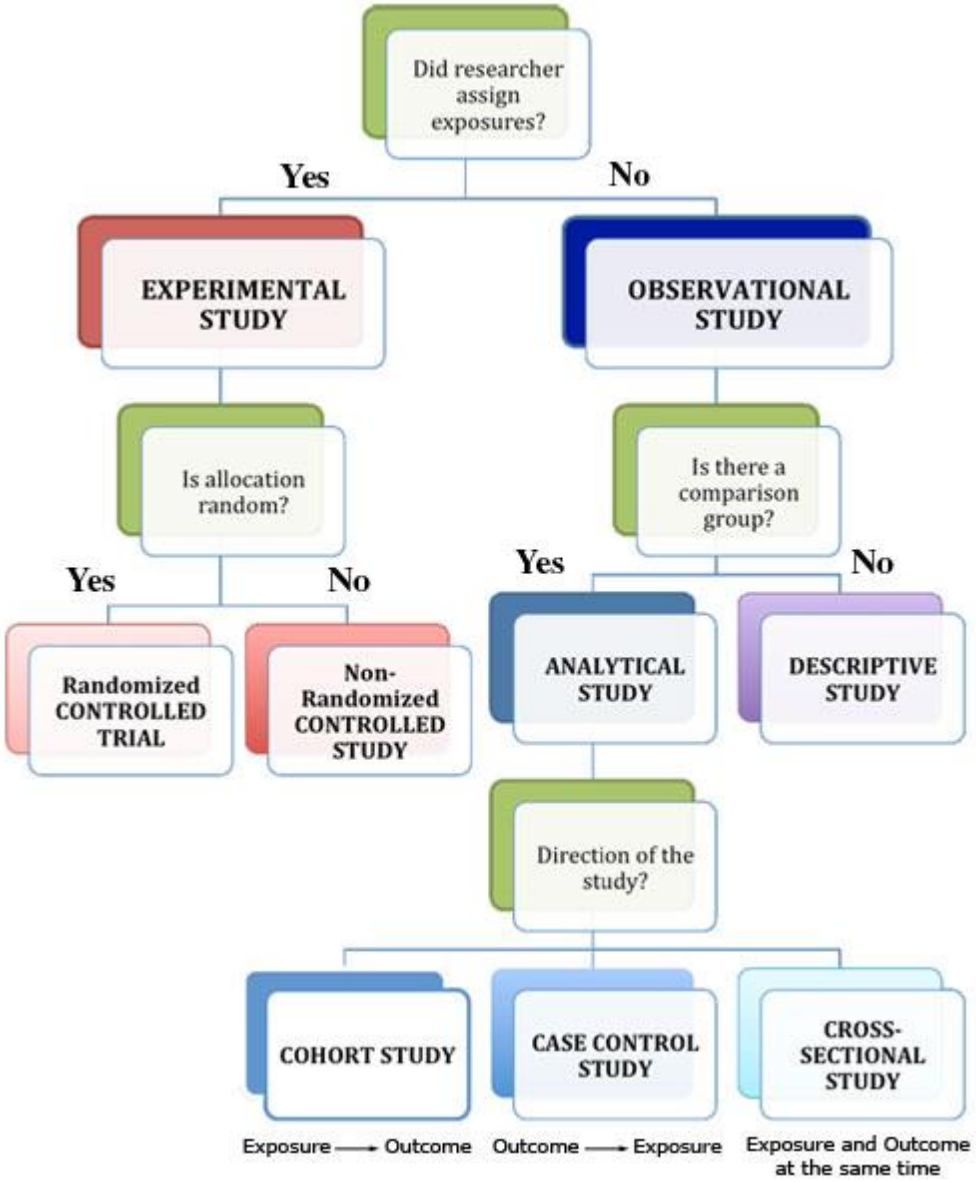
.....

(b) Type of study:

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

.....

Types of researches



TYPES OF RESEARCH STUDIES

- **Basic research**, also called **pure research** or **fundamental research**,
  - Its is a type of scientific research with the aim of improving scientific theories for better understanding and prediction of natural or other phenomenon.
- **Clinical trials** are
  - Research **studies** performed in people that are aimed at evaluating a **medical**, surgical, or behavioral intervention.
  - They are the primary way that researchers find out if a new treatment, like a new drug or diet or **medical** device (for example, a pacemaker) is safe and effective in people.
- **Epidemiological studies**
  - To measure the risk of illness or death in an exposed population compared to that risk in an identical, unexposed population (for example, a population the same age, sex, race and social status as the exposed population).

TYPES OF RESEARCH STUDIES

- **Social-behavioral**
  - A research applies the **behavioral** and **social sciences** to the study of humans.
  - Such research is commonly conducted in the following academic disciplines: education, sociology, psychology, anthropology, economics, political **science**, and history
  - Eg., Raising awareness of the health risks associated with smoking.
- **A systematic review** is defined as
  - "A review of the evidence on a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant primary research, and to extract and analyze data from the studies that are included in the review."
  - The methods used must be reproducible and transparent**.**
  - Example ; Evidence of past dental visits and incidence of head and neck cancers

TYPES OF RESEARCH STUDIES

- A **cross-sectional study**
  - Type of observational **research** that analyzes data of variables collected at one given point in time across a sample population or a pre-defined subset.
  - This **study** type is also known as **cross-sectional** analysis, transverse **study**, or prevalence **study.**
  - **cross sectional** is prevalence **study** and useful to look at single point of time
  - Example ; Prevalence of dental caries among 12 to 15 year old overweigh school children
- **Case control study** are used to **study** 2 groups **cases**(diseased) and **controls** (non-diseased) and to identify the risk factors **between** them . it looks back from the time of exposure and the occurrence of disease,
  - A **case-control study** is designed to help determine if an exposure is associated with an outcome (i.e., disease or condition of interest).
  - In theory, the **case-control study** can be described simply. First, identify the **cases** (a group known to have the outcome) and the **controls** (a group known to be free of the outcome).
  - Example ; Influence of feeding practices on dental caries. (outcome to exposure)
    - The impact of oral health problems on the quality of life of the families of preschoolers

- **Cohort studies** are a type of longitudinal **study**
  - An approach that follows **research** participants over a period of time (often many years).
  - Specifically, **cohort studies** recruit and follow participants who share a common characteristic, such as a particular occupation or demographic similarity.
  - Example; 'The influence of orthodontic treatment on dental caries : an Australian cohort study'. (Exposure to outcome)

- A **prospective study** (sometimes called a **prospective** cohort **study**)
  - is a type of cohort **study**, or group **study**, where participants are enrolled into the **study** before they develop the disease or outcome in question.
  - Example : 'Risk factors for tooth loss in adults.- a population based prospective cohort study'.

- A **retrospective study**
  - is an observational **study** that enrolls participants who already have a disease or condition. In other words, all cases have already happened before the **study** begins
  - Example- 'A retrospective analysis of the prevalence of dental diseases in patients with digestive system cancers'.

- **Qualitative research**
  - Involves collecting and analyzing non-numerical data (e.g., observations, interviews and surveys) to understand concepts, opinions, or experiences. It can be used to gather in-depth insights into a problem or generate new ideas for **research**.
  - Example : Patient's satisfaction with dental care: a qualitative study to develop a satisfaction instrument.

- **Quantitative research**
  - Is the process of collecting and analyzing numerical data. It can be used to find patterns and averages, make predictions, test causal relationships, and generalize results to wider populations.
  - Example : The emerging dental work force: why dentistry? A quantitative study of the final year dental students view on their professional career

➢ The term "**mixed methods**" refers to an emergent **methodology** of **research** that advances the systematic integration, or "mixing," of quantitative and qualitative data within a single investigation or sustained program of inquiry. ... Collecting and analyzing both quantitative (closed-ended) and qualitative (open-ended) data.

4.METHODOLOGY

(a)Sample size/ number of participants *(as applicable)*

At site……………………………………………… In India……………………………………………. Globally …………………………………………………… Control group…………………………………………………………………………Study group …………………………………………………………… Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation

……

……

……

……

……

[3] *Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*

(b)Is there an external laboratory/outsourcing involved for investigations?[4]

Yes ☐ No ☐ NA ☐

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

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

Date of review:

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 volunteers ☐ Patients ☐ Vulnerable persons/ 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)* .....

(b) i. Will there be vulnerable persons / special groups involved ? Yes ☐ No ☐ NA ☐

ii. If yes, type of vulnerable persons / 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 .....

.....

.....

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

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

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(d) Are there any incentives to the participants? 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[5] :

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[6] ? Yes ☐ No ☐ NA ☐

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

If Yes, Specify .....

- **Less than minimal risk**
  - Probability of harm or discomfort anticipated in the research is nil or not expected.
  - For example, research on anonymous or non- identified data/samples, data available in the public domain, meta-analysis, etc.,

- **Minimal risk**
  - Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely.
  - Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.

Minor increase over minimal risk or Low risk

- This category of risk refers to activities that would be more harmful than what would be encountered in daily life but may or may not cause temporary financial, emotional social or physical harm.
- Example :
  - Routine research on children and adolescents.
  - Research on persons incapable of giving consent.
  - Delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials;
  - use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing;
  - trying a new diagnostic technique in pregnant and breastfeeding women, etc.

More than minimal risk or High risk

- Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk.
- Examples:
  - Research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures

High Risk

4. High risk are those research activities that cause pronounced distress during the research activity or negative outcomes that impair or persist for more than a few days.

Examples Include:

- Depressive symptoms
- Major alteration of relationship dynamics
- Severe or long-term harm to social reputation (release of information leads to loss of insurance, social stigma, or criminal charges.)
- Permanent physical disability
- Severe pain or death

7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 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 (AV) 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 requirements 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)	☐				

.....

Participant Information Sheet

PIS(For Study Participants/Parents of children who would participate in the study)

Title of Project: _____. PIS IDENTIFIER NO :

Principal Investigator:

Name : Designation:

Contact details: Tel No : _____ Email Id :

You are invited to take part in this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the Participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet and discuss it with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this Participant Information Sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the Participant Information Sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

Krishnadevaraya College of Dental Sciences and Hospital Ethics Committee (KCDSH - EC) / Institutional Review Board (KCDSH -IRB) for Clinical / Non Clinical / Research Studies.
Email - ethicalcommittee@kcdsh.org; Tel - 080 28467083, Website - kcdsh.org

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is this research study about? _____
2. Who is the sponsorer for this study? _____
3. What information is known about this type of research study? _____
4. Why is this research study being done? _____
5. How will the research study be done? _____
6. What do you have to do if you agree to take part in the research study? _____

_____

9. What are the possible benefits to you by being in the research study? _____

_____

10. What are the possible risks and inconveniences that you may face by being in the research study?

_____

11. What are the tests that will be performed on the participant/ biological sample? _____

_____

12. How long will you be in the research study? _____

13. How long the biological samples will be stored and how will it be disposed? _____

_____

14. Under what conditions will your Participation in the study be terminated? _____

_____

15. What will happen if you change your mind about participation in this research study?

_____

17. How will your privacy and confidentiality be main-

tained? _____

18. Will you have to bear any Expenses or Costs by participating in the research study? _

_____

19. Whom do you call if you have questions or problems? _____

a. Research related : _____

b. Regarding rights as a Participant : _____

Ask a question about the study procedures or treatments :

Dr. .....

Department.....

Phone : _____ . , time to contact : anytime/ 9.00am to 5.00 pm

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form)

Dr. Joann Pauline George
Member- Secretary,
Tel.No.: 9448541637 Email : ethicalcommittee@kcdsh.org
Time to contact- 9.00am to 5.00 pm

The Krishnadevaraya College of Dental Sciences and Hospital Ethics Committee for (KCDSHEC) Research comprises of a group of people like doctors, researchers, and community people (non scientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute . Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.
If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records

Informed Consent Form

I.....have read /have had read the participant information sheet version no. .....dated.....bearing page numbers 1-.... of the research study entitled .....

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand. I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

Name of the Study Participant OR Signature/Thumb impression of Study Participant with date

Name of the Principal Investigator/collaborator

(Witness of the consent procedure if the participants is illiterate)

I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions.

Name of the Witness Signature of Impartial witness with date

Name of the Person administering the Consent with date

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 ☐ N/A ☐

If yes, then who will provide the treatment? .....

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

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ 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 ☐ N/A ☐

.....

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify.

Yes ☐ No ☐ N/A ☐

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 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 the application, which is not included elsewhere in the form? If yes, provide 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.
☐	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.
☐	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 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 confidentiality of 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-I): 1. .... 2. ....
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: .....

Signature: ..... dd mm yy

Name of Co-PI: .....

Signature: ..... dd mm yy

Name of Guide: .....

Signature: ..... dd mm yy

Name of HOD: .....

Signature: ..... dd mm yy

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 Participant 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 permissions	Required	Not required	Received	Applied dd/ mm/yy	EC Remarks
18	CTRI	☐	☐	☐		
19	DCGI	☐	☐	☐		
20	HMSC	☐	☐	☐		
21	NAC-SCRT	☐	☐	☐		
22	ICSCR	☐	☐	☐		
23	RCGM	☐	☐	☐		
24	GEAC	☐	☐	☐		
25	BARC	☐	☐	☐		
26	Tribal Board	☐	☐	☐		
27	Others (Specify)	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks
28		☐	☐	☐		
29		☐	☐	☐		

**For multicentre 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

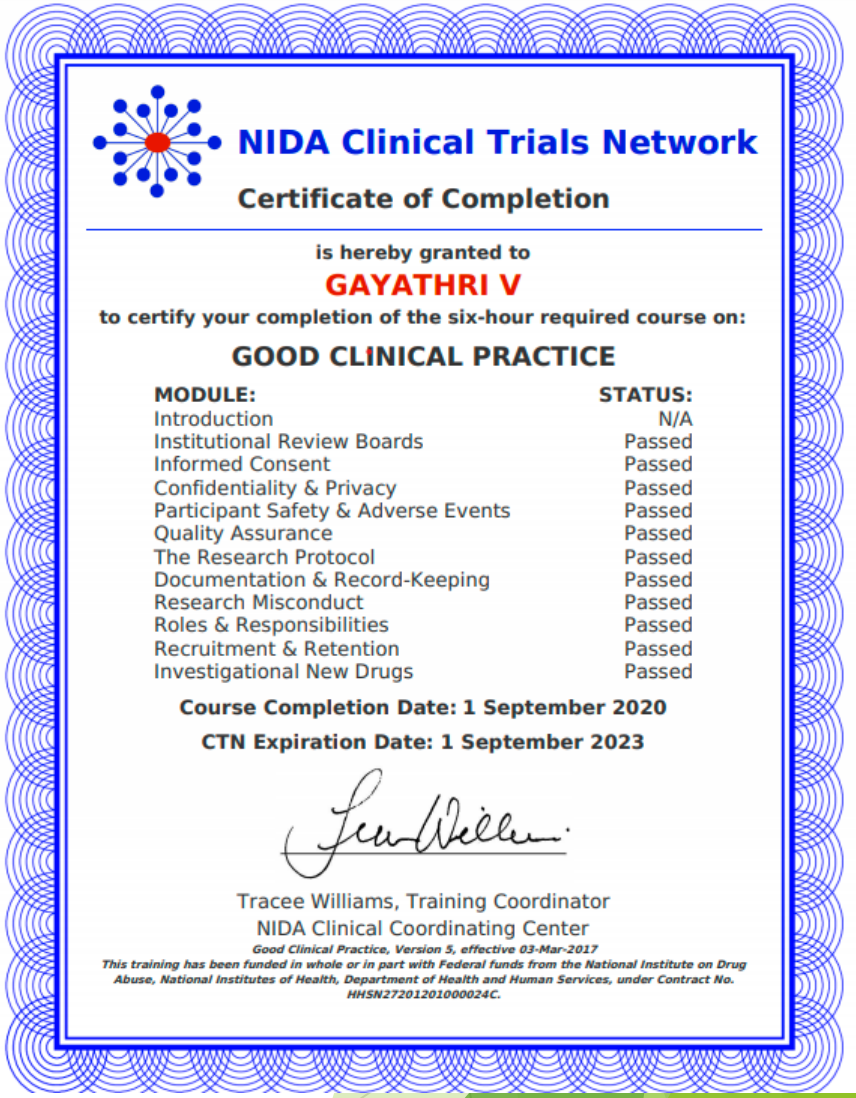
[11] Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)

To get certificate in ICH- GCP

- The International Council For Harmonization Of Technical Requirements For Registration Of Pharmaceuticals For Human Use (ICH) – GOOD CLINICAL PRACTICE (GCP)
  - FREE COURSE
    - https://gcp.nidatraining.org/
    - Go to this link and register your name and start your course
    - www.biopharmainstitute.com – ONLINE TRAINING COURSE
  - PAID COURSES for certificate in GCP

    Igmpiindia.org – IGMPI

    www.jli.edu.in



NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

GAYATHRI V

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICE

MODULE:	STATUS:
Introduction	N/A
Institutional Review Boards	Passed
Informed Consent	Passed
Confidentiality & Privacy	Passed
Participant Safety & Adverse Events	Passed
Quality Assurance	Passed
The Research Protocol	Passed
Documentation & Record-Keeping	Passed
Research Misconduct	Passed
Roles & Responsibilities	Passed
Recruitment & Retention	Passed
Investigational New Drugs	Passed

Course Completion Date: 1 September 2020

CTN Expiration Date: 1 September 2023

Tracee Williams, Training Coordinator
NIDA Clinical Coordinating Center

Good Clinical Practice, Version 5, effective 03-Mar-2017

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN27201201000024C.

Project Submission / Research Protocol Overview

Title	
Names of all Investigators (underline principle investigator)	
Introduction / background • Give the background, including human or animal research relevant to the design of the proposed study. • When new techniques or procedure are to be used, provide a description of preliminary work. • When an investigation drug is to be used, animal data and phase I or II data on the drug should be included. • A summary of how the study may help in the future should be included in the protocol.	
Aims / Objectives • Clearly state the aims or objectives of the study. • Whenever possible this should be in the form of a hypothesis.	
Design of the Study	
Phase-I, Phase-II, Phase-III, Phase-IV, NA	
Randomized [Double or single blind], Open [ ]	
If multicentric, is KCDSH the co-coordinating centre?	
Epidemiological [ ] Survey [ ] Observational [ ]	
Case control [ ], Any other (Specify)	

Study methodology	
• Explain, in sequence, the conduct of study and all data collection procedures. • Describe the involvement of human subjects including initial evaluation procedures and screening tests, phases, medical/surgical procedures and sequence of the study. • Separate standard and experimental aspects of the study as much as possible. • Give brief account of procedures for treatment, dose adjustments, etc. • Describe the randomization procedure, if applicable. • Specify if procedure involves banking of biological samples. • Define stop points and criteria for withdrawing subjects from the study.	
Eligibility (Explain inclusion and exclusion criteria; To be stated clearly in the summary) (specific explanation if participants will include Minor, Pregnant woman, Neonate, Person incompetent to give informed consent, Normal/ Healthy volunteer, Student, Staff of the institute).	
How many subjects will be screened? How many subjects are likely to be enrolled?	
Describe benefits to the subject/participant in this study. Also describe the benefits, if any, to the society.	

Power estimates Describe power calculations, if the study involves statistical comparisons between two or more groups. Mention evidence to support that adequate number of subjects can be enrolled during the study period by the investigators.	
Variables / Outcomes to be estimated Enumerate the variables, outcomes and end points that will be measured. Try to separate variables as response and explanatory variables. Describe the type and frequency of tests, admissions, outpatient visits, etc used to obtain these variables or variables.	
Statistical Analysis of the variables / data Describe how the variables obtained during the study will be statistically analyzed. e.g. Univariate comparison or Cox- proportional hazards model, etc	
Describe all possible risks and discomfort for subjects due to use of intervention and / or data collection methods proposed. Describe expected degree and frequency of such risks, discomfort, side effects of drug etc.	
If the procedures in the trial are invasive or potentially harmful, describe what arrangements have been made for treatment of the complications arising from the trial?	

Does your study involve testing of drug/s, device/s and/or biologics?	Yes. [ ]	No [ ]
Are they already approved by the regulatory authorities and available in the market or are they new ones?	Already approved [ ] New one [ ]	
Who has prepared and /or is manufacturing the drug/s, device/s and biologics under investigation?		
Who holds the patent or IND/IDE of the drug/s, device/s and biologics under investigation?		
What are the reasonable possibilities of the availability after the study of the investigational drug(s), device(s) and biologics for the study participants/subjects if it is found to be effective?		
Does your study require permission from regulatory authorities?	Yes [ ]	No [ ]
If yes,		
(i) from DCGI	Yes [ ]	No [ ]
(ii) from the ICMR	Yes [ ]	No [ ]
(iii) From other govt. departments	Yes [ ]	No [ ]
If yes, specify the department Whether permission is obtained	Yes [ ]	No [ ]
Does your study require you to send human biological material outside India?	Yes [ ]	No [ ]
If yes, have you obtained permission of the Principal, KCDSH?	Yes [ ]	No [ ]

Has KCSDH and the foreign party signed agreement/MOU for that? If yes, attach a copy of agreement/MOU	Yes [ ] No [ ]
If study will be conducted fully or partially outside the KCDSH, please describe the need for permission from institution(s), health centre(s), local government/administrative bodies, etc.	
Describe how you define adverse events in your study, how and to whom you propose to report them, and what rules you will use for stopping the study due to adverse events.	
In what way will you ensure the confidentiality and privacy of the subjects?	
If some procedures in this trial are emotionally upsetting describe what arrangements have been made for psychological counseling?	
Describe (i) How, where, when and by whom the Informed Consent will be obtained. (ii) how much time the subject/ participant will be given to consider participation and decide, (iii) describe additional plans/needs for informed consent in case the study involves special population such as minors, pregnant mothers, neonates, etc. (iv) Describe how you will assess that information is correctly understood by the participant.	

Who will be maintaining the trial records and where?	
For how long will the data be stored? Give details of where they will be stored, who will access	
Describe briefly, if any, the financial and other interests of any of the investigators and /or close relative/s, with the sponsor/s and outcome of the study.	
Have you made provision for insuring yourself, and against any legal action that may arise out of this project?	
Have you made provision for insuring trial subjects for any accidental unforeseen trial related injury?	
How is it intended the results of the study will be reported and disseminated?	- Peer reviewed scientific journals - Other publication - Conference presentation - Internal report - Submission to regulatory authorities - Access to raw data and right to publish freely by all the investigators in study or by independent steering committee on behalf of all investigators - Other ……

List of Common forms to be submitted to ethical committee

1. Application for initial review
2. Participant information sheet (PIS)
3. Informed concern form (ICF)
4. Project submission / synopsis in a given template
5. Principal investigator's current CV
5. PowerPoint presentation about their project proposal

Available in kcdsh website

All these to be submitted only as a soft copy

- ethicalcommitee@kcdsh.org
- gayathri.physiology@kcdsh.org

THANK YOU