PART I:(GENERAL AND FINNCIAL INFORMATION)

1. **Research Title:**

2. **Detail of Principal Investigator responsible for the proposed research:**

   Nationality:

   Email: contact no:

   Signature: Date:

   Institution associated with the principal Investigator

   Designation:

3. **Detail of Co-Principal Investigator /supervisor responsible for the proposed research:**

   Nationality:

   Email: contact no:

   Signature: Date:

   Institution associated

   Designation:

4. **Is this research part of your Thesis?**

   Yes ☐ No ☐

   If yes: please mention the name of institute address, name of degree duration of degree

   (Need to furnish the covering letter from the institute)

5. **Name of the staff of the institute involved in study**

6. Financial Information

5.1 Name and address of the funding organization:

5.2 Contact person of funding agency (name, designation, address, email and contact no.)

5.3 Total amount of funds (in NRs / US $) allocated for the proposed research project:

5.4 Itemized budget (in detail) and justify the resources required for the proposed research work (*use additional sheet*)

(***PLEASE ATTACH THE LETTER OF FUNDING,IF SELF FUNDED PROVIDE SELF DECLATION ON SELF FUNDING***)

PART II: PROPOSAL (SUMMARY AND DETAILED)

PART A: PROPOSAL SUNNARY

1. Full Title of Study:	
2. Name of Investigators / co-investigators with designation and departments 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 2.5_____ 2.6 Email ID of the Principal Investigator	Signatures 2.1_____ 2.2 _____ 2.3 _____ 2.4 _____ 2.5_____
3. Type of the study	☐ Qualitative☐Quantitative ☐ Mixed
3. Objectives of the study	Primary objective _____ Secondary objectives _____ _____ _____ _____
4. Justification for conduct of this study	
5. Methodology	_____

	5.1 Study design _____ 5.2 Duration _____ 5.3. Inclusion criteria a)_____ b)_____ c)_____ d)_____ 5.4. Exclusion criteria a)_____ b)_____ c)_____ d)_____ 5.5. Number of Patients(mention on sample size derivation) 5.6 Permission to use copyrighted Questionnaire/Performa 5.7 Others (if applicable) Control: Dose of drug:
6. Permission from Drug Development agency	1.Required 2.Not Required 3. ☐ Received 4. ☐ Applied when:
8. a) Safety measures for proposed interventions b) Results of relevant laboratory tests	a)_____ b)_____

c) Result of studies in human	c)_____
9. Plans to withdraw standard therapy during conduct of research	☐ Yes ☐ No Remarks:_____
10. Plan for provision of coverage for medical risk (s) during the study period	
11. How you will maintain confidentiality of subject?	
12. **Total Budget (Approx. in Rs.)** Who will bear the cost of investigation/ implants drugs / contrasts?	12.1_____ 1. Patient ☐ 2.Project ☐ 3. Exempted ☐ 4.Other Agencies (Name)☐
13. Participant Information Sheet **(mark √ if yes)**	English ☐ Nepali ☐
14.Participant Informed Consent Form **(mark √ if yes)**	English ☐ Nepali ☐
15. Conflict of interest for any other investigator(s) (if yes, please explain in brief	1. _____ ☐ Yes ☐ No 2. _____ ☐ Yes ☐ No 3. _____ ☐ Yes ☐ No 4. _____ ☐ Yes ☐ No
16. Whether any work on this project has started or not?	☐ **(mark √ if yes, X if no)** (Please enclose a separate certificate to this effect).
17.Attached documents(If any)	17.1 Covering letter and forwarding letter from department in case of projects involving institutional degree 17.2 Copy of the detailed protocol 17.3 Brief CV of Investigators 17.4 Definite undertaking as to who will bear the expenditure of injury related to the project 17.5 In case an insurance cover is intended, Insurance certificate must be provided (as per NHRC guidelines) 17.6 Investigator should provide dated

	17.7 Permission on use of copy righted questionnaire 17.8 Investigator should mention on SOP on sample processing and declaration on the unavailability of lab test in the country from appropriate body 17.9 Undertaking what they will do with the left over sample tissue 17.10 Declaration on termination of trial(based on interim analysis) 17.11 Declaration on conduction of research as per NHRC guidelines
18. In case of clinical trial Trial Registry number	

PART B: DETAILED PROTOCOL (can upload the proved protocol from institute/other ethical body)(should include information mentioned below)

1. **Introduction**: Please mention on back ground, statement of problem and rationale /justification

2. **Review of the literature**: please discuss about the literatures that discuss the topic being discussed and being looked for. Kindly provide in a tabulated form(summary of studies)
3. **Gaps in knowledge** :
4. **Rationale of the study**
5. **Research question**
6. **Research question and hypothesis:** Mention in the **PICO FORMAT**
7. **Objectives**: Primary and secondary

Objective	Outcome	Measurement
Primary		
Secondary		
1.		
2.		
3.		

8. **Methodology**((should include type of study, study population inclusion and exclusion criteria, ,sampling method, sample size with calculation, data collection technique, detail on data collection tool, mention the validity and reliability of tool if any, plan for supervision and Monitoring: plan for data management and analysis expected Outcome of the Research, plan for Dissemination of Research Results)

Study design:

Study period

Place of the study

Study population

Inclusion criteria

Exclusion criteria

Informed consent

Ethical issue

Safety of intervention (if any)

Trail registration (if any)

Sample size: calculation of sample size. Please give reference to the study based on which sample size is calculated

Patient enrollment details

Details of the enrollment process

Please mention the proposed study flow

Details on statistical analysis

9. References

10. Work Plan ***(should include duration of study, tentative date of starting the project and work schedule / Gantt chart):***

11. Ethical Consideration

1. Are human participants required in this research?

2. Clearly indicate the participant's responsibilities in the research. What is expected of the research participants during the research?

3. Are vulnerable members of the population required for this research? If yes, provide justification.

4. Are there any risks involved for the participants? If yes, identify clearly what are the expected risks for the human participants in the research and provide a justification for these risks.

5. Are there any benefits involved for the participants? If yes, identify clearly what are the expected benefits for the participants.

ACCEPTANCE OF GENERAL CONDITIONS AND DECLARATION

BY THE PRINCIPAL INVESTIGATOR

I hereby certify that the above mentioned statements are true, I have read and understood the regulation of the IRC Kanti children's Hospital on the approval of research proposal and will act in conformity with the said regulation in all respects.

If the research is terminated, for any reason, I will notify IRC of this decision and provide the reasons for such actions. I will provide IRC kanti Hospital with a written notice upon the completion of the research as well as a final summary/full report of the research study. If I publish the results in a journal, I shall acknowledge the IRC and shall provide the Council with three copies of any such articles.

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Signature of Applicant **Date:** ……

Documents to be uploaded

1. Covering letter and forwarding letter from department in case of projects involving institutional degree
2. Non plagiarism declaration
3. PIS(English and Nepali)
4. PICF(English and Nepali)/Assent if applicable
5. Self declaration on true translation
6. Declaration on financial support
7. Case record form(mention on format if any audio visual)
8. SOP for processing of audio-visual data taken if any after the study is over
9. Definite undertaking as to who will bear the expenditure of injury related to the project
10. Declaration of SOP on sample processing and declaration on the unavailability of lab test in the country from appropriate body
11. Undertaking what they will do with the leftover sample tissue
12. Permission to use copyrighted questionnaire(if any)
13. Brief CV of Investigators
14. Non commencement declaration
15. Declaration on confidentiality guidelines on qualitative discussion
16. Covering letter from director(external study) on permission to use institute for sample collection
17. Data safety monitoring board for RCTS