(complete address of the hospital with logo)(*Department*)

PATIENT INFORMATION SHEET (*Template with instructions*)

a. You are being invited to participate in a research study.

b. Before you take part in this research study, the study is being explained to you and you are given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form. You will be given a copy of this document to take home with you.

(*Language in the Patient Information Form to be at par with the reading level of an 8th to 10th Grade school student. Long technical terms should be avoided or explained in detail. Every effort to ensure the language is clear and simple should be made*).

2. STUDY INFORMATION

a. Protocol Title:

b. Principal Investigator(s):

(*Insert the identity of other health professionals involved in the study or the funding organisation associated with the research. Delete this section if this is an investigator initiated study without specific funding.*)

3. PURPOSE OF THE RESEARCH STUDY

a. You are being invited to participate in a research study of (*state what is being studied*). We hope to learn (*state what the study is designed to discover or establish*). You were selected as a possible subject in this study because (*explain why patient is being selected*). This study will recruit (*insert number of subjects*) subjects from (*state whether from the Principal Investigator's institution, or multiple institutions*) over a period of (*state recruitment and/or study period*). About (*state number of subjects recruited in this or previous related studies*) subjects will be involved in this study.

b. Any samples of tissues, blood and/or body fluids obtained during the course of this study will be stored and analyzed only for the purposes of this study for a period not exceeding (*Insert intended duration of storage*), and will be destroyed after completion of the study, unless you have signed a consent form to donate the samples to (*insert name of repository*).When your participation in the study ends,

you will no longer have access to (*the study medication/device*), unless special additional arrangements are made by the Principal Investigator.

4. STUDY PROCEDURES AND VISIT SCHEDULE

   a. If you agree to take part in this study, you will be randomised to receive (*expand with details of study as necessary*). Randomisation means assigning you to one of (*insert number of study groups*) groups. (*Delete para if there is no randomization*). If you agree to take part in this study, you will be asked to (*insert brief explanation of study procedures here*). Your participation in the study will last for (*insert length of time subject will be required for the study*). You will (*take the study medication / use the study device)* for about (*insert number of times study intervention will be performed*) and be followed up for (*state length of time of follow-up within the study*). You will need to visit the doctor's office (*state number of times*) times in the course of the study.

   b. Schedule of visits and procedures:

      i. Visit 1:

      ii. Visit 2, 3 (Weeks____,____) etc.

      iii. Final Visit (Week____)

      iv. Follow-up: The follow-up part consists of (state number of contacts)

5. Additional Study Procedures

   (*Insert additional procedures that must be performed.*)

6. Additional Blood Tests

   (*State how many blood specimens are required and the amount in teaspoons as part of this study.*)

7. YOUR RESPONSIBILITIES IN THIS STUDY

   a. If you agree to participate in this study, you should (*choose applicable points*):

      i. Take the study drug as instructed and follow the advice given to you by the study team. (*if device, explain what is required for study compliance*).

      ii. Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.

      iii. Inform the Principal Investigator as soon as possible about any side effects that you may have encountered.

      iv. Be prepared to visit the hospital (*insert number of visits*) and undergo all the procedures that are outlined above.

8. WITHDRAWAL FROM STUDY

a. You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator. If you withdraw from the study, or the study medication is stopped for any reason, Or your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons: (*Add anticipated consequences, if any, of discontinuing the study drug or device and Clearly state the protocol-specific termination procedures):*

i. Failure to follow the instructions of the Principal Investigator and/or study staff.
ii. The Principal Investigator decides that continuing your participation could be harmful.
iii. Pregnancy (if applicable.)
iv. You need treatment not allowed in the study.
v. The study is cancelled.
vi. Other administrative reasons.
vii. Unanticipated circumstances,

Your treatment will not be affected and will continue as per standard of care. You may have to return all study-related supplies, including unused study drug

9. WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

a. The study is being conducted because (*the intervention or device*) is not yet proven to be a standard (*investigation, treatment*) in subjects with (*condition under investigation in this study*). We hope that your participation will help us to determine whether (*investigation or treatment*) is equal or superior to existing (*investigation or treatment*). Use of a placebo (inactive agent), blinding (one or more parties unaware of the treatment assignment), and randomization (study drug selection by chance) are only done for research studies. (*Modify as relevant for your study*). Although (Investigation or Treatment) may be part of standard medical care, in this study this / these procedure(s) are being performed for the purposes of the research.

10. POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

a. There are risks, discomforts and inconveniences associated with any research study.

- (*Describe the discomforts and inconveniences reasonably expected.*
- *Describe the expected adverse outcomes. If there is a washout period, describe the risks of discontinuing medications.*

- *Describe any reasonably foreseeable risks. Note that if this is a placebo-controlled study, there may exist the risk that the disease/condition may go untreated and the subject's condition may worsen.*
- *Include a statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.*
- *This section should also describe the risks associated with other medications used in the study, other procedures done (i.e., venipuncture, concomitant medications, exposure to radiation, etc.).*

11. POTENTIAL BENEFITS

a. If you participate in this trial you may reasonably expect to benefit from the trial (investigation / intervention / drug) in the following way: (*explain how subject might benefit*)

OR

b. There is no assurance you will benefit from this study. However, your participation may contribute to the medical knowledge about the use of this (medication / device / intervention /investigation).

12. ALTERNATIVES (Delete or modify as necessary)

a. If you choose not to take part in this study, the alternative is to have what is considered standard of care for your condition. In our institution this would be (*investigation / treatment / procedure*). This procedure has the following potential benefits (*Insert list of possible benefits of the "standard" alternative*).and the following potential risks (*Insert list of possible risks from the "standard" alternative*)

13. SUBJECT'S RIGHTS

a. Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction. In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you or your legal representative will be informed in a timely manner by the Principal Investigator or his/her representative. You have the right to refuse to allow your tissues to be studied now or saved for future study. By signing and participating in the trial, you do not waive any of your legal rights to revoke your consent and withdraw from the trial at any time.

14. CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

a. Information collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

Only your Investigator(s) will have access to the confidential information being collected. However, the Sponsoring company (Name of company, if relevant). Regulatory Agencies, Institution Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you or your legal representative is authorizing such access to your study and medical records. Data collected and entered into the Case Report Forms are the property of (Institution or Company). In the event of any publication regarding this study, your identity will remain confidential.

15. COSTS OF PARTICIPATION

a. If you take part in this study, the following will be performed at no charge to you: (*Insert list of procedures / drugs/ tests for which the subject will NOT pay*).

16. RESEARCH RELATED INJURY AND COMPENSATION

a) For Clinical Trials sponsored by pharmaceutical companies*: (mention that the investigator shall report all Serious Adverse Events (SAE) to the Central Licensing Authority (CLA), the sponsor or its representative, who has obtained permission from the CLA for conduct of clinical trial and the Ethics Committee, within twenty-four hours of their occurrence. State that* 'If it is established that the new illness/injury is related to the drug/ intervention the sponsor take care of the expenses and give compensation.' Mention that *the quantum of compensation will be calculated as per recommendations given in New Drugs & Clinical Trial Rules, 2019, Chapter VI and for determination of the quantum of compensation in the cases of Clinical Trial related injury or death as per Seventh Schedule of New Drugs and Clinical Trials Rules, 2019).*

b) For non-funded, biomedical research, the Hospital does not make any provisions to compensate trial subjects for research related injury. However, you would be treated for the same at no additional costs at this hospital.

17. WHO TO CONTACT IF YOU HAVE QUESTIONS

a. If you have questions about this research study/ your rights/ in the case of any injuries:
Name of PI
Designation
Address
Phone No.,
e-mail
Name of Chairman/ Member Secretary
Institutional Ethics Committee, CNBC
Ph No
e-mail

CNBC, New Delhi (complete address and logo)

(Department of_____)

ASSENT FORM

1. Title: [Insert Name]
2. Study Investigator: [Insert Name]
3. Why am I here?
4. This is a research study. Only people who choose to take part are included in research studies. You are being asked to take part in this study because [insert reason for selection].
5. This study is being done to find out [insert purpose of study]
6. What will happen to me? [Describe what will take place from the child's point of view in a language that is both appropriate to the child's maturity and age]
7. How long will I be in the study? [describe how long and how often visits will occur].
8. Will the study help me?
9. Select appropriate selection • "You [choose correct verbiage may/will] not benefit from being in this study; however, information from this study may help other people in the future [explain aim(s)]." • "You may benefit from being in this study [describe any direct benefit to the participant]. If there is also an indirect benefit, please add: "Information gained from this study may help other people in the future [explain aim(s)]."
10. Will anything bad happen to me?
11. Describe any risks appropriate for the child's age and maturity
12. What other options are there? [Delete if not an intervention/treatment study.]
13. Do my parents or guardians know about this? (If applicable)
14. This study information has been given to your parents/guardian. You can talk this over with them before you decide.
15. What about confidentiality?
16. Every reasonable effort will be made to keep your records (medical or other) and/or my information confidential; however I do have to let some people look at your study records.
17. Your records will be private unless we are required by law to share any information. The law says we have to tell someone if I might hurt yourself or someone else. The study doctor can use the study results as long as I cannot be identified.

18. What if I have any questions?

19. For questions about the study please call [Insert PI's name] at [insert PI's phone number].

20. Do I have to be in the study?

21. You don't have to be in this study if you don't want to or you can stop being in the study at any time. Please discuss your decision with your parents and researcher. No one will be angry if you decide to stop being in the study.

AGREEMENT TO BE IN THE STUDY

Your signature below means that you have read the above information about the study and have had a chance to ask questions to help you understand what you will do in this study. Your signature also means that you have been told that you can change your mind later and withdraw if you want to. By signing this assent form you are not giving up any of your legal rights. You will be given a copy of this form.

_____ _____

Signature of Participant (12 yrs. & older) Date

_____

Name of Participant (12 yrs & older)

_____ _____ Signature

Signature of Person who explained this form Date

_____

Name of Person who explained form

IEC, CNBC, New Delhi

(complete address and logo)(Department

INFORMED CONSENT FORM

S. No. Date

Patient's Name

Name Parent/Guardian/LAR: Age: Sex:

I have been explained the details of study entitled "....." and my question (s) regarding the study have been answered to my satisfaction in a language understood by me.

1. I understand that I have the right to withdraw from the study at any time and to decline to answer any particular question.
2. I understood that my participation in this study is confidential and that no material that could identify me will be used in the analysis and in any reports based on this study.
3. I consent to *my blood being drawn/ procedure* for the purpose of this study (*whatever is applicable*). I understand that on completion of the study or if I withdraw from the study, *my blood sample (s)* will be destroyed. I also understand that there is any problem with any of the blood tests or measurement taken, I will be informed and the report will be kept confidential.

I hereby provide the consent to take part in the study entitled "....."

Signature/ Thumb Impression of volunteer subject/LAR

Signature of witness/Signature of Guardian Signature of investigator

Name & Address of Witness/Guardian