**Guidelines for the Preparation of the Child Information Sheet (CIS), Assent Form (AF), Parent Information Sheet (PIS), and Parent Informed Consent Form (PICF)**

**FOR RESEARCHERS’ USE ONLY**

While submitting your project to the CNU-ERC, ensure that you have included an ICF that is prepared as per the guidelines for ICMR Ethical Guidelines 2006, ICH-Good Clinical Practice, Declaration of Helsinki and PHREB National Ethical Guidelines.

Note to investigators regarding the process of obtaining informed and understood consent:

1. ICF in English and dialect spoken and understood by research participants who are minors.
2. Font style: Arial Narrow; Size: 12.
3. All the consent forms must have version no., date, page no. in the footer.
4. Use PIS and ICF for participants of legal age. Use AF for mature minors (7-18 years old) and PICF for the parents.
5. The PIS/ CIS describes minimal requirements. Feel free to add other information if you wish to. Be sure to include any elements of informed consent that are appropriate to your study. If they apply to your study, they must be included.
6. The prospective participant should be given a PIS first.
7. The CNU ERC encourages the researchers to assist the minor participants in the readthrough of the CIS. The researchers should then give the minor participants 24 Hrs to decide.
8. Lead researchers are urged by the CNU ERC to use the simple non-technical words or should add the glossary and follow the sample template of CIS, AF, PIS, and PICF.
9. Use of alternative wording or different formats may slow down the review process. The form should be written in second person ("You are invited..."). Use of first person ("I") can be interpreted as suggestive and coercive.
10. The AS must have the name and contact no. of the lead researcher or of any other co- investigator in case of an emergency, or even to seek answers to their queries.
11. A copy of the signed AF must be given to prospective participants. A receipt of a copy of ICF/AS by the subject should be documented by the investigator in the source documents.
12. Please tailor your ICF to suit the needs of the research participants/population.
13. If your form is more than one page, there should be a line at the bottom of each page for the subject’s initials, except for the last page where the signature is obtained.
14. Please make provision on the form of signature/thumb impression if the participant is unable to provide signature/ written consent by virtue of medical reasons/ disability.

**CHILD INFORMATION SHEET (CIS)**

| Study Title: |
| --- |

**Introduction**

We want to tell you about a research study we are doing. A research study is a special way to find out about something. We are trying to find out more about (**purpose of study in simple language).** You are being asked to join the study because **(insert the name of medical condition or other reasons for inclusion).**

You are being invited to be part of this study. The study is about **(insert general statement about the study).** Your parents, **(name of parents or legal guardian, if applicable)**  have already been told about the study. Your accompanying parent/ guardian will also sign a similar form called the Parent Informed Consent Form (PICF). Please read this form and ask the researcher any questions you have. It is your choice to be part of the project or not. The assent form describes the research study and states that you have been explained the purpose and the nature of the study to your satisfaction by the attending doctor/ researcher and you are ready to follow the study procedures:

**List all study procedures. Point out any that are considered experimental/ or otherwise, and explain technical and medical terminology in simple, non-technical and direct language.**

**Risks, discomforts and side effects**

If you experience any of these side effects you can contact your doctor/ researcher immediately (**Name and contact number of PI**). (**Describe in simple language provisions for treatment/ hospitalization for side effects/ injury**). We want to tell you about some things that might hurt or upset you if you are in this study. (**Describe risks - e.g. painful procedures, other discomforts, things that take a long time. For example: the needle we use to take the blood may hurt. You might get a bruise on your arm).** You will not bear the expenses regarding the therapy. If you follow the directions of the doctors/ researchers in charge of this study and you are injured due to any substance or procedure given under the study plan, the study team will pay for the medical expenses for the treatment of that injury.

**Benefits**

If you are in the study it may not help you to get better or benefit you. But we hope to learn something that will help other people some day.

**Confidentiality**

The information collected about you during this study will be kept safely locked up. Nobody will know it except the doctor doing the research. The doctor will not tell your friends or anyone else. The information will only be accessed by the doctor, the Ethics Committee and the regulatory authority. The study information about you will be given to your father/ mother/ guardian if required.

**Right to refuse or withdraw**

You do not have to be in this study. If you do not want to be. If you do not want to be in this study, we will tell you what other kinds of treatments there are for you. If you decide that you don’t want to be in the study after we begin, that’s okay too. Nobody will be angry or upset. We are discussing the study with your parents and you should talk to them about it too.

**Whom to contact**

You can ask questions if you do not understand any part of the study. If you have questions later that you don’t think of now, you can call the doctor/researcher. **<Name of PI> Phone: <contact no.>**. If you have any queries regarding your rights you may contact **<Name of CNU ERC Chair> Phone <contact no.>.**

**Your responsibilities**

It is the responsibility of your parent/ guardian to come along with you to the hospital during the study period for all the visits unless you withdraw or do not continue to receive treatment/ care as per the study. It is also your responsibility and your parent/ guardian to report any side effects that you may experience while on the study. It is also the responsibility of your parent/ guardian to inform the doctor if you consume any other medication apart from the study treatment. We expect your cooperation throughout the study.

**ASSENT FORM (AF)**

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, agree to participate in the study **“TITLE OF THE STUDY”**.

I have been informed, to my satisfaction, by the attending researcher, about the study. I know that my parents/ guardians do not have to bear the expenses of the treatment if I suffer from any study related injury, which may be related to the study drug/ procedure/ device.

I am also aware of my rights to not be part of the trial, at any time, without having to give reasons for doing so.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Name and signature of the study participant or Date

Legally Acceptable Representative

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Name and signature of Primary Investigator Date

**PARENT INFORMATION SHEET (PIS)**

| **Title:** |
| --- |
| **Researcher/s:** |

**Introduction:**

Your child is invited to participate in a study/ research/ experiment. This document gives you a description of the study/trial in which you are being asked to participate. Your participation in this study is voluntary, and you can enquire about all details before giving your written consent to participate in the study.

**Purpose:**

The purpose of this study is to <**state the purpose of the study**>

**Participant Selection/ Voluntary Participation**

*Indicate clearly that they can choose to have their child participate or not. State, if it is applicable, that they will still receive all the services they usually do if they decide not to participate. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.*

*Example: Your decision to have your child participate in this study is entirely voluntary. It is your choice whether to have your child participate or not. If you choose not to consent, all the services you and your child receive ai this clinic will continue and nothing will change. You may also choose to change your mind later and stop participating, even if you agreed earlier, and the services you and/ or your child receives at the clinic will continue.*

**Information on the trial drug procedures and protocol**

*Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and the drugs that will be given. Describe very clearly which procedure is routine and which is experimental or research.*

**Duration**

*Include a statement about the time commitments of the research for the participants and for the parent including both the duration of the research and follow-up, if relevant.*

*Example: The research takes place over (number of days/ or number of months) in total. During that time, it will be necessary for you to come to the clinic/ hospital/ health facility (number of days), for (number of hours each day. We would like to meet with you six months after your last visit for a final check-up. Altogether, we will see you and your child 4 times over a year.*

**Side effects**

*Parents should be told if there are known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.*

*Example: These vaccines can have some unwanted effects or some effects that we are not currently aware of. However, we will follow your child closely and keep track of these unwanted effects or any problems. We will give you a telephone number to call if you notice anything out of the ordinary, or if you have concerns or questions. You can also bring your child to this health facility at any time and ask to see (name of nurse, doctor, researcher). We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.*

**Risks**

*A risk can be thought of as being the possibility that harm may occur. Explain and describe any such possible or anticipated risks. Provide enough information about the risks that the parent can make an informed decision. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.*

*Example: By participating in this research it is possible that your child will be at greater risk than he/she would otherwise be. There is a possibility that \_\_\_\_ may happen as a result of taking this drug. While the possibility of this happening is very low, you should still be aware of the possibility. If something unexpected happens and harm does occur, we will provide you with \_\_\_\_\_\_\_\_\_. (Explain the level of care that will be available, who will provide it, and who will pay for it. Inform the parent if there is a particular insurance in place.)*

**Discomforts**

*Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.*

*Example: By participating in this research , it is possible that your child may experience some discomfort such as the discomfort of the injections. There may be a slight hardening and/ or swelling where the needle stick goes into the skin. This should disappear in one day. Your child may also be fussier than usual or more tired. These behaviors usually stop within one day but if you are concerned, please call me or come to the clinic.*

**Benefits**

*Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.*

*Example: If your child participates in this research, he/she will have the following benefits: any interim illness will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any other benefits for your child but his/her participation is likely to help us find the answer to the research question. There may not be any benefit to society at this stage of the research , but future generations are likely to benefit.*

**Confidentiality**

*Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant, which would otherwise be known only to the physician but would now be available to the entire research team. Because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.*

*Example: The information that we collect from this research project will be kept confidential. Information about your child that will be collected from the research will be put away and no one but the researchers will be able to see it. Any information about your child will have a number on it instead of his/her name. Only the researchers will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except (name who will access to the information, such as research sponsors, your clinician, etc.).*

**Sharing of the results**

*Your plan for sharing the information with the participants and their parents should be provided. If you have a plan and a timeline for the sharing of information, include the details. Also, inform the parent that the research findings will be shared more broadly, for example, through publications and conferences.*

*Example:The knowledge that we get from this study will be shared with you before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. Afterwards, we will publish the results in order that other interested people may learn from our research.*

***Right to refuse or withdraw***

*This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section well to ensure that it fits for the group for whom you are seeking consent. The example used here is for a parent of an infant at a clinic*

*Example: You do not have to agree to your child taking part in this research if you do not wish to do so and refusing to allow your child to participate will not affect your treatment or your child’s treatment at this center in any way. You and your child will still have all the benefits that you would otherwise have at this center. You may stop your child from participating in the research at any time that you wish without either you or your child losing any of your rights as a patient here. Neither your treatment nor your child’s treatment at this center will be affected in any way.*

**Alternatives to participating**

*Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.*

*Example: If you do not wish your child to take part in the research, your child will be provided with the established standard treatment available at the center/ institute/ hospital. People who have malaria are given………..*

**Whom to contact**

*Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted.) State also that the proposal has been approved and how.*

*Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/ telephone number/email]. This proposal has been reviewed and approved by [name of the CNU-ERC], which is a committee whose task it is to make sure that research participants are protected from harm. If you have any queries regarding your rights as a study participant, you may contact the Chair of the CNU ERC, <name of chair> <phone number>.*

**PARENT INFORMED CONSENT FORM**

The nature and the purpose of the above research study have been explained to my child and me; we have agreed to have my child participate in the research study. We also agree that my child’s personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. We will receive a signed copy of this consent form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of parent/ guardian Date

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Signature of minor participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Primary Investigator Date

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Signature of impartial witness Date