Documents for Protocol Submission

The study protocol should be accompanied with the following relevant supporting documents for scientific and ethical review. These are –

1. Checklist (Refer AX 2-V1/SOP 03/V2)
2. Project Submission Form A. Grouping of Project
B. Project Fact Sheet
C. Project Submission Overview
D. Budget Sheet for the Proposed Study

3. Essential Documents
a. Informed Consent Documents (Refer (AX4-V1/SOP 03/V2)
b. Participant Information Sheet
4. Decision of other Ethics Committees (If required / asked for)

Details of Essential Documents along with protocol

1. Participant Information Sheet, Informed Consent Forms (ICFs), Assent Forms and Parent consent forms (if children / adolescents between 7 – 18 years of age are participants in the trial) - in English and Malayalam (Refer (AX5-V1/SOP 03/V2)
2. Investigator's Brochure
3. CRF
4. One page, recent, signed and dated curriculum vitae of the investigators indicating qualifications and relevant experience.
5. Agreement to comply with national and international GCP protocols for clinical trials
6. Details of Funding agency / Sponsors and fund allocation
7. Regulatory clearance for all types of studies from appropriate regulatory authorities i.e.DCGI approval, DGFT approval (for export of study samples), ICMR, DBT, other local government agencies (as applicable)
8. For exchange of biological material in international collaborative study a MOU / MTA between the collaborating partners and of Health Ministry Screening Committee (SGSC)
9. CTA or MOU between the collaborators
10. Insurance/Indemnity policies, indicating who are covered
11. Any other information relevant to the study

AX2-V1/SOP03/V2 Checklist of Documents

Item No.	Mandatory Documents	Yes	No	NA
1	IRB processing fee (applicable for sponsored trials) PG Students (Rs.1000/-) to be paid at accounts department			
2	Project Submission Form (both hard and soft copies) duly signed by the Principal Investigator			
	A. Grouping of Project			
	B. Project Fact Sheet			
	Investigators Declaration			
	Conflict of Interest Statement			
	Consent of Head of the PI's Department			
	Consent from Working Group			
	C. Project Submission Overview			
	D. Budget Sheet for the Proposed Study Detailed Budget for the Proposed Study			
3	Study Protocol			
4	Participant Information Sheet & Informed consent forms			
	(ICFs) in English & Malayalam			
	(and if required any other language)			
5	Back translations of ICFs			
	(not mandatory for Malayalam)			
6	Case Record Form			
7	Investigator Brochure			
8	Insurance policy			
9	DCGI approval letter / DCGI submission letter			
10	NOC from DCGI / DGFT/ICMR			
11	Appendix VII (Schedule Y) Undertaking by the Investigator			
12	Clinical Trial Agreement (CTA) / Memorandum of Understanding (MOU) / Material Transfer Agreement (MTA) if applicable			
13	Brief resume of PI and Co-investigators (1 Page each)			

AX4-V1/SOP03/V2 Guidelines for devising ICF and Sample format of an Informed Consent Document. Guideline for preparation of the informed consent form

While submitting your project report to the Human Ethics Committee, ensure that you have included an informed consent form that is prepared as per the guidelines for ICH – GCP,ICMR ethical guidelines 2006, and the Declaration of Helsinki. The consent form must necessarily include the following points listed below. Any further information you wish to add, is your choice.

The following are instructions for devising Informed Consent Form:

- Informed consent forms in English and Malayalam
- Font: Arial
- Size: 12
- All the consent forms must have Version No, Date, Page no in the footer
- Separate forms should be prepared when minors (children) are study participants; assent form for the mature minors (teenagers) and consent form for the parents

The consent form must necessarily include the following points listed below and any further information you wish to add.

AX4-V1/SOP03/V2 Guidelines for devising ICF and Sample format of an Informed Consent Document.

Guideline for preparation of the informed consent form

While submitting your project report to the Human Ethics Committee, ensure that you have included an informed consent form that is prepared as per the guidelines for ICH – GCP, ICMR ethical guidelines 2006, and the Declaration of Helsinki. The consent form must necessarily include the following points listed below. Any further information you wish to add, is your choice.

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-	Font: Arial
-	Size: 12
-	All the consent forms must have Version No, Date, Page no in the footer
-	Separate forms should be prepared when minors (children) are study participants; assent form for the mature minors (teenagers) and consent form for the parents

The consent form must necessarily include the following points listed below and any further information you wish to add.

"Template for devising an "Informed Consent Form"
(Include or exclude information, as applicable)

Informed Consent Form
[The title of the project here exactly as it is in the project design with names of Principal Investigator and all other investigators.]

Introduction:
You are 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 ……

Information:

List all procedures, which will be employed in the study. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, non-technical & direct language.

Graphics could be used if helpful in making the text meaningful to the research subject.

If this is a randomized trial, details of both arms of the trial must be explained in writing to the subject being enrolled.

State the amount of time required of the subject per session, for the total duration of study and the expected duration of the study.

If applicable to your study, list:

i. The number of participants who will be participating in the research.

ii. Information concerning taping or filming.

iii. If tissues or biological samples are being retained for research, describe what will be done to the tissues in simple lay person's terms.

Alternative treatments:

Disclose appropriate alternative treatments available, if any.

Risks:

List the foreseeable risks, if any, of each of the procedures to be used in the study, and any measures which will be used to minimize the risks, or treat them should they occur. Explanation of anticipated side effects, and even rare side effects, or known idiosyncratic reactions.

Costs:

Describe the cost for participating in the study to the subject/participant. The information must be written in clear terms regarding the cost which will be borne by sponsors/Principal Investigator/s of the project, and study participant.

Reimbursement for Participation:

Describe plan to reimburse or compensate participant for the inconvenience, time spent and for expenses incurred. If yes, the amount of payment proposed. Discuss travel details for trial subjects &/or attendant who need to come for follow-up, and spell out methodology for the reimbursement for travel.

Emergency Medical Treatment:

(If applicable, add here)

If physical injury is suffered in the course of research, or for more information, please notify the investigator in charge (list PI name and phone number).

Describe available medical treatment in case of complications.

Benefits:

List the benefits you anticipate will be achieved from this research, either to the participants, others, or the body of knowledge.

Also mention that the many of the most effective treatments used today are the result of clinical trials done in the past.

Confidentiality:

The information in the study records will be kept confidential and the clinical charts will be housed in the TMH/CRS. Data will be stored securely and will be made available only to persons conducting the study and to the regulatory authorities. The data will not be made available to another individual unless you specifically give permission in writing. No reference will be made in oral or written reports which could link you to the study. Result of the project will not be communicated to the subject unless deemed necessary

Compensation for protocol Related Injury:

Describe the details of compensation or insurance for protocol related injury to the trial subject. Explain who will bear the cost in case of trial related injury?

Contact:

If you have questions at any time about the study or the procedures, (or you experience adverse effects as a result of participating in this study,) you may contact the researcher, [Name], at [Office Address], and [Office Phone Number]. If you have questions about your rights as a participant, contact the member secretary, IEC [Name], at [Office Address], and [Office Phone Number].

Participation:

Your participation in this study is voluntary; you may decline to participate at anytime without penalty and without loss of benefits to which you are otherwise entitled.

If you withdraw from the study prior to its completion, you will receive the usual standard of care for your disease, and your non participation will not have any adverse effects on your subsequent medical treatment or relationship with the treating physician

If you withdraw from the study before data collection is completed, your data will not be entered in the project report. Your legal rights will not be affected by signing this documents.

Consent I have read the above information and agree to participate in this study. I have received a copy of this form.	
Participant's name (print):	
Participant's signature:	
Address (capital letters):	
Phone Nos.:	
Legal Representative name:	
Legal Representative signature & date:	
Witness's name (Print):	
Witness's signature & date:	
Name of PI or the person administering the consent (Print):	
PI or person's Signature & date:	

Note to Investigators Regarding the Process of Administering Informed and Understood Consent
(The templates for Participant Information Sheet have been provided herewith):

The prospective participant should be given Participant Information Sheet first.
The participant should then be encouraged to read the Information Sheet and think over, preferably for a period of 24 hours. Following which, the participant should be served a questionnaire to ensure that he/she is aware of his/her own rights as a participant in the clinical trial. The informed consent form should be served to the participant only after ensuring that the participant is now prepared for informed decision making. The PIs are urged by the IEC to download and use the wording in the glossary available on the SGMC website and follow the sample format of Informed Consent Form, unless the PI support reasons for alternative wording.

Use of alternative wording or different format 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.

The study participant should be explained all the details in a language she/he understands.
The Informed Consent Form must have the name and Telephone No. of the Principal Investigator or of any other co-investigator, as the subject must know who to contact in case of an emergency, or even to seek answers to their queries.

The consent form must be dated.
If the prospective participant so desires, a Xerox copy of the Informed Consent Form must be given to him/her.
Copies of the consent form must be available in English & vernacular languages .
Please tailor your ICF to suit the needs of our Indian population, and if this is a multinational Pharma based project, an additional ICF specifically designed for us may be used.
Separate forms should be prepared when minors are used; one for the mature minors (teenagers) and one for the parents.

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.

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. If informed consent form requires more than one page, print the informed consent form front to back.

Please make provision for the assent of the child to the extent of the child's capabilities such as in the case of mature minors and adolescents.

Please make provision on the form for signatures/thumb impression of the participant/parent or legal guardian, if minor and of the investigator, or person administrating the consent form, and of a witness.

AX5-V1/SOP 03/V2: Child Information Sheet and Assent Form

Study title: " ……"

Introduction

You have come to meet the doctor as you are suffering from.....You may be having symptoms……..

Describe briefly the purpose of this study

If this is a randomized trial, details of both arms of the trial must be explained in writing to the subject being enrolled.

Disclose appropriate alternative treatments available, if any.

We invite you to participate in this study.

What will you have to do?

To participate in this research study, you will be examined by your doctor and if found to fulfill pre-specified criteria, you will be eligible to be enrolled in this research study.

Since you are in the age group of 8-12 years we ask you to sign this assent form if you agree to participate. The assent form describes the research study and states that you havebeen explained the purpose and the nature of the study to your satisfaction by the attending doctor and you are ready to abide by the trial procedures. Your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form.

List all procedures, which will be employed in the study. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, nontechnical & direct language.

In addition, to record the same parameters daily your parent / guardian will also be provided with a diary where they will enter the same findings accordingly. You will have to tell them about your symptom and they will mark accordingly in the diary

Side effects

All medicines/procedures produce some side effects – the medicine you will take/the procedure you will undergo can produce (Describe the side effects). Your Physician will take due precautions so that you do not experience these side-effects. If you experience any of these listed effects or any other unlisted effects do contact your study doctor immediately. The study doctor will treat you accordingly.

Your parents will not have to bear the cost of the medical treatment / hospitalization as a

result of these side effects.

In addition, during the trial period if you suffer from any other diseases, if you consider some of the side effects as serious or you undergo hospitalization during the study period, please immediately contact the study doctor:

Dr. **Phone:**

The occurrence of any of the side effects (known / unknown) and concomitant diseases will be noted by the physician at every visit. The assessment of acceptability of the formulation/procedure will be performed by the treating physician at the end of the study.

Risks and discomforts

There is no foreseen significant risk / hazard to your health, if you wish to participate in the study. You will not bear the expenses regarding the therapy. If you follow the directions of the doctors in charge of this study and you are injured due to any substance or procedure given under the study plan, the Sponsor will pay for the medical expenses for the treatment of that injury.

Benefits

If you participate in the study you will receive ..... If you appear to have any acute illness ……you will be offered free treatment for those visits in accordance with local standard medical care. You will not be offered free treatment for chronic diseases or conditions not related to study procedures. Your participation in the study may help others, because this participation will help us determine if the study drug/procedure is safe.

Confidentiality

Your existing medical records may be accessed; personal health information about you may be collected and processed by study investigators for the purpose of performing the study. Information about you will be collected and stored in files with an assigned number, and not directly with your name. All documents related to the study will only be accessed by the study investigator, sponsor, the Ethics Committee and the Regulatory authority.

Your parent / guardian will have the right to access personal information about you at any time with the study doctor and the right to correct this personal information. Your parent /guardian can take away your authorization to collect process and disclose data about you at any time.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so. Refusing to participate will not affect your treatment. You will still have all the benefits that you would otherwise have got at this clinic/hospital. You may stop participating in the research at any time you wish without losing any of your rights. Your treatment will not be affected in any way.

The study doctor may decide to withdraw you from the study if he/she considers it is in your best interest

You will be informed of important new findings developed during the course of the study so you will be able to consider your participation in the study in light of new information

Whom to contact

If you have any questions, please ask them now. You may also ask questions later. If you wish to ask questions later, contact

Dr. **Phone:**

If you have any queries regarding your rights as a study participant, you may contact, the Chairperson of the Institutional Ethics committee

Dr. **Phone:**

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 are prematurely discontinued from the study. It is also your responsibility and your parent / guardian to report any expected or unexpected reactions (side effects) that you notice during the study period.

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 co-operation throughout the study.

Child Assent Form

I_____, exercising my free power of choice,
hereby give my consent for participation in the study entitled:
"……"
I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any trial related injury, which has causal relationship with the said trial drug

I am also aware of right to opt out of the trial, at any time during the course of the trial, without having to give reasons for doing so

_____

Name and Signature of the study participant Date:

_____

Name and Signature of the attending Physician Date: