



AX4-V2/SOP 03/V2

Guidelines for devising Participant Information Sheet and Informed Consent Form and Sample format of an Informed Consent Document.

Guideline for preparation of the informed consent document

While submitting your project to the IEC, ensure that you have included an informed consent document that is prepared as per the Schedule Y of ICMR ethical guidelines, ICH- Good Clinical Practice (ICH – GCP) and the Declaration of Helsinki.

Kindly note:

- Informed consent documents in English and Assamese are mandatory and any Language if applicable
- Font: Arial
- Size: 12
- All the consent documents must have Version No, Date, Page no in the footer
- Separate documents should be prepared when minors (children) are study participants; assent form for the mature minors (age 7-17 years) and consent document for the parents
- Glossary of technical words/medical terminology for participant understanding
- Schedule of investigations to be performed for the study as a chart.

The consent document template describes the minimal requirements. You are free to add additional information, if you wish to.

Template for a “Participant Information Sheet & Informed Consent Form” (Include or exclude information, as applicable)

Participant Information Sheet & Informed Consent Form

[The simplified title of the project as per the project submission form with name of Principal Investigator]

Name of the funding agency (if applicable)

Name of the sponsor (if applicable)

Address of Research Site

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.

This research study is approved by the Institutional Ethics Committee of BBCI, Guwahati. A copy of the ICF will be given to you for your record

Purpose:

The purpose of this study is to

.....

Statement that the study involves research and explanation of the purpose of the research.

Clearly state

1. The Aim/ objectives of the study to be mentioned
2. Statement of type of cancer patients/healthy volunteers enrolled

.....

Information:

List all procedures, which will be carried out in the study. Clearly state experimental procedures 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 participant.

If this is a randomized trial, details of both arms of the trial must be explained.

State the amount of time required by the participant for the study with clearly stating the total duration of the study.

Clearly state

- i. The number of participants who will take part in the research
- ii. Information concerning taping or filming (If applicable)
- iii. For clinical studies which require regulatory approval - Please include
 - a) A statement that there is a possibility of failure of investigational product to provide intended therapeutic effect
 - b) A statement that in the case of placebo controlled trial, the placebo administered to the participants shall not have any therapeutic effect
- iv. Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the Subject's consent
- v. Statement that the subject or subject's representative will be notified in timely manner if significant new findings develop during the course of the research which may affect the subject's willingness to continue participation will be provided
- vi. Information regarding patient's roles and responsibility (follow-up/ QOL assessment)

Alternative treatments:

Disclose appropriate alternative treatments available, if any.

Clearly state if you refuse to participate in the trial - Standard treatment will be given (if applicable)

Risks:

List the foreseeable risks, discomforts or inconvenience, if any, of each of the procedures to be carried out in the study and measures to minimize the risks or treatment in case of occurrence. Explanation of anticipated side effects, including rare side effects, or known idiosyncratic reactions.

A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable

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 for reimbursement or amount for expenses incurred, time spent and any inconvenience. State clearly the details for travel reimbursement for trial participants &/or attendant.

Emergency Medical Treatment

(If applicable, add here)

In case of the physical injury to the participant during the course of research please state the name and contact details of the PI.

Describe available medical treatment in case of complications.

Benefits

List the anticipated benefits from this research, either to the participants, others, community, scientific community.

If no benefit is expected subject should be made aware of this

- May benefit other patients/society in future
- Information may help the doctor to learn more about disease condition, treatment etc.

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 (specify the location). Data will be stored securely for a period of _____ years 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 study will not be communicated to the participant unless deemed necessary.

Compensation for study related Injury or death

(As per the DCGI directive for regulated studies, it is mandatory for sponsors to comply to the following requirement: in case of study related injury, sponsor should provide completed medical care as well as compensation for the injury (Death) as per the provisions of law and same should be included in ICF)

Compensation of participants for disability or death resulting from such research related injury;

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

Research participants who suffer physical injury as a result of their participation in the research study are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability participant to confirmation from IEC. In case of death, their dependents are entitled to material compensation.

Statement describing the financial compensation and medical management as under

- In the event of an injury occurring to the clinical trial participant, such participant shall be provided free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier
- In the event of a trial related injury and death, the sponsor or his representative, whosoever has obtained permission from the Licensing Authority for the conduct of clinical trial, shall provide financial compensation for the injury or death

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, [PI Name], at [Office Address], and [Office Phone Number].

If you have any questions about the informed consent process or your rights as a participant, contact the Member Secretary, IEC-BBCI, Clinical Research Secretariat, Power-Ggrid Building, Ground Floor, Dr. B Borooah Cancer Institute, A K Azad Road, Gopinath Nagar, Guwahati-16.

Participation

Your participation in this study is voluntary; you may decline to participate at any time 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 study report.

If staff /student is involved - Your participation in this research will not bestow upon you any competitive academic or occupational advantage over other students or staff who do not volunteer, and we will not impose any academic or occupational penalty on those students or staff who do not volunteer.”

Consent

Informed Consent form to participate in a clinical trial/research (main study)

Study Title:

Study Number:

Participant' Initials: _____ Participant's Name: _____

Date of Birth / Age: _____

1. I understand that I am being invited to take part in the research study. I confirm that I have read/ been read to and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand the risks and potential benefits of this research study that were explained to me. I freely give my consent to take part in research study described in this form.
4. I understand that the Sponsor of the research study, others working on the Sponsor's behalf, IEC and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
5. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
6. I agree to take part in the above study.

I have read/have been read the above information and agreed to participate in this study. I have received a copy of this form.

| | |
|---|--|
| Participant's name (print): | |
| Participant's Signature/Thumb impression & date: | |
| Address: Qualification (please attach supporting documentation) (if applicable) _____ Occupation: Student / Self-Employed / Service / Housewife /Others (Please tick as appropriate) and attach supporting documentation (if applicable) Annual Income of the participant (please attach supporting documentation) (if applicable): _____ | |
| Phone Nos: | |
| Legal Acceptable Representative name | |
| Legal Acceptable Representative Signature/Thumb impression & date (if applicable): | |
| Address (capital letters): Phone Nos: | |
| Impartial Witness's name : | |
| Impartial Witness's signature & date (if applicable): | |
| Address (capital letters): Phone Nos: | |
| Name of PI or Co-PI/Co-I: | |
| PI or Co-PI/Co-I sign & date: | |

Guidelines for developing informed consent documents for Biological sample study:

The ICF for use of biological sample may include the following points:

- Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research.

Other specifics are as follows:

- a) Period of storage of the sample/data and probability of the material being used for secondary purposes.
- b) Whether material is to be shared with others, this should be clearly mentioned.
- c) Right to prevent use of her/his biological sample, such as DNA, cell-line, etc., and related data at any time during or after the conduct of the research.
- d) Risk of discovery of biologically sensitive information and provisions to safeguard confidentiality.
- e) Post research plan/benefit sharing, if research on biological material and/or data leads to commercialization.
- f) Publication plan, if any, including photographs and pedigree charts.

Template of consent for Biological sample study

As part of this protocol the investigators may store your blood/tissue/serum samples for future research. The investigators may also store and use the tumor tissues that are removed as part of routine biopsy or surgery, for future research. The tissue could be either paraffin blocks or fresh tissue that is frozen at very low temperatures as part of the Hospital Tumor Tissue Repository. Such blood, plasma, serum or tissue samples could be used for pathology, immunohistochemical, genetic, genomic, proteomic, transcriptomic or other studies in the future. The investigators will maintain your confidentiality at all times and at no time point will your individual data be linked to yours identify.

If you are willing to participate in the biological study, kindly give your consent by ticking at appropriate box in this consent form.

You may choose not to let your sample be used for the additional research and still become part of this study. At any time during and after the study if samples are remaining with the sponsor, you have rights to discard the sample material or to take it back. If you choose to discard your samples or to take them back, please contact your study doctor.

Informed consent form to participate in a biological sample study

Study Title:

Study Number:

Participant' Initials:_____ Participant's Name:_____

Date of Birth / Age:_____

Do you consent to biological sample study?

YES, I consent

NO, I do not consent

- a) I understand that I am being invited to take part in the research study. I confirm that I have read/been read to, and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.
- b) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
- c) I understand the risks and potential benefits of this research study that were explained to me. I freely give my consent to take part in research study described in this form.
- d) I understand that the Sponsor of the research study, others working on the Sponsor's behalf, IEC and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
- e) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
- f) I agree to take part in the above study.

I have read/been read to, the above information and agreed to participate in this study. I have received a copy of this document.

| | |
|--|--|
| Participant's name (print): | |
| Participant's Signature/ Thumb impression & date: | |
| Address : | |
| Qualification (please attach supporting documentation) (if applicable) _____ | |
| Occupation: Student / Self-Employed / Service / Housewife /Others (Please tick as appropriate) and attach supporting documentation (if applicable) | |
| Annual Income of the participant (please attach supporting documentation) (if applicable):_____ | |
| Phone Nos.: | |
| Legal Acceptable Representative name | |

| | |
|--|--|
| Legal Acceptable Representative Signature/ Thumb impression & date(if applicable): | |
| Address (capital letters): Phone Nos.: | |
| Impartial Witness's name : | |
| Impartial Witness's signature & date(if applicable):: | |
| Address (capital letters): Phone Nos.: | |
| Name of PI or Co-PI/Co-I: | |
| PI or Co-PI/Co-I sign & date: | |

Note to Investigators Regarding the Process of Obtaining Informed and Understood Consent

- 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 use the simple non-technical words or should add the glossary and follow the sample template of Participant Information Sheet & Informed Consent Form
- 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 Document must have the name and Telephone No. of the Principal Investigator or of any other co-investigator in case of an emergency, or even to seek answers to their queries.
- The consent document must bear version no. & date.

A copy of the signed Informed Consent Document (ICD) must be given to prospective participant. A receipt of copy of ICF by the participant should be documented by the investigator in the source documents. Copies of the consent document must be available in English and Hindi.

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 the trial site may be used. Separate forms should be prepared when minors are used; one for the mature minors (age 7-18 years) and one for the parents.

If your document is more than one page, there should be a line at the bottom of each page for the participant'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 document front to back.

Please make provision for the assent of the child to the extent of the child's capabilities as is the case with 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 administering the consent document, and of an impartial witness. If the LAR's sign has been taken for medical reasons (e.g. patient is unconscious, then the patient has to be consented when conscious and able to grant consent and this should be documented.)

†The investigator, or a suitably qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the form at the same time as the participant.

‡ Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the participant or the participant's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the participant. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance.

Legally Acceptable Representative (LAR): An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective participant, to the participant's participation in the clinical trial.

Note: Copy of the Participant Information Sheet and duly filled in Informed Consent Document should be handed over to the participant or his/her attendant.

AX5-V2/SOP 03/V2
Dr. B Borooah Cancer Institute
Tata Memorial Centre

Child Information Sheet and Assent Form

Study title: “.....”

Introduction- Background and Rationale would be more appropriate

We want to tell you about a study we are doing. This study is a “research” study. It 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]**. The reason why we are doing this need to do this is because [gap in knowledge in simple words]. This might help other children like you in future.....

We invite you to participate in this study.

What will you have to do?

You are being asked to be part of this project. The project is about [insert general statement about study]. Your [parents or legal guardian, if applicable] have already been told about the project. Your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form Please read this form and ask the researcher any questions you have. You can decide whether or not to take part in the study. You can say no as well. 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 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 & direct language.

Risks, discomforts & Side effects

If you experience any of these side effects, you can contact your doctor immediately. The doctor will treat you

Dr.....

Phone:.....

(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 and your parents 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 study doctor who is treating you will be responsible for paying for the medical expenses for the treatment of that injury.

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 for reimbursement or amount for expenses incurred, time spent and any inconvenience. State clearly the details for travel reimbursement for trial participants &/or attendant.

Emergency Medical Treatment

(If applicable, add here)

In case of the physical injury to the participant during the course of research please state the name and contact details of the PI.

Describe available medical treatment in case of complications.

Benefits

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

Confidentiality

The information collected about you during this study will be kept safely locked up. Data will be stored securely for a period of _____ years. 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 OK 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.

Name of PI:.....

Phone:.....

If you have any queries regarding your rights you may contact:

Member Secretary, IEC-BBCI, Clinical Research Secretariat, Powergrid Building, Ground Floor, Dr. B Borooah Cancer Institute, A K Azad Road, Gopinath Nagar, Guwahati-16.

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 your responsibility and that 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 _____, agree to participate in the study.
“.....”

I have been informed, to my satisfaction, by the attending physician, 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 right to not be part of the trial, at any time, without having to give reasons for doing so

Name and Signature /Thumb impression of
the study participant

Date

Name and Signature/ Thumb impression
of Legally Acceptable Representative

Date

Name and Signature of Impartial Witness

Date

Name and Signature of Attending Physician

Date

AX6-V2/SOP 03/V2
Dr. B Borooah Cancer Institute
Tata Memorial Centre

Parent Information sheet and 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:

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

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 at 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 participant 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 any 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.

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 for reimbursement or amount for expenses incurred, time spent and any inconvenience. State clearly the details for travel reimbursement for trial participants &/or attendant.

Emergency Medical Treatment

(If applicable, add here)

In case of the physical injury to the participant during the course of research please state the name and contact details of the PI.

Describe available medical treatment in case of complications.

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 illnesses 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 or may not be any other benefit 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 the 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. Data will be stored securely for a period of _____ years.

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 have access to the information, such as research sponsors, DSMB board, 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 Centre in any way. You and your child will still have all the benefits that you would otherwise have at this Centre. 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 Centre 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/e-mail] This proposal has been reviewed and approved by [name

of the IEC], 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:

Member Secretary, IEC–BBCI, Clinical Research Secretariat, Power-Grid Building, Ground Floor, Dr. B Borooah Cancer Institute, A K Azad Road, Gopinath Nagar, Guwahati-16.

Consent

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.

| | |
|---|-------|
| _____ | _____ |
| Name and Signature /Thumb impression of Parent/Guardian | Date |
| _____ | _____ |
| Name and Signature/ Thumb impression of Participant (when appropriate) | Date |
| _____ | _____ |
| Name and Signature of Person Obtaining Consent/Authorization | Date |
| _____ | _____ |
| Name and Signature of Impartial Witness | Date |

AX7-V2/SOP 03/V2

Consent for prospective audit study

Participant Consent for Participation in the study

Participant Information: (Should be concise and simple)

To state the purpose of the study (What the study is about and why the study is being done)

Consent

I understand that a study “Titled _____”
conducted by “Dr.” _____ (name, phone no.)

involves the analysis of my medical data that has been collected as part of my routine medical care.

Purpose of the study-

I understand that there will not be any additional medical procedures over and above those which I would encounter during standard treatment.

I understand that this study has been approved by the Institutional Ethics Committee, Tata Memorial Centre and does not pose any additional risk to me beyond that which I would encounter while undergoing routine physical or psychological examinations or tests and/or which I would encounter in routine daily life activities. I further understand that confidentiality with regard to my medical data will be ensured and my data will be stored for ___ years, and that the results published will not in any way be linked to me. I understand that the Principal Investigator (name) would be willing to provide me with any additional information that I would want to know regarding the study.

I understand that if I have any queries regarding my rights I may contact,
Member Secretary, IEC-BBCI, Clinical Research Secretariat, Power-Grid Building, Ground Floor, Dr. B Borooah Cancer Institute, A K Azad Road, Gopinath Nagar, Guwahati-16.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I am willing to allow the use of my data for the study.

Name and Sign/Thumb impression of the participant

Date

Name and Sign/Thumb impression of
Legally Acceptable Representative

Date

Name and Sign/Thumb impression of Impartial Witness

Date

Name and Sign/Thumb impression of Principal Investigator

Date

AX8-V2/SOP 03/V2
Consent for prospective audit study
Parental/LAR consent

Parent Information: (Should be concise and simple)

To state the purpose of the study (What the study is about and why the study is being done)

Consent

I understand that a study "Titled _____"
conducted by "Dr." _____ (name, phone no.) involves
the analysis of my ward's medical data that has been collected as part of his/her routine
medical care.

I understand that there will not be any additional medical procedures over and above those
which my ward would encounter during standard treatment.

I understand that this study has been approved by the Institutional Ethics Committee, Tata
Memorial Centre and does not pose any additional risk to my ward beyond that which he/she
would encounter while undergoing routine physical or psychological examinations or tests
and/or which he/she would encounter in routine daily life activities. I understand that the
Principal Investigator (name) would be willing to provide me/my ward with any additional
information that I/my ward would want to know regarding the study.

I understand that if I have any queries regarding my ward's rights I may contact,
Member Secretary, IEC-BBCI, Clinical Research Secretariat, Powergrid Building, Ground
Floor, Dr. B Borooah Cancer Institute, A K Azad Road, Gopinath Nagar, Guwahati-16.

I further understand that confidentiality with regard to my ward's medical data will be ensured,
that his/her privacy would be maintained and that the results published will not in any way be
linked to him/her.

I am willing to allow the use of my ward's data for this study.

I understand that my ward's participation in the study is voluntary and that I am free to
withdraw consent for my ward's participation at any time, without giving any reason, without
my ward's medical care or legal rights being affected.

Name and Sign/Thumb impression of Guardian/Parent/ LAR

Date

Name and Sign/Thumb impression of Impartial Witness

Date

Name and Sign/Thumb impression of Principal Investigator

Date

AX9-V2/SOP 03/V2
Assent for prospective audit study

Child Information: (Should be concise and simple)

To state the purpose of the study (What the study is about and why the study is being done)

Assent for Participation in the study

I understand that a study “Titled _____”
conducted by “Dr.” _____ (name, phone no.) involves the
analysis of my medical data that has been collected as part of my routine medical care.

I understand that there will not be any additional medical procedures over and above those
which I would encounter during standard treatment.

I understand that this study has been approved by the Institutional Ethics Committee, Tata
Memorial Centre and does not pose any additional risk to me beyond that which I would
encounter while undergoing routine physical or psychological examinations or tests and/or
which I would encounter in routine daily life activities. I further understand that confidentiality
with regard to my medical data will be ensured, and that the results published will not in any
way be linked to me. I understand that the Principal Investigator (name) would be willing to
provide me with any additional information that I would want to know regarding the study.

I understand that if I have any queries regarding rights I may contact,
Member Secretary, IEC-BBCI, Clinical Research Secretariat, Powergrid Building, Ground
Floor, Dr. B Borooah Cancer Institute, A K Azad Road, Gopinath Nagar, Guwahati-16.

I understand that if I decline to participate in this study or withdraw my consent at any stage
of the study my medical treatment will not be affected.

I am willing to allow the use of my data for the study.

Name and Sign/Thumb impression of the minor

Date

Name and Sign/Thumb impression of the
Guardian/Parent/Legally Acceptable Representative

Date

Name and Sign/Thumb impression of Impartial Witness

Date

Name and Sign/Thumb impression of Principal Investigator

Date

AX10-V2/SOP 03/V2
Informed Consent Template for Audio-Visual Recording

Audio-video recording of the consent process (applicable for DCGI regulated studies in case of vulnerable participants in clinical trials of New Chemical Entity or New Molecular entity).

Protocol Number

Protocol Title

Sponsor

Name of Principal Investigator (Study Doctor)

Site Name & Address

(Institute)

Contact Number of the Study Doctor

Alternate Numbers for Contact

Patient ID:

The Indian Regulatory Authority Drugs Controller General, India (DCGI) (an authority which approves and monitors conduct of clinical studies in India), who has approved this Study, has laid down new Rules that in addition to the requirement of obtaining written informed consent, an audio-visual recording of the informed consent process of each trial participant, including the procedure of providing information to the participant and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality and such audio-visual recording and related documentation would be preserved for a period of 15 years under the responsibility of the Institute and study doctor.

Statement by the Participant/ LAR

By signing this form, I hereby give my consent to the study doctor and Institute for an audio-visual recording of my informed consent process, including the procedure of providing information to me and my understanding on such consent, preservation/ archival of such audio-visual recording and related documentation for a period of 15 years under the responsibility of the Institute and study doctor. The extent of this recording is understood to be limited to discussion of contents of Informed Consent Form for this study.

The study doctor and Institute will adhere to the principles of confidentiality for such an audio-visual recording of my informed consent process, however

I understand that such an audio-visual recording of my informed consent process may be seen by the representatives of the DCGI office and/or Ethics Committee.

- I understand that my consent is voluntary and is applicable to the entire duration of my participation in this study.
- If I refuse to provide an audio-visual recording of my informed consent process, in compliance with regulations I would not be able to participate in this study.
- If I have any questions about my data protection or privacy rights under this form, I understand that I may contact the Study Doctor
- I confirm that I have read and understood the contents of this Consent Form and have had the opportunity to ask questions before signing it

To be completed by Participant/ LAR/ Impartial Witness, as applicable

| | |
|---|--|
| Participant's name (print): | |
| Participant's Signature/Thumb impression & date: | |
| Legal Acceptable Representative name | |
| Legal Acceptable Representative Signature/Thumb impression & date(if applicable): | |
| Impartial Witness's name : | |
| Impartial Witness's signature & date(if applicable): | |
| Name of PI or Co-PI/Co-I: | |
| PI or Co-PI/Co-I sign & date: | |