AX4-V6.1/SOP03/V6.1

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 New Drugs and Clinical Trials Rules 2019, ICMR ethical guidelines, ICH- Good Clinical Practice (ICH – GCP) and the Declaration of Helsinki.

Kindly note:

- Informed consent documents in English, Marathi, and Hindi are mandatory and any Language if applicable
- Font: Arial and appropriate Hindi & Marathi e.g. Shivaji
- Size: 12
- All the consent documents must have Version No, Date, Page no in the footer
- 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 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 Tata Memorial Centre. 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 patients 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 foetus, 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: incase 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

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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 [], at [Office Address], and [Office Phone: <022-24177262 /4268 (IEC-I/II) 022-27405154 (IEC-III)]

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:	
Legally Acceptable Representative name	
Legally 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 your 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.:	
Legally Acceptable Representative name	
Legally 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, Marathi 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.

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 administrating 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

A copy of the participant feedback form also needs to be provided along with the copy of the signed informed consent form.