R.D. Gardi Medical College, Ujjain

Guideline for devising Informed Consent Form and Sample format of an Informed Consent Document.

Faculty, Post graduate students and Supervisor ensure that they have included **patient information sheet** and **informed consent form** while submitting your project synopsis/Research Proposal to Research Guidance Committee and Ethical Committee as per the guidelines for ICMR ethical guidelines, Schedule Y, ICH- Good Clinical Practice (ICH – GCP) and the Declaration of Helsinki.

1. **Both informed consent form and patient information sheet should be submitted in English and Hindi and any other language if applicable.**

2. **Each page of consent forms must have date, study name and page number in the footer.**

3. **Separate forms should be prepared when minors (children) are study participants; assent form for the mature minors (age 7-18 years) and consent form for the parents.**

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

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

Participant Information Sheet & Informed Consent Form [The simplified title of the project as per the project submission form with names of Principal Investigator and all other investigators.]

1. **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_____

2. **Participant Information Sheet & Informed Consent Form Information:**
   - List all procedures, which will be carried out in the study.
   - Clearly state experimental procedures and explain technical and medical terminology in simple, nontechnical & 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 . State the amount of time required by the subject 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. If case tissues or biological samples, are being retained for research, describe what will be done to the tissues in simple lay person's terms. (If applicable) ----

3. **Alternative treatments:** Disclose appropriate alternative treatments available, if any
4. **Risks:** List the foreseeable risks, 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.
5. **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
6. **Reimbursement for Participation** Describe plan for reimbursement or compensation amount for expenses incurred, time spent and any inconvenience. State clearly the details for travel reimbursement for trial subjects &/or attendant ----------
7. **Emergency Medical Treatment** (If applicable, add here) In case of the physical injury to the subject during the course of research please state the name and contact details of the PI. Describe available medical treatment in case of complications.
8. **Benefits** List the anticipated benefits from this research, either to the participants, others, community, scientific community. Also mention that the many of the most effective treatments used today are the result of clinical trials done in the past.

9. **Confidentiality**: The information in the study records will be kept confidential and the clinical char will be housed (specify the location). 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 study will not be communicated to the subject unless deemed necessary.
10. **Compensation for study related Injury**: Compensation of subjects for disability or death resulting from such research related injury; Describe the details of compensation or insurance for study related injury to the trial subject. Explain who will bear the cost in case of trial related injury? Research subjects 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 In case of death, their dependents are entitled to material compensation.
11. **Contact Information**: 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 questions about your rights as a participant, contact the Member -Secretary, IRB, RDGMC [Name], at [Office Address], and [Office Phone Number].
12. **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."

Informed Consent form Template

Study Title :

Study Number: [For Office Use Only] Subject'

Subject Initials:_____ Subject's Name:_____

Date of Birth / Age:_DD/MM/YYYY /_____

1) I confirm that I have read 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 that the Sponsor of the research study, others working on the Sponsor's behalf, IRB and the regulatory authorities will not need my permission to look at my health records in respect of both the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial/study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

4) 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)

5) I agree to take part in the above study. I have read the above information and agreed to participate in this study. I have received a copy of this form.

Participant's name (in Capital Letters)

Participant's signature & date

Full Address(capital letters):

Phone Nos.:

Impartial Witness's name

Impartial Witness's signature & date:

Name of PI /CO-PI

Signature of PI/ Co-PI

Phone No. of PI & Co-PI

Contact No. of Institutional Ethics Committee

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. 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 study. 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 IRB 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 Form 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.

A Xerox copy of the Informed Consent Form(ICF) must be given to prospective participant.

A receipt of copy of ICF by the subject should be documented by the investigator in the source documents.

Copies of the consent form must be available in English & Hindi.

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 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. 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

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 5-18 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 have been 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, non-technical & direct language.

In addition, to record the same parameters daily your parent/ guardian will also be provided with a dairy 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. The document linking your name with the assigned study number will be kept for 5 years in a locked cabinet at the study site, after which the linking document will be destroyed. 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.

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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,

<Name of PI > **Phone**:<Contact No.>

If you have any queries regarding your medical rights and ethical responsibilities you may contact,

<Name of Secretary of IRB > **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 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 drugs/procedures/therapies/any other form of interventions.

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:

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/Therapy/Procedure/Any other form of Intervention

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 anytime and ask to see [names of Nurse, Doctor and 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 will 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 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 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.

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, 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 centre/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 IRB], 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 Member-Secretary, of the IRB-Institutional Ethics committee of R.D. Gardi Medical College, Ujjain

Dr. Phone:

Consent To Participate In Research & Authorization To Use And Share Personal Health Information: For Subjects less than 18 Years of Age

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

_____ _____

Signature of Subject (when appropriate) Date

_____ _____

Signature of Person Obtaining Consent/Authorization Date

_____ ____ _____

Signature of Witness Date