

Informed Consent Form Template

Instructions for use

This Informed Consent Form Template has been developed to aid investigators intending to carry out clinical research. It was originally published as the following reference: “*Shafiq N, Sidhu S, Pandhi P, Malhotra S. Informed consent form template for investigators conducting clinical research. Bulletin PGIMER 2005;39:106-111*”. It was subsequently modified following institutional ethics committee and Indian Council of Medical Research (ICMR) guidance. It attempts to include most of the necessary components as per the Drug Controller General of India (DCGI) and ICMR requirements. It can be downloaded from the institutional website and modified to meet the specific needs of any clinical study.

It broadly consists of two sections – Patient Information Leaflet and Informed Consent Form. The subsections in each section appear have been designed to make the research participant understand the procedures involved but can be altered, if necessary. Sponsor initiated studies provide the investigators with enough number of Patient Information Leaflets and Informed Consent Forms. A copy of the Patient Information Leaflet and the signed consent form should be retained with the investigators and one should be given to the study participant. The informed consent form should be signed in duplicate.

Investigator initiated clinical studies (including those of MD, DM, PhD students) are resource constrained and it may not be possible for these investigators to photocopy so many pages for all the participants. In such a case we suggest that the investigators may keep one copy of Patient Information Leaflet with them which they can use as a guide while explaining about the study to the participants. They should give the same to participants for reading on the spot as well. However, informed consent form (along with the page containing contact addresses) should be signed in duplicate and a copy should be given to each patient and another should be retained with the investigator.

Text in blue font is meant for pediatric studies and should be excluded in case of adult studies. For observational studies in nature or those in which only patient’s tissue, body fluids are collected for any kind of analysis, the following elements in the patient information leaflet will need be included - background of the study; the purpose for which the sample will be used; confidentiality of data and right to refuse to give specimens should be included. **Points 5,7,8,9,10,11,14 of consent document may be excluded in such cases (text in red font).**

Please clarify from the sponsor whether the selected participants will be covered by any kind of insurance cover? If so, a suitable clause requires to be incorporated in this document.

Information to participants and consent form

PROTOCOL NO:

SPONSOR:

INVESTIGATOR (Principal and at least one Co-Investigator):

Name of Participant: _____

Title: A single/multiple-center, randomized/non-randomized, double-blind/ open-label trial to determine the efficacy and safety of (name of the investigational drug/intervention/surgery) in patients with (*name of the condition*).

You are invited to take part in this research study. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

You are being asked to participate in this study being conducted in (name of the institution) because you satisfy our eligibility criteria which are:

(1) Diagnosis of (name of the disease)

(2) Age between ... to ... years

(3) No contraindication to the use of the agents to be used in the study, which means absence of any disease or condition likely to get worsened by the drugs under study, which are (mention contraindications for patient participation)

[(4) Neither pregnant nor breast-feeding in case of female patients.—If appropriate]

You will be one of the (give total number of patients to be enrolled in the study) patients we plan to recruit in this study. You will be assigned to either of the (two or more) study groups. One group of patients will receive standard medication(s), which are,,, plus(the investigational drug/intervention/surgery) while other group of patients will receive standard medication(s) and..... (placebo or any other control, which may be an active drug; if any other design is planned, describe here in a similar manner) . [For placebo - controlled studies, add the following statement: A placebo is an inactive or a dummy medication, which is given to increase the scientific validity of our study. Moreover, a placebo is needed so that it does not become known either to you or your investigator to which group you are being assigned. This method, in scientific terms is known as blinding. This is important for unbiased evaluation of the study medication.]

[For active-controlled studies, add: The drug/procedure/intervention is being used so that we can compare the effect of with our investigational drug/procedure/ intervention . When neither the investigator nor the patient knows who is getting which drug/procedure/ intervention, the study is called double-blind.]

What is the purpose of research?

..... (name of the condition) is a.....(common/uncommon/rare) disorder characterized by(important characteristic of the condition) . It usually presents as (symptoms) . These symptoms may last for (usual course of the disease). (You may add a few sentences to explain more about the disease).

..... (disease) is caused by (mention in simple words brief pathophysiology of the disease).

If not treated, the condition is known to lead to..... (consequence of the disease in terms of morbidity and mortality)

The present treatment for this disease includes , , and

We want to test the efficacy and safety of a new (drug/intervention/surgery) in this disease. This [new] (drug, intervention, surgery) has been found to possess good (activity/benefit) in earlier (animal/human) studies. The proposed benefit(s) of the (new drug, intervention, surgery) over the existing treatment include(s)

This [drug/intervention/surgery] has been shown to be well tolerated as shown in results obtained from earlier studies done in (animals/humans).

In the present study, we plan to see the effect of (combining this drug/intervention/surgery with already existing standard treatment Or new drug/intervention/surgery alone) in patients with

Information obtained from this study would be beneficial to other patients with (the same disease).

We have obtained permission from the Institutional Ethics Committee [and the Drug Controller General of India] for conducting this study.

The study design

All patients in the study will be divided into..... (two or more) groups. You will be assigned to either of the..... (two or more) groups. One group will receive (study drug and dose/intervention/surgery) and the other group(s) will receive[or] for a period of days. [Add, if necessary: Standard treatment will be given to all patients].

[For randomized studies, add: Which treatment group you will be assigned to will be determined purely by chance, which, in scientific language, is called 'randomization'. Randomization improves the scientific quality of research.]

This study will be [double-blind / single-blind / open-label]. This means that [neither the investigator nor you / the investigator (or you) will be aware of whether you are receiving or / it will be known to you as well as your investigator whether you are receiving..... or].

[Explain similarly if any other design is being used]

Study Procedures

The study involves evaluation of (investigational drug/intervention/surgery) for which we will be monitoring your (symptoms / blood or urine levels / ECG / MRI, etc).

[For studies in which a run-in period is being used, add: We will initially observe you for a period of days during which you will be given (investigational drug/dummy medication/no medication). If at the end of this period, you are found eligible, you will be randomized to either of the study groups.]

Once you are enrolled in the study, you will be required to follow the instructions..... [diet / take the drugs as instructed and detailed on the envelope / avoid alcohol / smoking / any other precautions]. You will be given (tablets / capsules / any other), which you will need to take times a day for (days /months/ years - in case of intervention/surgery modify this section accordingly).

You will be told about your visit schedules and you will have to report to the hospital (study site). The planned scheduled visits involve visits at , , and (days / weeks) after your initial visit. You will be required to visit the hospital number of times during the study.

You are not allowed to take any medications other than the ones prescribed by your investigator. If you need to take some treatment (drug / physiotherapy / other), you must consult your investigator before taking that treatment.

At each visit, the study physician will examine you. Some [blood / urine / other] tests will be carried out at each visit. [..... ml of blood will be collected at each visit. Blood collection involves prick with a needle and syringe.]

[You will have to refrain from smoking / alcohol / other for hours before giving blood. The potential risks of providing blood may occasionally include pain, bruising, fainting or a small infection at the puncture site]

These tests are essential to monitor your condition, and to assess the safety and efficacy of the treatment given to you.

In addition, if you notice any physical or mental change(s), you must contact the persons listed at the end of the document. [You will be required to return unused study medicines when you report for your scheduled visits. This will enable correct assessment of the study results.]

You may have to come to the hospital (study site) for examination and investigations apart from your scheduled visits, if required.

[For research excluding that on HIV, add: Current guidelines recommend that we test you for HIV before we enroll you in our study. If you are found HIV positive, we will not include you in our study. You are required to go through the separate information sheet for HIV testing and you will need to give a separate consent to allow us to do HIV testing on you. However, you will be given the report and advice for further treatment for HIV. Your report will be kept confidential]

Women of childbearing potential

You must not participate if you are pregnant, breastfeeding a child, or if you are of childbearing potential and not practicing two forms of effective methods of contraception. These forms could be either an oral contraceptive pill plus a condom or diaphragm; or two barrier methods (e.g. a condom and diaphragm). You may also consider participating, if you are surgically sterile or postmenopausal. If you become pregnant during the study, you or your unborn child may be exposed to risks, which are currently unknown.

Your urine will be tested for pregnancy at screening and at each visit for weeks. If the test is positive at any time, you will be withdrawn from the study.]

Possible risks to you

Some of the common adverse effects of standard therapy (drug / intervention / surgery) which will be given to you, include There are other side effects of these..... (drug(s)/intervention/surgery), which are..... (less / more common or are less / more severe in nature) and include

The study [drug / intervention / surgery] is a new treatment, and so far, in earlier studies, has not demonstrated side effects other than ,, and (symptoms, lab abnormalities) , which are [temporary, minor and self-limiting reversible on discontinuation of medicine / serious, may be irreversible]. Earlier data show that the levels of [AST / ALT / any other lab abnormality] came to normal after remaining elevated for [weeks / days] after completion of treatment. In case (any lab test report) continue to be abnormal, you will be withdrawn from the study .

[If this information is available, add: From the available data, only out of patients studied so far have experienced these side effects.] It is possible that other rare side effects could occur which are not described here.

Possible benefits to you

You are not expected to get any benefit from being on this research study, other than the treatment benefit and free investigations/tests.

Compensation

You will receive a sum of INR as compensation for the inconvenience and travel. This amount has been approved by the Institutional Ethics Committee. You will also benefit from being on this research study in terms of free treatment and free investigations/tests.

Possible benefits to other people

The results of the research may provide benefits to the society in terms of advancement of medical knowledge and/or therapeutic benefit to future patients.

[The sponsor of the research (write name of the pharmaceutical company or other sponsor) will also benefit from the results of study, if positive.]

The alternatives you have

If you do not wish to participate, you have the alternative of getting the standard treatment for your condition. At present, to the best of our knowledge, no other new agent is being tried out for research in humans.

Cost to the participant

You will not be required to pay for the medications or lab tests. [You will be paid for your traveling expenses / You will not be paid to participate in this research study.] In case of any adverse event occurring due to the study medications, you will be provided free treatment at our Institute and proper referral if necessary.

Who is paying for this research?

The (Pharmaceuticals, manufacturers of drug / ICMR / Any other agency) are the sponsors of the study and are paying for the research. [PGIMER receives money from the sponsor to conduct this study. The investigator or any of his/her team member does not receive any direct payment from the sponsor.]

What should you do in case of injury or a medical problem during this research study?

Your safety is the prime concern of the research. If you are injured or have a medical problem as a result of being in this study, you should contact one of the people listed at the end of the consent form. You will be provided the required care/treatment.

[Investigator to clarify from the sponsor whether the participants will be covered by any insurance cover. If so, please add: In case of injury, the participants are entitled to claim insurance provided by the sponsor. (The insurance policy may be shown to a legal expert)]

You will be entitled to your legal rights besides this.

Confidentiality of the information obtained from you

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you will be allowing the research team investigators, other study personnel, sponsors, institutional ethics committee and any person or agency required by law like the Drug Controller General of India to view your data, if required.

The results of clinical tests and therapy performed as part of this research may be included in your medical record. The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

How will your decision to not participate in the study affect you?

Your decision not to participate in this research study will not affect your medical care or your relationship with the investigator or the institution. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

Can you decide to stop participating in the study once you start?

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during the course of the study without giving any reasons. However, it is advisable that you talk to the research team prior to stopping the treatment. You may be advised about how best to stop the treatment safely. If you withdraw, you may be asked to undergo some additional tests to which you may or may not agree. Though advisable that you give the investigators the reason for withdrawing, it is not mandatory.

Can the investigator take you off the study?

You may be taken off the study without your consent if you do not follow instructions of the investigators or the research team or if the investigator thinks that further participation may cause you harm.

Right to new information

If the research team gets any new information during this research study that may affect your decision to continue participating in the study, or may raise some doubts, you will be told about that information.

Contact persons

For further information / questions, you can contact us at the following address:

Principal Investigator:

Dr.
Dept. of.....,
[Name and address of the institution] Ph:
Fax:

Co-Investigator

Dr.
Dept. of
[Name and address of the institution] Ph:
Fax:

Contact person(s):

Dr.
Dept. of
[Name and address of the institution] Ph:
Fax:
Email:

In case of conflicts, you can contact the chairperson (convener) of our institutional ethics committee at the following address:

Dr
Department of
Convener/Chairperson, Institutional Ethics Committee
PGIMER, Chandigarh
Telephone:
Fax:

Patient consent form

[Title of the study]

Name of the participant: _____

Name of the Principal (Co-) Investigator: _____

Name of the Institution: _____

Name and address of the sponsoring (funding) agency(ies): _____

Documentation of the informed consent

I, _____, have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in "....." (title of the study)

- (1) I have read and understood this consent form and the information provided to me.
- (2) I have had the consent document explained to me.
- (3) I have been explained about the nature of the study.
- (4) My rights and responsibilities have been explained to me by the investigator.
- (5) I have been advised about the risks associated with my participation in the study.
- (6) I have informed the investigator of all the treatments I am taking or have taken in the past months including any *desi* (alternative) treatments.
- (7) I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.
- (8) I have not participated in any research study within the past month(s).
- (9) [I have not donated blood within the past months — Add if the study involves extensive blood sampling]
- (10) I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in the hospital.
- (11) I am also aware that the investigators may terminate my participation in the study at any time, for any reason, without my consent.
- (12) I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Government agencies, and ethics committee. I understand that they may inspect my original records.
- (13) My identity will be kept confidential if my data are publicly presented.
- (14) If, despite following the instructions, I am physically harmed because of any substance or any procedure as stipulated in the study plan, [my treatment will be carried out free at the investigational site / the sponsor will bear all the expenses], if they are not covered by my insurance agency or by a Government program or any third party.
- (15) I have had my questions answered to my satisfaction.
- (16) I have decided to be in the research study.

I am aware, that if I have any questions during this study, I should contact at one of the addresses listed above. By signing this consent form, I attest that the information given in this document and the HIV consent form has been clearly explained to me and apparently understood by me. I will be given a copy of this consent document.

For adult participants

Name and signature / thumb impression of the participant (or legal representative if participant incompetent):

_____ (Name) _____ (Signature)

Date: _____ Time: _____

Name and signature of impartial witness (required for illiterate patients):

_____ (Name) _____ (Signature)

Date: _____ Time: _____

Address and contact number of the impartial witness: _____

Name and signature of the Investigator or his representative obtaining consent:

_____ (Name) _____ (Signature)

_____ (Date)

For children being enrolled in research

Whether child's assent was asked: Yes No (Tick one)

[If the answer to the above question is Yes, write the following phrase:

You agree with the manner in which assent was asked for from your child and given by your child. You agree to have your child take part in this study.]

[If answer to the above question is No, give reason(s):

Although your child did not or could not give his or her assent, you agree to your child's participation in this study.]

Name and signature / thumb impression of the participant's parent(s) (or legal representative):

_____ (Name) _____ (Signature)

_____ (Name) _____ (Signature)

Date: _____ Time: _____

Name and signature of impartial witness (required if parents of participant child illiterate):

_____ (Name) _____ (Signature)

Date: _____ Time: _____

Address and contact number of the impartial witness: _____

Name and signature of the Investigator or his representative obtaining consent:

_____ (Name) _____ (Signature)

_____ (Date)]

Investigator Certificate

I certify that all the elements including the nature, purpose and possible risks of the above study as described in this consent document have been fully explained to the subject. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate,

Signature of the Investigator: _____

Dated: _____

Name of the Investigator: _____