AN7-V1/KSSSCISOP 03/V1

Guidelines for Devising a Participant / Legally Acceptable Guardian Information Document (PID) in English

Kindly refer to Table 3.2 for the essential elements of an informed consent document. For example, of PID in non-interventional studies, see appendix (AP7/V1). For 'Recommended Terms for use in Informed Consent Document', see appendix (AP12/V1)

1. Study Title

Is the title self-explanatory to a lay person? If not, an additional simplified title may also be included.

2. Invitation Paragraph

You should explain that the Participants is being asked to take part in a research/trial study. "You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part."

3. What is the purpose of thestudy?

The background and aim of the study should be given here.

4. Why have I beenchosen?

You should explain how and why the Participants/volunteer was chosen and how many other participants will be studied.

5. Do I have to takepart?

You should explain that taking part in the research/trial is entirely voluntary. States:

"It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive."

6. What will happen to me if I take part?

You should say how long the participants will be involved in the research/trial, how long the research/trial will last (if this is different), how often they will need to visit the hospital/lab or a clinic (if this is appropriate) and how long these visits will be. You should explain if the Participants will need to visit the doctor (or clinic) more often than for the usual treatment and if travel expenses are available. What exactly will happen e.g. blood tests, x-rays, interviews etc.? Whenever possible you should draw a simple flow chart or plan indicating what will happen at each visit. What are the Participants's responsibilities? Set down clearly what you expect of them in the form of simple instructions, for example asking them to come to the clinic at 8.00 am without having eaten anything/on an empty stomach/fasting. You should explain simply and briefly the research/trial methods you intend to useStates:

Randomized Trial: Sometimes, because we do not know which way of treating Participantss is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer, which has no information about the individual –

i.e. by chance. Participantss in each group then have a different treatment and these are compared. This way, the chances of something happening as a result of our choosing to put you in a specific group or bias is reduced. You should tell the Participantss what chance they have of getting the study drug/treatment: e.g. a one in four chance.

Blind Trial: In a blind trial you will not know which treatment group you are in. If the trial is a double-blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so). This is done to ensure that the trial is carried out without a bias that may result from knowing which group you are in, which can adversely affect theresults.

Cross-over Trial: In a cross-over trial both the groups have the different treatments in turn. There may be a break between treatments, a washout period, so that the effects of the first drug or treatment are cleared from your body before you start the new treatment.

7. What do I have todo?

Are there any lifestyle restrictions? You should tell the participants if there are any dietary restrictions. Can the Participants drive? Drink? Take part in sport? Can the Participants continue to take his/her regular medication? Should the Participants refrain from giving blood? What happens if the Participants becomes pregnant?

Explain (if necessary) that the Participants should take the medication regularly and dangers of non-compliance.

8. What is the drug or procedure that is being tested?

You should include a short description of the drug or device and give the stage of development. You should also state the dosage of the drug and method of administration. participants entered into drug trials should preferably be given a card (similar to an identify card) with details of the trial they are in. They should be asked to carry it at all times.

9. What are the alternatives for diagnosis or treatment?

For therapeutic research/trial the participants should be told what other treatment options are available.

10. What are the side effects of taking part?

For any new drug or procedure, you should explain to the participants the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned or in case of emergency. The known side effects should be listed in terms the participants will clearly understand (e.g. 'damage to the heart' rather than 'cardiotoxicity'; 'abnormalities of liver tests' rather than 'raised liver enzymes'). For any relatively new drug it should be explained that there may be unknown side-effects.

11. What are the possible disadvantages and risks of taking part?

For studies where there could be harm to an unborn child if the participants were pregnant or became pregnant during the study, States:

"It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should woman who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the investigator.

Use the pregnancy statement carefully. In certain circumstances (e.g. terminal illness) it would be inappropriate and insensitive to bring up pregnancy.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of fetal damage.

If future insurance status, e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected). If the Participantss have private medical insurance, you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should clearly state what will happen if you detect or find a condition of which the Participants was unaware. It is treatable? What are you going to do with this information? What might be uncovered (e.g. high blood pressure, HIVstatus)?

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the participants from taking part in the trial this should be stated clearly.

It is important not to exaggerate the possible benefits to the participants during the course of the study, e.g. saying they will be given extra attention. States:

"We hope that both (all) the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future Participantss with (name of condition) better".

13. What if new information becomesavailable?

If additional information becomes available during the course of the research/ trial, you will need to tell the participants about this. States:

"Sometimes during the course of a research project/trial, new information becomes available about the treatment/drug that is being studied. If this happens, your research/trial doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research/trial doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form.

Also, on receiving new information your research/trial doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue."

14. What happens when the research/trial study stops?

If the treatment will not be available after the research/trial finishes this should be explained to the participants. You would also explain to them what treatment will be available instead. Occasionally the company sponsoring the research/trial may stop it. If this is the case the reasons should be explained to the participants.

15. What if something goes wrong?

You should inform participantshow complaints will be handled and what addresses may be available. Is there a procedure in place? You will need to distinguish between complaints from participantsas to their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the trial, i.e. a reportable serious adverse event. You should incorporate following line in PID "In case of study related injury or death, (name of CRO/ company), will provide the complete medical care as well as compensation for the injuries or deaths".

16. Will my taking part in this study be kept confidential?

You will need to obtain the participants permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. "If you consent to take part in the research/trial any of your medical records may be inspected by the company sponsoring (and/or the company organizing) the research/trial for purposes of analyzing the results. They may also be looked at by people from the company and from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/clinic/laboratory"

"All information collected about you during the course of the research/trial will be kept strictly confidential. Any information which leaves the hospital/clinic/laboratory will have your name and address removed so that you cannot be recognized fromit."

17. What will happen to the results of the research/trial study?

You should be able to tell the participants what will happen to the results of the research/trial. You might add that they will not be identified in any report/publication.

18. Who is organizing and funding the research/trial?

The information should include the organization or company sponsoring or funding

the research/trial (e.g. Govt. agency, pharmaceutical company, NGO, academic institution).

The participants should be told whether he has to pay for drugs/tests, the doctor conducting the research/trial is being paid for including and looking after the participantsin the study. The information regarding payment and compensation should be included in PID.

19. Will the drug be made available after trial is over? (new drug requires continued use, till it is marketed in India)

Please explain to participant regarding the query of availability of study drug.

20. Who has reviewed thestudy?

You may should mention that IEC has reviewed and approved the study (you should not however list the members of the Committee).

21. Contact for further information

You should give the participantsa contact address for further information. This can be your name or that of another doctor/nurse involved in the study. **Name of the PI, Address, Telephone Numbers and Name of the Member Secretary of Ethics Committee and address with telephone numbers.**

Remember to thank your Participants for taking part in the study!

The PID should be dated and given a version number. It should state that the participant will be given a copy of the information sheet and the signed consent form.

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Signature of PI

Name_____ **Date**_____

Department_____