**Patient Information Sheet Guide**

**Note to Researchers**

This template Participant Information Sheet (PIS) is suitable for use in adults who are capable of giving consent. Guidance on additional Participant Information Sheets (eg information sheets for children or adults that are incapacitated) can be obtained from the Research Governance Team via researchgovernance@abdn.ac.uk.

The following Participant Information Sheet should be tailored to your project. Not all sections will be relevant to each project. Headings 1, 2, 3, 4, 5, 6, 10, 12, 14, 15, 16, 17, 18, 19 and 20 shall **always** be included within the information sheet.

The first page should be printed on headed paper that contains the Sponsor’s logo(s). Charity or patient group logos etc may also be used to indicate that they have endorsed the project. The document should contain a version number and date that appears on every page; this should be added in the header or footer. The PIS must also include the IRAS reference number. Page numbers should also be included in the format ‘page x of y’.

The Chief Investigator **must** be named on the first page.

It is imperative that lay language is used throughout the document. Any abbreviations or acronyms shall be fully explained.

Use the provided headings as appropriate.

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|  | **Study title and Chief Investigator** |
|  | Is the title self-explanatory to a lay person? If not,a simplified title should be included. Please ensure that the title is the same as the title used in the protocol. Please also name the Chief Investigator.  |
|  | **Invitation paragraph (may be amended to ‘introduction’ if preferred)** |
|  | This should explain that the participant is being asked to take part in a research study. The following is a suitable example:*‘You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others, such as your GP and relatives, 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 you wish to take part. Thank you for reading this.’* |
|  | **What is the purpose of the study?** |
|  | The background and aim of the study should be given here in lay man terms. Also, mention the duration of the study and the length of time that the participant will be involved in the study for. |
|  | **Why have I been chosen?** |
|  | You should explain why the participant has been chosen and how many other participants will be included. |
|  | **Do I have to take part?** |
|  | You should explain that taking part in the research is voluntary. The following is a suitable example:*‘No. It is up to you to decide whether 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. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.’* |
|  | **What will happen to me if I take part?** |
|  | You should say how long the participant will be involved in the research, how long the research will last (if this is different), how often they will need to visit a clinic (if this is appropriate) and how long these visits will be. * You should explain if the participant will need to visit their consultant/GP/clinic more often than for his/her usual treatment and if travel expenses are available.
* What exactly will happen eg interventions such as blood tests (give clear details of what the blood samples are for, how much blood will be taken at each visit and whether the participant will have to fast overnight), X-rays or scans, (give clear details of what type of X-rays/scans and whether or not they will involve additional injections) etc.
* In the case of interviews, participants should be made aware if these will involve video/audio-taping or photography*.* If interviews will be transcribed by an external company, the participant must be made aware of this and their consent must be given to do so.
* Some studies may require the participant to complete Quality of Life questionnaires, MMSE (Mini Mental State Exam) etc. It is worth reminding the participants to bring their reading glasses with them in such cases.
* Some studies may require the participant to do ‘a walk test’ or use a treadmill– in this case they should be asked to wear appropriate footwear and clothing.
* It should be clear to the participant in the description of study procedures whether: new samples will be taken (eg blood, tissue, specifically for this study) or samples excess to a clinical procedure will be taken. You should inform the participant if you intend to do any genetic testing on the samples.
* If you plan for any samples to go into a Biorepository or existing tissue bank this should be documented.
* Long-term monitoring/follow-up should be mentioned. You should explain other essential study requirements, eg keeping diaries, filling questionnaires.
* You should consider whether any vouchers, gifts, etc which you are intending to give as a ‘thank-you’ for participation, should be detailed in the information sheet.
* Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit. What are the participant’s responsibilities? Set down clearly what you expect of them.
* Are there any lifestyle restrictions while taking part in the study? For example dietary and alcohol restrictions. Can the participant drive? Drink? Take part in sport? Can the participant continue to take their regular medication? Should the participant refrain from giving blood? What happens if the participant becomes pregnant?
* Explain (if appropriate) that the participant should take the medication regularly and return all unused medication/empty containers at the next clinic visit if appropriate.
* Explain if the participant will be contacted again in the future to take part in any further research for this study or others as appropriate.
* Explain that if a participant withdraws then the data collected up until the point of withdrawal may still be used in analysis.
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|  | **What is the drug 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 be given a card (similar in size to a credit card) with details of the trial they are in, the name of the local Investigator and an emergency contact number. They should be asked to carry it at all times.
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|  | **What are alternatives for diagnosis or treatment?** |
|  | For therapeutic research, the participant should be told what other treatments are available, or if they will be exempt from any particular treatment. |
|  | **What are the side effects of any treatment received when 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 or immediately if these side effects are serious. (As per the instructions on the study card mentioned in section 7). * The known side effects of the drug should be listed in terms the participant will clearly understand (eg ‘damage to the heart’ rather than ‘cardiotoxicity’; “Low blood pressure” rather than ‘hypotension’, ‘abnormal liver function blood tests’ rather than ‘raised liver enzymes’). Additionally, for any relatively new drug, it should be explained that there might be unknown side effects. Therefore it is recommended that participants notify investigators of any new or unusual symptoms, however trivial.
* You should inform the participant if they are unable to take certain medications, food supplements, herbal remedies etc. You should also make them aware if any food substances/alcohol should be avoided.
* If X-rays are used as part of the study procedures, participants must be made aware of any potential hazards and whether or not the radiation dosage is different from standard X-rays.
* If the ionising radiation is part of the research study, then information must be given to the participant on any radiation involved and dosage (whether part of standard care or the research protocol), in everyday terms that they can understand.
* MRI / PET-CT – If MRI/PET-CT are to be used as part of the study procedures this should be detailed as should the inclusion of any contrast or imaging agents. If these have side effects, these should be listed also.
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|  | **What are the possible disadvantages and risks of taking part?** |
|  | Any risks, discomfort or inconveniences should be clearly outlined. All potential side effects and risks of taking part in the study should be detailed eg additional visits, risk of infection, exposure to radiation etc. If future insurance status eg for life insurance or private medical insurance, could be affected by taking part this should be stated (if eg high blood pressure is detected.) If the participants 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 state what happens if you find a condition of which the participant was unaware. Is it treatable? What are you going to do with this information? What might be uncovered? |
|  | **Harm to the unborn child: Therapeutic Studies** |
|  | For studies where there could be harm to an unborn child if the participant were pregnant or became pregnant during the study, or where a male participants partner could become pregnant the following (or similar) should be said:***For women:****‘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 women 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 tell her research doctor. It may be that access to your medical records and/or those of the child is required.’****For men:****‘It is possible that this treatment could damage sperm and possibly harm an unborn child. Partners of pregnant women must not therefore take part in this study; neither should partners of women who plan to become pregnant during this study. If you decide to take part in the study, you must agree to use effective contraception. If your partner should become pregnant you should advise the research team.* *It may be that access to your medical records, your partner’s medical records and/or those of the child is required.’* |
|  | **What are the possible benefits of taking part?** |
|  | Where there is no intended clinical benefit to the participant from taking part in the trial this should be stated clearly.It is important not to exaggerate the possible benefits to the particular participant during the course of the study, eg by saying they will be given extra attention. This could be seen as coercive. It would be reasonable to say something similar to:*‘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 participants with (name of condition) better.’* |
|  | **What if new information becomes available?** |
|  | If additional information becomes available during the course of the research, you will need to tell the participant about this. You could use the following: -*‘Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research 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 doctor will arrange for your care to continue. If you decide to continue in the study, you will be asked to read a new information sheet and sign an updated consent form.**In addition, on receiving new information your research 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.’* |
|  | **What happens when the research study ends?** |
|  | If the treatment will not be available after the research finishes this should be explained to the participant. You should also explain to them what treatment would be available instead. Occasionally, the company sponsoring the research may stop it. If this is the case, the reasons should be explained to the participant. |
|  | **What if something goes wrong?** |
|  | You should inform participants how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from participants as to their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the trial ie a reportable serious adverse event. **For CTIMPS and high risk studies (eg surgical intervention, device trial etc)***If you are harmed due to someone’s negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms (or equivalent University complaints mechanisms) should be available to you.***All other research** *If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can do this [insert details eg NHS complaints procedure or UoA complaints procedure. Contact details for these services should also be given].* |
|  | **Will my taking part in this study be kept confidential?****You should always bear in mind that you, as the researcher, are responsible for ensuring that when collecting or using data, you are not contravening the legal or regulatory requirements in any part of the UK. As of 25th May 2018, the new General Data Protection Regulation (GDPR) and the Data Protection Act 2018 came into force. As part of this legislation, researchers are required to insert information to fulfil transparency requirements for health and care research.** **The text to be inserted can be found on the HRA website:** [**https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/**](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/)**The link to the University of Aberdeen privacy policy is available here:** [**http://www.abdn.ac.uk/privacy**](http://www.abdn.ac.uk/privacy)**The recommended transparency wording must be included in the PIS. Sections A, B or C should be added if applicable to the project. Checks will be made throughout the approval process and failure to comply with this will result in delays for the project. If you require any further help or guidance please contact** **researchgovernance@abdn.ac.uk** **for advice.**  |
|  | You will need to obtain the participant’s permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You will also need to obtain consent from the participant for storing their electronic data on either a University or NHS server. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for Commercial Company sponsored research is: *‘If you consent to take part in the research, any of your medical records may be inspected by the company sponsoring (and/or the company organising) the research for purposes of analysing 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/GP surgery.’*Alternatively, for other research:*‘All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.’*If you are recruiting NHS patients as participants, all identifiable data must be kept and stored securely within the NHS. If you intend on keeping patient identifiable data within the University of Aberdeen or on a University computer, you **must** make the participant aware of this in the information sheet and seek consent to do so on the informed consent form before any data is transferred. It must be clear if the data and/or samples are to be retained for use in future studies and whether further REC approval will be sought. You should explain if the participant’s GP (or other health care practitioner) needs to be notified of their participation, and seek consent for this. |
|  | **What will happen to the results of the research study?** |
|  | You should be able to tell the participants what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which arm of the study they were in? You should also add that they would not be identified in any report/publication. |
|  | **Who is organising and funding the research?** |
|  | The answer should include the organisation funding the research (eg Medical Research Council, Pharmaceutical Company, charity, academic institution and the organisation sponsoring the study). For an academic study this may be the University of Aberdeen or NHS Grampian either solely or jointly.The participant should be told whether the doctor conducting the research is being paid for including and looking after the participant in the study. **This means payment other than that to cover necessary expenses** such as laboratory tests arranged locally by the researcher, or the costs of a research nurse.  |
|  | **Who has reviewed the study?** |
|  | You should give the name of the Research Ethics Committee(s) which reviewed the study for example the North of Scotland Research Ethics Committee, which is the local committee, or a University Ethics Committee. |
|  | **Contact for Further Information** |
|  | You should give the participant a contact point for further information. * This can be your name or that of another doctor/nurse involved in the study.
* The participant can be given further information on participating in Clinical Trials eg The UK Clinical Trials Gateway website: [https://www.ukctg.nihr.ac.uk/](https://www.ukctg.nihr.ac.uk/%20%20)
* Remember to thank your participant for considering taking part in this study!
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| ***The Participant Information Sheet must be dated and given a version number.*** |