**Guide to Writing a Participant Information Sheet**

The principles of this guidance should be used as a guide for writing participant information sheets for research, which involves patients, patient volunteers and/or healthy volunteers.

 **A INTRODUCTION**

1. Potential recruits to research studies must be given sufficient information to allow them to decide whether or not they want to take part. A Participant Information Sheet should contain information under the headings given below, where appropriate, and in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Short words, sentences and paragraphs should be used. ‘The readability’ of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most word processing packages. The language used should be invitational and not coercive or overly persuasive. It is good practice to try out the information sheet on representatives of the group likely to be recruited and where possible to involve representatives in the writing of the information sheet.

1. If you are the Principal Investigator, the Participant Information Sheet should be printed on local hospital/surgery paper with local contact names and telephone numbers before it is submitted to the host organization for any locality assessment or for Trust local capacity and capability review. If after reading this guide anything is unclear, or you would like to discuss writing a Participant Information Sheet further, please contact a member of the Research Governance and Integrity Team (RGIT) who will be able to clarify any queries (see contact details in SOP for Informed Consent).

 **B. PROCEDURES**

 **i.** Each Participant Information Sheet must have a version number and date in the footer.

* **Study title**

The document should be headed ‘Patient Information Sheet’ or ‘Participant Information Sheet’ where the participants are not patients.

Is the title self explanatory to a lay person? If not, a simplified title should be included (usually the simplified title given on the Research Ethics Committee (REC) application). One consistent title for the study should appear on all the documents. It must have the version number to track any changes made.

* **Invitation paragraph**

This should explain that the subject 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 if you wish.*

*(You may wish to split your information sheet into Part 1 and Part 2):*

*Part 1 tells you the purpose of this study and what will happen to you if you take part.*

*Part 2 gives you more detailed information about the conduct of the study*

*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.*

*Thank you for reading this.’*

* **What is the purpose of the study?**

The background and aim of the study should be given here. The purpose should be brief, but informative and should not mislead.

If the study is being conducted for a student research project, this should be stated here.

* **Why have I been chosen?**

You should explain how the subject was chosen and how many other participants will be studied. This is particularly important if the participant has been approached by someone other than the clinician responsible for their care.

* **Do I have to take part?**

You should explain that taking part in the research is entirely voluntary. You could use the following paragraph:-

*‘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. 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 include:

* 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)
* how long these visits will be.
* what exactly will happen e.g. blood tests, X-rays, (over and above those involved in standard diagnosis and treatment), interviews etc.?

If the subject will need to visit the GP (or clinic) more often than for his/her usual treatment, this should be explained here, and whether travel expenses are available. Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit. What are the subject’s responsibilities? Set down clearly what you expect of them.

You should set out simply the research methods you intend to use - the following simple definitions may help:-

Randomised Trial:

*‘Sometimes because we do not know which way of treating patients 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. Subjects in each group then have a different treatment and these are compared’.*

You should tell the subjects 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)’.*

Cross-over trial:

*‘In a Cross-over trial the groups each have the different treatments in turn. There may be a break between treatments so that the first drugs are cleared from your body before you start the new treatment’.*

Placebo:

*‘A placebo is a dummy treatment such as a pill which looks like the real thing but is not. It contains no active ingredient’.*

Specific consent is needed if the study will involve videoing, audiotaping, or photography. The confidentiality issues should also be discussed.

Expenses and Payments: If the participant needs to make more visits because of the study than they would usually have done as part of their usual treatment, it should be specified whether expenses such as travel will be provided.

* **What do I have to do?**

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

Explain (if appropriate) that the subject should take the medication regularly as directed. It should also be explained that they should not normally be involved in any other drug studies at the time.

* **What is the drug or intervention that is being tested?**

You should include a short description of the drug, device or treatment and give the stage of development, process and what the treatment does.

You should also state the dosage of the drug and method of administration. They should be told if there are any contraindicated drugs. Subjects entered into drug trials should be given a card (similar to a credit card) with details of the trial they are in. They should be asked to carry it at all times.

* **What are the alternatives for diagnosis or treatment?**

For therapeutic research the subject should be told what other treatments are available. For multi-site studies the Chief Investigator should check on local variations in alternative treatments, and the relevant information can then be given to participants at each site.

* **What are the side effects of any treatment received when taking part?**

For any new drug or procedure you should explain to the subjects 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. The name and number of the person to contact in the event of an emergency (if that is different) should also be given.

The known side effects should be listed in terms the participant 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.

Good Clinical Practice also requires that participants should be told about ‘reasonably foreseeable risks’, with the information prioritised in terms of seriousness, severity and frequency. This should reflect what a reasonable person would expect to be mentioned i.e. rare side effects should be mentioned if they may be serious or permanent.

For very new or potent investigational drugs, a fuller list of suspected side-effects might be appropriate. If participants suffer these or any other symptoms, they should be given clear guidance on when, how and whom to report them to.

 • **What are the possible disadvantages and risks of taking part?**

For studies where there could be harm to an unborn child if the subject were pregnant or became pregnant during the study, the following (or similar) should be said:

*‘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.’*

The pregnancy statement should be used with sensitivity and should include information on what happens if they do become pregnant.

Consideration of appropriate contraception methods (as per the MHRA guidance if applicable) should also be noted.

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 a damaged foetus.

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 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?

 • **What are the possible benefits of taking part?**

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

It is important not to exaggerate the possible benefits to the particular patient during the course of the study, e.g. by saying they will be given extra attention, and to emphasise that there is no guarantee that they will experience a benefit. This could be seen as coercive. It would be reasonable to say something similar to:

*‘We cannot promise the study will help you but the information we get might help improve the treatment of people with (name of condition)’*

What if new information becomes available?

If additional information becomes available during the course of the research you will need to tell the subject 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 make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.*

Also, 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.’

It should also be described what will happen if any incidental findings are discovered and the reporting mechanism and procedure for these.

* **What happens when the research study stops?**

The arrangements after the trial must be given, especially if this differs from that normally expected for their medical condition. If the treatment will not be available after the research finishes this should be explained to the subject. You should also explain to them what treatment will be available instead. Occasionally if an external company is sponsoring the research the Sponsor may decide to stop it. If this is the case the reasons should be explained to the subject.

You should consider whether and when it may be possible to tell participants which arm of the study they were in.

* **What if something goes wrong?**

You should inform subjects 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 subjects as 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.

 For **Imperial College London** sponsored studies select one of the following / applicable indemnity clauses

1. **Where studies involving invasive clinical procedures on human participants, eg medicines, radiation, MRI, tissue or blood samples, the following (or similar) should be said**:

*‘Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.*

*If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team’.*

1. **Where studies involving invasive clinical procedures on human participants that are conducted on potentially excluded participants, ie HIV/AIDS, CJD, Hepatitis studies the following (or similar) should be said**:

*‘Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault.*

*This provision does not apply to claims which arise as a result of Hepatitis, Creutzfeldt-Jakob Disease, HIV/AIDS (DELETE AS APPROPRIATE) or any related conditions.*

*This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service complaint mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.’*

1. **Where Studies involving human participants, requiring ethics, which do not involve invasive clinical procedures, eg tissue bank studies, studies involving discarded excess tissue, questionnaires, the following (or similar) should be said**:

*‘If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service complaints mechanisms are also available to you.’*

For **Imperial College Healthcare Trust** sponsored studies use the following indemnity clause:-

*‘Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS resolution for NHS Trusts in England, which apply to this study. This does not affect your legal rights to seek compensation.*

*If you are harmed due to someone’s negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator*

*The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Research Governance and Integrity Team.’*

**HRA GDPR Approved wording for summary PIS**

If you are providing a summary information sheet, under GDPR the following phrases should be use as applicable.

Black = Wording which is not optional

Red = Wording which can be amended/deleted to study specifics

Blue = Optional wording according to the study specifics

**Summary Information sheet (for use only if you are using a summary information sheet)**

**Research Study Title: [insert title]**

**Summary sheet**

[insert ID if applicable e.g. IRAS ID or other relevant ID]

**(For College and Trust Sponsored Studies)**

In this research study we will use information from [you] [your medical records] [your GP] [**OTHER**]. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. **(For College Sponsored Studies only)** These will include Imperial research Team members and support staff

**For Trust Sponsored/College Sponsored delete as applicable)** Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules/Everyone involved in this study will keep the data collated as part of this study, including your personal data, safe and secure. We will also follow all privacy laws and legislation that are relevant to the specifics of the study.

At the end of the study we will save some of the data [in case we need to check it] **AND/OR** [for future research].
We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

**HRA GDPR Approved wording in the PIS or document provided to participants**

Under GDPR the following phrases should be use as applicable. The black wordings are mandatory (remain unchanged) and red wording should be amended/deleted as needed. Blue wording are optional.

**HOW WILL WE USE INFORMATION ABOUT YOU?**

Research Study Title: [insert title]

[insert ID if applicable e.g. IRAS ID or other relevant ID]

**(For College sponsored studies only)**

Imperial College London is the sponsor for this study and will act as the Data Controller/Joint-Controller with ‘THIRD PARTY ORGANISATION NAME’ for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for:

* [insert number of years] after the study has finished in relation to data subject consent forms.
* [insert number of years] after the study has completed in relation to primary research data.

The study is expected to finish in Month / Year

For more information / confirmation regarding the end date please contact the study team, see ‘**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED’** for contact information.

**(For College and Trust Sponsored Studies)**

We will need to use information from [you] [from your medical records] [your GP] [**OTHER**] for this research project.

This information will include your [initials/ NHS number/ name/ contact details/ **provide a bullet list of identifiers held by site and/or sponsor for the research**].

People **(for College sponsored studies use highlighted wording, delete highlighted section here for Trust sponsored)** within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact) details is accurate

**OPTION where applicable:** People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

**OPTION where applicable**: Some of your information will be sent to [**country X**]. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**(For College Sponsored Studies Only)**

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research.  This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - “performance of a task carried out in the public interest”); Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)
• **OPTION if a third party that is not a public authority and will be a data controller** ‘THIRD PARTY ORGANISATION NAME’– legitimate interests held by the data controller or a third party

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), (both organisations / Imperial College London) rely/relies on “scientific or historical research purposes or statistical purposes

**INTERNATIONAL TRANSFERS**

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

**SHARING YOUR INFORMATION WITH OTHERS**

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

* Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
* the following Research Collaborators / Partners in the study (NON OPTIONAL IF THIRD PARTIES INVOLVED OR EXPECTED);
* Third Party University – explain what data and why it will be shared
* Third Party Company – explain what data and why it will be shared
* Third Party Government department – explain what data and why it will be shared

**POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH**

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

**COMMERCIALISATION**

Samples / data (delete as required) from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate ‘personal data’.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

**(For Trust and College Sponsored Studies)**

**WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. **(For College Sponsored Studies only)** because some research using your data may have already taken place and this cannot be undone.

* **OPTION if follow up data will be collected after withdrawal:** If you choose to stop taking part in the study, we would like to continue collecting information about your health from [central NHS records/ your hospital/ your GP]. If you do not want this to happen, tell us and we will stop. (**For College Sponsored studies only)** This will not affect any healthcare or support you may be receiving separately
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you. **(For College sponsored Studies only)** if this could affect the wider study or the accuracy of data collected.
* **OPTION if data will be used for future research:** If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. [**Insert details of any specific bank/ repository**]

**(For Trust and College sponsored Studies)**

**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED**

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* **OPTION** our leaflet available from [**X**]
* by asking one of the research team
* by sending an email to [**email**], or
* by ringing us on [**phone number**].
* **OPTION** Link to Research website – if there is one

**(For College Sponsored studies only)**

**COMPLAINT**

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to [**email**], or by ringing us on [**phone number**].

Following our response, if you are not satisfied please contact Imperial College London’s Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO)- via [www.ico.org.uk](http://www.ico.org.uk). Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

* **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 might add that they will not be identified in any report/publication.

* **Who is organising and funding the research?**

The answer should include the organisation or company sponsoring or funding the research (e.g. Medical Research Council, Pharmaceutical Company, charity, academic institution).

The subject should be told whether the doctor conducting the research is being paid for including and looking after the subject 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. You could say:-

*‘The sponsors of this study will pay (name of hospital department or research fund) for including you in this study’ or*

*‘Your doctor will be paid for including you in this study.’*

* **Who has reviewed the study?**

You may wish to give the name of the Research Ethics Committee which reviewed the study (you do not however have to list the members of the Committee). E.g. This study was given a favourable ethical opinion for conduct in the NHS (or private sector) by xxxx REC.

**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 (who must have sufficient knowledge/understanding of the study in order to deal with any questions/problems that may arise). For CTIMP only, you should also provide a 24hr contact number should the participant wish to speak to a member of the study team. The following wording can be used.

Please contact xxx on the following 24-hour contact details:

Name: xxxx

Telephone: xxx

Email (if applicable): xxx

Note, the 24 hour contact number is optional for non-ctimp studies.

Remember to thank the participant for taking part in this study!

The Participant Information Sheet should be dated and given a version number.

The Participant Information Sheet should state that a copy of the written information and signed Informed Consent form will be given to the participant to keep.