**Guide to Writing a Participant Information Sheet for Healthcare related Research**

* **Study title**

*The document should be headed ‘Participant Information Sheet’.*

*Is the title self-explanatory to a lay person? If not, a simplified title should be included. One consistent title for the study should appear on all the documents. It must have the version number to track any changes made.*

*Below the title add the PI name and the collaborators and coinvestigators names*

* **Invitation paragraph**

*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 if you wish.

*Invitation paragraphs can be adapted to suit the research study, consider a COVID-19 study for example* “We are sorry that you have been admitted to hospital with a diagnosis of COVID-19; this must be very worrying for you and your family. It is difficult to ask anything of you at the moment but we really need your help. In truth we know little about the virus which is why we are conducting research. This is where you could help…”

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 invited?**

You should explain how the participant was invited and how many other participants will be studied.

* **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.

* **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 the site (if this is appropriate)
* how long these visits will be?
* what exactly will happen e.g. blood tests, X-rays), interviews, focus groups etc.?
* **What do I have to do?**

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

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

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 participant from taking part in the study this should be stated clearly.

It is important not to exaggerate the possible benefits to the particular participant 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 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 i.e. a reportable serious adverse event.

For survey studies where participants are entirely anonymised (i.e. anonymous surveys) the wording in this section is not required.

Where there are no-fault compensation arrangements, and the study carries risk of physical or significant psychological harm, the following (or similar) should be said:

1. **Studies involving invasive clinical procedures on human participants, e.g. medicines, radiation, MRI, tissue or blood samples**

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). If you are still not satisfied with the response, you may contact the Imperial College Research Governance and Integrity Team (rgitcoordinator@imperial.ac.uk)

1. **Studies involving invasive clinical procedures on human participants that are conducted on potentially excluded participants, i.e. HIV/AIDS, CJD, Hepatitis studies**

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)*. If you are still not satisfied with the response, you may contact the Imperial College Research Governance and Integrity Team (rgitcoordinator@imperial.ac.uk).

1. **Studies involving human participants, requiring ethics, which do not involve invasive clinical procedures, e.g. tissue bank studies, studies involving discarded excess tissue, questionnaires**

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).  If you are still not satisfied with the response, you may contactthe Imperial College Research Governance and Integrity Team (rgitcoordinator@imperial.ac.uk).

* **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. If you are sending participants data, tell them if it is their individual data or grouped study data.

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

The answer should include the organisation or company sponsoring or funding the research (e.g. charity, academic institution including department name).

* **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 favourable opinion by Imperial College Research Ethics Committee (ICREC) and approval by (individuals name), Head of Department (name the department) / This study was given approval by (individuals name), Head of Department (name the department) and Research Governance Integrity Team (RGIT).

**Contact for Further Information**

You should give the participant a contact point for further information. This can be your name or that of another researcher involved in the study (who must have sufficient knowledge/understanding of the study in order to deal with any questions/problems that may arise). You should also provide a 24hr contact number should the participant wish to speak to a member of the study team.

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*.*

**Transparency Notice**

Black = mandatory wording

Red = Wording which is able to be amended/deleted

Blue = Optional wording

**SUMMARY INFORMATION SHEET (for use only if you want to include a summary information sheet)**

In this research study we will use information from [you] [**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. These people will include Imperial Research Team members and support staff.

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 following information pack tells you more about this.

**How will we use Information about you?**

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

**[Study number]**

Imperial College London is the sponsor for this study and will act as the Data Controller or 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.

We will need to use information (including personal data and data created as part of the study) from [you] [**OTHER**] for this research project.

This information will include your [initials/name/ contact details/ **provide a bullet list of identifiers held by site and/or sponsor for the research**].  People 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 (see information to be collected) to make sure that the 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 unique study 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**] (see section ‘International Transfers’ and ‘Sharing your information with others’). 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.

**LEGAL BASIS**

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 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 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.

**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 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 (also known as opting out), we would like to continue collecting information about your health from [give details] If you do not want this to happen, please tell us and we will stop. 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 may not be able to let you see or change the data we hold about you 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**]

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

You can find out more about how we use your information:

* **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

**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.