# Guidance Notes: Preparation of Participant Information Sheets for Research For adult participants with capacity to consent

**Introduction**

A Participant Information Sheet (PIS) provides potential research participants with information to support their decision as to whether or not to participate in a research project. It supports their understanding of the purpose of the research; what would be involved if they agreed to participate; risks, burdens and benefits; and the planned use of the data that will be collected.

The purpose of these Guidance Notes is to provide advice on the preparation of information sheets that are required to support applications to one of Aston University’s Research Ethics Committees (RECs), an NHS REC and/or the Health Research Authority.

# Scope of the Guidance

The guidance is applicable to all Aston research projects with the exception of:

* Regulated Investigational Medicinal Product trials
* Regulated Medical Device trials

Researchers who plan to undertake these types of projects should seek advice from the Aston University Research Integrity Office (AURIO) on the preparation of their documents via research\_governance@aston.ac.uk

**Studies involving scanning**

The Aston Institute of Health and Neurodevelopment in collaboration with the University Research Ethics Committee has developed a suite of documents available to researchers for projects that involve neuroimaging technologies hosted by the Aston Neuroimaging Facility. These include information sheets, consent forms, screening forms in relation to MEG and MRI and are intended for use without alteration.

To access the latest templates, please contact IHN Admin via ihn\_admin@aston.ac.uk .

These must be used **in addition** to your study specific information sheets.

**Studies involving use of topical diagnostic drugs in research**

The Ophthalmic Research Group has provided agreed text for use where projects involve dyes and drugs used in normal **optometry** practice. This text is to be incorporated in to all participant information sheets.

To access the latest version of this text, please email ethics@aston.ac.uk.

**Your study identification number**

Upon **submission** of your ethics application for review, you will be issued with a Research Ethics Committee Identification number (REC ID). This number must be added to the footer of all approved participant facing documentation prior to use. As principal investigator, it is your responsibility to ensure that this detail is added to the documents when the project is approved. The Version Number and Date must be added to the footer of all documents prior to submission, however.

Applicants submitting an application via IRAS will be issued with a reference number by the system upon creation of their form. As such, this number can be added to the document footer at any point.

**\*\*NOTE – This template below contains suggested text and guidance\*\***

Yellow highlighted text is guidance and must be deleted before you submit for review.

Green highlighted sections are optional text and should only be included where relevant to your study (or deleted if not). Remove highlighting if being used.

Ensure that the document speaks to participants directly e.g. “*we will invite you to sign a consent form*” not “*subjects will sign a consent form*”.

Where guidance indicates you must not amend or delete any text within this template, please do not do so, as this will delay your ethics application.

Finally, please DELETE all formatting and guidance notes and ensure black font is used throughout. Proofread to ensure readability and check for spelling and typographical errors before submitting your document. The document should be considered ready to hand to a potential participant.



**Site/collaborator/funder Logo**

(to be added if required – remove if no other sites/collaborators/funder)

**ADD PROJECT TITLE AS STATED ON ETHICS APPLICATION FORM**

**Participant Information Sheet**

**Invitation**

We would like to invite you to take part in a research study forming part of a PhD project for [ADD NAME].

Before you decide if you would like to participate, take time to read the following information carefully and, if you wish, discuss it with others such as your family, friends or colleagues.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

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

Provide a brief explanation of the purpose of the study, ensuring that it is in lay language and any essential technical terms have been defined for a lay audience.

You should consider: why you are doing the study; what you hope to find out; how many participants there will be etc.

This section should **not** be produced by copying a section of the Protocol, but be a **brief summary** of the objectives of the study and why it is being run.

**Why have I been invited?**

You are being invited to take part in this study because [Add text to explain why the potential participant has been invited to join the study e.g. you have responded to an advert, you are registered on a database, you work in/at/for... etc]

You should then state the **main** inclusion and exclusion criteria for the study in **lay** language (bullet points or a numbered list may be useful). For example:

* You are between 18 – 30 years of age
* You have a current driving licence;
* You are left handed;
* You have experience of...

In certain circumstances, after consenting to participate, the research team may also ask participants to complete a screening questionnaire to further determine their eligibility prior to the study commencing. You should provide details here if this applies.

**What will happen to me if I take part?**

In lay language, add text to describe what will happen to the potential participant if they decide to join the study. This is an important section and it is helpful to put oneself in the position of a participant and explain what would happen to them, where, how many times and in what order.

You can also outline the process for receiving **consent**, the study obligations e.g. number of interviews/focus groups/ examinations they will be asked to undertake, **how** these will be arranged and **where** they will take place. The **time commitment** for each visit and overall time commitment for the study should be stated.

For studies with multiple visits a summary flow chart is also useful – these can be added in the body of the text or as an appendix.

**Do I have to take part?**

**No.** It is up to you to decide whether or not you wish to take part.

If you do decide to participate, you will be asked to provide informed consent.

You can halt your participation in the research at any time [indicate how e.g. by telling the researcher or closing down browser] and any data collected up to that point will not be used.

If you wish to withdraw your data after participation then you have up to xx days to do so [state how e.g. contacting the research team and giving your name or study ID number]. After this point, your data will be anonymised and it will not be possible to withdraw it.[if withdrawing data is not possible after the research is complete, explain why this is the case]

[The process for receiving consent should be explained to the participant depending on the nature of the research. For example, if you are conducting interviews online via Teams, how will you provide their consent form and how will it be returned? If it is in person, will a paper copy be used?]

**Will my taking part in this study be kept confidential?**

**Yes.** A code will be attached to all the data you provide to maintain anonymity. Analysis of your data will be undertaken using coded data.

If we need to collect personal data (such as a name and contact details) we will only use this for the purposes outlined in this participant information sheet e.g. to contact you to arrange an interview.

The data we collect will be stored in a secure document store (paper records) or electronically on a secure encrypted mobile device, password protected computer server or secure cloud storage device [this section should be amended as applicable e.g. if no paper records are being kept].

To ensure the quality of the research Aston University [optional: and the NHS Organisation supporting the study] may need to access your data to check that the data has been recorded accurately e.g. for the purposes of audit. If this is required your personal data will be treated as confidential by the individuals accessing your data [optional: delete if not collecting personal data].

**[OPTIONAL] How will the conversation during the interview be recorded and the information I provide managed?**

With your permission we will audio record the interview and take notes.

The recording will be typed into a document (transcribed) by a member of the research team/transcriber approved by Aston University. This process will involve removing any information which could be used to identify individuals e.g. names, locations etc.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

We will ensure that anything you have told us that is included in the reporting of the study will be anonymous.

You of course are free not to answer any questions that are asked without giving a reason.

**[OPTIONAL] How will the conversations that take place during the focus groups be recorded and the information I provide managed?**

With the group’s permission we will audio record the focus group.

The recording will be typed into a document (transcribed) by a member of the research team/transcriber approved by Aston University. During the transcription process any names that have been used will be replaced with a pseudonym.

Audio recordings will be destroyed as soon as the transcripts have been checked for accuracy.

Any extracts from the group discussions that are included in the reporting of the study will be anonymous.

If you agree to take part in a focus group full confidentiality cannot be guaranteed on behalf of the other focus group participants, although all participants will be asked to maintain confidentiality at the start of the focus group. It also may not be possible to withdraw your data after the focus group has ended.

**[OPTIONAL] How will the video recordings made during the study be managed?**

The video recordings will be destroyed as soon as the research team have analysed the information in them to answer the research question.

We will ensure that anything from the analysis of the videos that is included in the reporting of the study will be anonymous.

**[OPTIONAL] Will my GP be informed of my involvement in the study?**

With your consent your GP will be notified of your participation in this study.

**[OPTIONAL non-MEG/MRI studies] What happens if something is discovered during the study which requires further clinical investigation?**

The investigations undertaken during this study are not intended to be diagnostic but occasionally we discover something unusual that we feel should be investigated. We call these incidental findings.

Should this occur we will write to your GP who will be able to arrange further investigations for you.

**[OPTIONAL] What happens if I tell you something that concerns you about my health or welfare or that of the person I care for?**

In the unlikely event of this happening, we will discuss with you how this should be addressed. If necessary, to protect you and the person you care for, we will report your concern to the appropriate person or bodies.

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

Add text to say what potential benefits there are to taking part in the study. Note that financial incentives e.g. (a £10 voucher for participating) is not a benefit and any such information should be added to the “Expenses” section below.

If there will be no direct benefit to the participants then state this is the case and provide justification of what benefit you hope others will receive from the research in the future, for example: “*although you may find participation in this research interesting, there may be no direct benefit to you as a result. However we hope that the findings of this research will...*”.

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

Add text to say what the risks of taking part are – remembering that although the risks may be small there is **never** no risk.

Provision of information which may impact on employment or participant safety because of the views expressed must be addressed here.

The participants must be made aware of any research related activity which may impact on them after participation e.g. receipt of dilating eye drops affecting their vision and being unable to drive or cycle [in which case add ORG approved text in this section].

Burdens include: time commitment; requirement to travel to attend study visits, fasting/avoiding food, alcohol, nicotine etc and **must** be addressed here

For some studies there may be a risk of psychological distress, e.g. if you are collecting data on mental wellbeing or quality of life. This should be acknowledged and appropriate signposting should be added here, such as contacting their GP or a suitable charitable organization who may offer support.

**[OPTIONAL]** Information about the risks associated with having [a MRI scan / a MEG scan / MRI and MEG scans]\*\* can be found in the separate information sheet(s)\*\* that you have been given.

**What will happen to the results of the study?**

The results of this study may be published in scientific journals and/or presented at conferences. If the results of the study are published, your identity will remain anonymous.

Add details here if you intend to share a copy of the results of the study with your participants. For example: “*A lay summary of the results of the study can be forwarded to you when the study has been completed. Should you wish to receive a copy, please provide your email address on the consent form or contact a member of the research team*.”

[**OPTIONAL**: The results of the study will also be used in *[Name of Student]*\* either

*[MSc/MD/PhD* thesis*]* **or** *[Project report]*]

[**OPTIONAL**: The anonymised results may be shared with the company providing funding for this study.]

[**OPTIONAL**: The anonymised results may be used for research by other research teams as described in Appendix A]

**[OPTIONAL] What will happen to any samples that I provide?**

The samples will be stored using your unique identification code and used in accordance with the Human Tissue Act, which ensures appropriate management of all human materials.

At the end of the study any remaining samples will be destroyed in accordance with the Human Tissue Act.

**OR** (delete as applicable)

With your permission any samples remaining at the end of the study will be retained in an anonymised form for future research. Any future research involving the samples will require review by a research ethics committee before it commences.

**Expenses and payments**

State what expenses (e.g. travel and time) and payments will be made or that there will be no expenses and payments. Ensure you have worked out in advance the best way of reimbursing participants for their time/expenses.

Payment by cash is not permitted. Should participants receive reimbursement then this should be offered in vouchers (contact University finance for the approved brand). It is possible for participants to claim expenses e.g. for parking costs, however, an approved Expenses Claim Form should usually be completed by participants and submitted via the University Finance Office.

**Who is funding the research?**

The study is being funded by Aston University. Amend if in receipt of external funding.

**Who is organising this study and how is my data being used?**

Aston University is organising this study and acting as data controller for the study. Research data will be used only for the purposes of the study or related uses identified in this Information Sheet or Appendix A.

**Who has reviewed the study?**

This study was given a favorable ethical opinion by the [add name of REC] Research Ethics Committee.

**[OPTIONAL: NHS Studies only] Where can I obtain independent advice about participating in clinical research?**

If you would like independent advice on any aspect of this study, please contact the PALS (Patient Advice and Liaison Service) at [add Name of NHS organisation and contact details].

**What if I have a concern about my participation in the study?**

If you have any concerns about your participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research\_governance@aston.ac.uk or via the University switchboard on +44 (0)121 204 3000.

**Research Team**

[Provide the Research Team names and **Aston** contact details (name, contact number, Aston e-mail)]

Do not provide personal email addresses or phone numbers.

PhD studies must provide supervisory contact details.

If research is being undertaken overseas, please add UK code (+44) ahead of all numbers. A local (in country) contact must also be provided.

 **Thank you for taking time to read this information sheet. If you have any questions regarding the study please don’t hesitate to ask one of the research team.**



[DO NOT AMEND THIS WORDING].

Aston University takes its obligations under data and privacy law seriously and complies with the Data Protection Act 2018 (“DPA”) and the General Data Protection Regulation (EU) 2016/679 as retained in UK law by the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (“the UK GDPR”).

Aston University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study. Aston University will process your personal data in order to register you as a participant and to manage your participation in the study. It will process your personal data on the grounds that it is necessary for the performance of a task carried out in the public interest (GDPR Article 6(1)(e). Aston University may process special categories of data about you which includes details about your health. Aston University will process this data on the grounds that it is necessary for statistical or research purposes (GDPR Article 9(2)(j)). Aston University will keep identifiable information about you for 6 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at https://www.aston.ac.uk/about/statutes-ordinances-regulations/publication-scheme/policies-regulations/data-protection or by contacting our Data Protection Officer at dp\_officer@aston.ac.uk.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied 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).

**[ADD THE OPTIONAL TEXT BELOW IF DATA WILL BE SHARED]**

When you agree to take part in a research study, the information about you may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research, and cannot be used to contact you.