The template below contains examples of the main points an information sheet should include. Instructions are *italicised*, example wording isn’t. Remember to delete the advisory text and change the footer to be specific to your study.

[Study title – this may need to be a shorter, lay version]

**PARTICIPANT INFORMATION SHEET**

Central University Research Ethics Committee Approval Reference: [Insert]

Version 1.0 Date: dd/mm/yyyy

We would like to invite you 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 friends, family or your GP if you wish. If there is anything that you do not understand, or if you would like more information, please ask us. Please take time to consider whether you wish to take part.

# What is the purpose of the research?

*State the background, purpose and aims of the research. Remember to be brief and don’t use overly complicated language that a* [*lay person*](https://researchsupport.admin.ox.ac.uk/files/writingforparticipantspdf) *wouldn’t understand. Consider what a potential participant would want to know.*

# Why have I been invited to take part?

*Explain how they have been identified as a potential participant and mention any inclusion or exclusion criteria, including age range. You should explain how the participant was chosen and say how many other participants will be recruited.*

# Do I have to take part?

*It is important that participants understand that they have a choice about whether they take part. For example, you could say:*

No. It is up to you to decide whether or not to take part. Even after you have signed the consent form, you are free to withdraw from the study at any time without giving any reason, [and without negative consequences – *include if appropriate*], by advising me/us of this decision. Any personal data will be destroyed. [*If applicable -* The deadline by which you can withdraw any information you have contributed to the research is [*insert deadline before publication/ submission of thesis*]. [*Please explain what will happen to any data that has already been collected if they decide to withdraw*.]

# What will happen to me if I take part?

*This section should explain what will be involved in your research from a participant’s point of view, and in the order they will experience it. This should include:*

* *where the research will take place, including any information as to what to expect on arrival if a physical visit is planned;*
* *how consent will be taken;*
* *how long the participant will be involved in the research;*
* *what the activity/ activities will involve – e.g., interviewees should normally be told what topics will be covered, particularly if any of these are likely to be sensitive. It might be helpful to explain the questioning style. If any unusual equipment is going to be used it may be helpful to include a picture.*
* *If applicable*: With your consent, I/ we would like to audio record you/ video record you/ take photographs of you [*delete as appropriate*] because…[*give reasons why this is necessary here, e.g.* for audio recording: so I/ we can have an accurate record of our conversation].
* *how long the research will last (if this is different);*
* *how often they will need to participate and for how long each time;*
* *that participants can ask to pause or stop the research activities at any time;*
* *For longer sessions explain that they will be offered regular breaks. If there are multiple activities/sessions, describe them in turn, using a new paragraph/ section for each;*
* *if any follow-up sessions will be necessary, stating duration and frequencies – if it’s complicated, it may be easier to include a timeline or a diagram to explain*

# What is [Insert Drug/supplement name]

*Give brief information including what it is normally used for, how it is administered and how it works*

# Are there any risks in taking part?

*Give full details of any risks and/or side effects involved in taking the drug/supplement under study, and of any other study procedures. Explain how these risks will be addressed. It is important that participants understand how identifiable they will be from the data and from the research outputs.*

*Include this statement:*

Participants in research studies, as with all private purchasers of insurance policies, need to include accurate answers to any questions insurers might ask in proposal and renewal documents regarding their medical conditions. If you are a healthy volunteer in a research study there is no requirement to declare this to an insurer unless specifically asked to do so.

# Are there any benefits in taking part?

*Any benefits to the participants that can reasonably be expected should be stated. However, where there is no intended benefit to the participant from taking part in the project this should be explained. It is important not to exaggerate the possible benefits to the particular participant during the course of the project, this could be seen as coercive. Note that reimbursement should be mentioned in the following section rather than here.*

*For example you could say:* While there are no immediate benefits for those people participating in the project, it is hoped that this research will lead to…

*Or* There will be no direct or personal benefit to you from taking part in this research.

# Expenses and payments

**Either:** You will receive [x amount/voucher/gift] for [participation/reasonable travel costs/meals/child-care].

**Or:** There will be no payment for taking part in this study.

# What will happen to any samples I give?

*Please state what you will do with any samples that are collected in terms of storage location and duration, and what tests will be performed on them.*

*If there are plans to share samples with other parties, then add the following:*

Your samples may be shared with [*insert details of any organisations or other recipients the samples may be shared with*] and may be transferred to, and stored at, a destination outside the UK and the European Economic Area. We will make sure that identifiable data is removed whenever possible and that any data transfer is done securely and with a similar level of data protection as required under UK law (including by using standard data protection clauses adopted by the European Commission, where relevant).

# What information will be collected and why is the collection of this information relevant for achieving the research objectives?

*To enable participants to make an informed decision about taking part it is important they understand what information will be collected and why, and how this information will be used. The amount of detail will depend on the nature of the project; think through what would be appropriate for your participants.*

*Clearly list all types of data that will be collected from participants (as described on your ethics application form), where it will be stored, and how long for. Explain why this data is needed and how it will be used. Specify any* [*special category data*](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#S) *that is to be collected.*

Identifiable data (including consent forms) will be stored [*insert location,* [*security measures*](https://researchsupport.admin.ox.ac.uk/files/bpg09datacollectionandmanagementpdf) *and explain how long each type of data collected will be stored*]. Other research data will be stored for [**x**] years after publication or public release of the work of the research. *Mention if personal details need to be shared (and with whom) in order for participants to receive payments/ vouchers, if applicable.*

The researcher [*and/ or research team, supervisor, collaborator/ translator/ transcriber/ other authorised personnel*…] will have access to the research data.

*If applicable*: Research data may be transferred to, and stored at, a destination outside the UK and the European Economic Area. [*If applicable* – Identifiable data will be removed whenever possible and any data transfer will be done securely and with a similar level of data protection as required under UK law.]

*If applicable*: I/We would like to use this data in future studies, and to share this with other researchers (e.g. in online databases). *Explain how identifiable participants will be from this data. It is important that you use language that participants understand when explaining how identifiable they will be from the data. It can be difficult/ impossible to fully anonymise data, particularly qualitative data, and participants may not understand terms like pseudonymisation.*

# Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will/may be written up [*please describe - e.g. in a thesis, dissertation, academic publications, conference presentations, a report commissioned by an external organisation, websites, videos etc.*] *Explain whether it will be possible for participants to be identifiable from the outputs and clarify whether they have a choice about this.*

*If applicable*: I/We would like your permission to use direct quotations [*and for your name to be attributed to these/ but without identifying you*] in any research outputs.

*NB: For doctoral students or other qualifications where a thesis or dissertation needs to be deposited in the* [*Oxford University Research Archive*](https://ora.ox.ac.uk/deposit)*, include the following*: A copy of my thesis/ dissertation will be deposited both in print and online in the [Oxford University Research Archive](https://www.bodleian.ox.ac.uk/finding-resources/theses/theses) where [it will be publicly available to facilitate its use in future research/ its access will be restricted].

# Data Protection

The University of Oxford is the data controller with respect to your personal data and, as such, will determine how your personal data is used in the study.

The University will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest.

Further information about your rights with respect to your personal data is available from the University’s Information Compliance web site at <https://compliance.admin.ox.ac.uk/individual-rights>.

# Who has reviewed this research?

This study has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: **xxxxx)**.

*Include details of any other reviews, e.g. from a local ethics committee if the research is taking place overseas.*

# Who is organising and funding the research?

*To be completed appropriately for each study (organiser refers to the Principal Investigator at the University of Oxford)*

# Who do I contact if I have a concern about the research or I wish to complain?

If a participant in research is ever considered to have suffered harm through their participation, the University has arrangements in place to provide for compensation. If you have a concern about any aspect of this research, please contact *[insert primary researcher name and University tel. no./ ox.ac.uk email address*] or [*insert supervisor name and University tel. no./ ox.ac.uk email address*], and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at [rgea.complaints@admin.ox.ac.uk](mailto:rgea.complaints@admin.ox.ac.uk) or on 01865 616480.

# Further Information and Contact Details

*You should give the participant a contact point for further information. This can be your name, address and telephone number or that of another researcher in the project. If this is a supervised-student project, the student and supervisor should discuss whether to include the student’ contact details as well as those of the student’s supervisor. The use of personal phone numbers and email addresses should be avoided.*

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

[Insert Primary Researcher Name]

[Insert Department Name]

[Insert Department Address]

Tel: [Insert Number]

Email: [insert address]