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

*\*\*\*Please tailor the information sheet to the participant group (e.g. literacy level) and simplify if needed. Note that you should aim for a reading age of 12 for an adult information sheet\*\*\**

# **[Study Title – this may need to be a shorter, lay version]**

## PARTICIPANT INFORMATION SHEET

Central University Research Ethics Committee Approval Reference: [Insert]

*Explain that the prospective participant is being asked to consider taking part in a research study. For example, you could say:*

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. 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.

### Why is this research being conducted?

*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.*

Blood glucose levels refer to the amount of glucose sugar in a person’s blood. Researchers are interested in how blood glucose levels change in different situations. . It is normal for blood glucose to fluctuate within a given range throughout the day depending on when and what you have eaten. As such, there is no reason to be alarmed if your blood glucose is tested more than once and it is different the second time round compared to what it was the first time. The researcher is aware of the normal range of fluctuations found in blood glucose levels.

### 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. 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:*

It is up to you to decide whether or not to take part. You can withdraw yourself from the research, without giving a reason, by advising me/ us of this decision. [*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 in the research?

*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*

*You need to include the below specific information about the glucose testing at the appropriate point:*

The blood glucose test itself is minimally invasive and very quick. It will happen as follows:

1. The researcher will ask you to wash your hands thoroughly with warm soapy water. This is to reduce your chance of infection and to increase the blood flow to your fingers, one of which will be used to obtain the blood sample.
2. Whilst wearing gloves to make sure everything is clean, the researcher will prepare a testing strip and place it into the glucose monitor. They will also prepare a new lancing device. Again, this is to ensure that everything is sanitary and that you are at minimal risk of infection.
3. When you are ready, the researcher will prick the side of the tip of one of your fingers. It is typically done here as it is easy to access, produces a good sample and causes minimal pain. If, for whatever reason, you would prefer not to have your finger used, please talk to the researcher about alternative testing sites. This ‘lancing’ is like a very fast pinprick and is designed to minimise pain whilst allowing a small sample of blood to be collected.
4. The drop of blood will be applied to the testing strip and the monitor will calculate a reading of your blood glucose.
5. The researcher will give you a tissue to apply to the lanced point, and should you need it, you will also be provided with a plaster.
6. The researcher will dispose of the used lancet in a sharps bin, and the used test strip in a lined bin. The sample will not be kept.

### What are the possible disadvantages and risks in taking part?

*Any reasonably foreseeable discomforts, disadvantages and risks need to be stated. 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.*

If for whatever reason your blood glucose levels fall outside the expected range, the researcher will inform you. They will then encourage you to make an appointment with your GP, and to allow them to share the results of the test with your GP. It is important to note that if this happens, the researcher will not be able to interpret the results or provide a diagnosis. You must see your GP for this. It is also important to note that unusual blood glucose levels may be due to a number of things. However, as there can be serious health implications associated with unusual blood glucose levels, you are strongly urged to contact your GP should the researcher advise you of this. If you feel unwell and your blood glucose is outside the normal range, you should seek more urgent medical attention, for example by calling 111.

### Are there any benefits of taking part in the research?

*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 research this should be explained. It is important not to exaggerate the possible benefits to the particular participant during the course of the research, this could be seen as coercive. Note that reimbursement should be mentioned in the* [*following section*](#_[Optional_–_this) *rather than here.*

*For example you could say:* While there are no immediate benefits for those people participating in the research, 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/ childcare*] **or**: There will be no payment for taking part in this research.

### 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.*

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

Identifiable data (including consent forms) will be stored [*insert location,* [*security measures*](https://researchsupport.admin.ox.ac.uk/files/bpg09datacollectionandmanagementpdf) *and explain how long the 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.*

*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 research.

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 <https://compliance.web.ox.ac.uk/individual-rights>.

### Who has reviewed this research?

This research 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 another UK University, or a local ethics committee if the research is taking place overseas.*

### Who is organising and funding the research?

*Give details of the organiser (named researcher at Oxford University) and funder.*

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

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 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 team. If this is a supervised-student project, the student and supervisor should discuss whether to include the student’s contact details as well as those of the student’s supervisor. The use of personal phone numbers should be avoided. Email addresses should be provided by the University (ending in ox.ac.uk).*

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

[*Insert the name of the primary researcher*]
[*Insert the name of the Department*]
[*Insert the postal address*]
University tel: [*insert number*]
University email: [*insert address*]