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| **HEADER:**The PIS should be written on headed letter paperYou should include the version number and date on the PIS |

**Participant Information Sheet (PIS)**

* The following is a guide to writing an information sheet.
* You can adapt this sheet or use your own document and formatting. However, you should consider the items below.
* For all studies that are sponsored by the University of Oxford: text that is highlighted in blue should be included. This is a **legal requirement** and applies irrespective of whether the research is taking place inside or outside the UK/EEA.
* The PIS should provide **sufficient**, **understandable** information, as **simply** and **briefly** as possible, so that potential participants can decide whether or not to take part in the study.
* If juveniles are involved, consider whether a separate PIS in very simple language is appropriate.

**Title of Study**

*Use the short title. Ensure it is understandable to potential participants and matches the title on the consent form. It is NOT necessary to use the detailed ‘scientific’ title.*

**OxTREC reference number:**

**1. What’s the purpose of this research?**

*Give a brief overview of the study—just enough for potential participants to decide if they wish to read further.*

**2. Why have I been invited to take part?**

*Explain why the potential participant has been selected as suitable to take part in the study.*

**3. What’s involved for me?**

*Give full details of what’s involved in the study. Include the number of visits, questionnaires, tests, samples to be taken, etc. Ensure that you concentrate on the* ***research******procedures*** *rather than providing details about standard care.*

*Include details of any compensation given to participants.*

*Use language understandable to potential participants. Do not cut and paste directly from the protocol.*

**4. What will happen to my data?**

*Distinguish between* ***research data*** *(i.e. data that is collected as part of the study) and* ***personal data*** *(i.e. research data from which participants can be identified, such as name, gender, date of birth).*

*State that use of personal data in the study will be minimised as much as possible.*

*Give details of how, and for how long, both research and personal data will be stored. Explain how confidentiality will be maintained.*

*You should make it clear if:*

* *the data will be transferred/stored overseas*
* *the data will be retained and used in future research studies*
* *the data will be shared with other researchers.*

**5. What will happen to my samples?**

*Give details of how the samples will be stored. Explain how confidentiality will be maintained.*

*You should make it clear if:*

* *the samples will be shipped/stored overseas*
* *the samples will be retained and used in future research studies*
* *the samples will be shared with other researchers*
* *genetic testing will be carried out on the samples, in this study or possibly in the future.*

*In addition, for studies involving genetic testing, you should make it clear that complete anonymisation of the genetic data is not possible. For example:*“Your sample and any information recorded about you in this study will be ‘de-identified’ and assigned a study code. However, your DNA is unique to you so it can never be completely anonymous.”

**6. Are there any risks in taking part?**

*Give details of all inconvenience, risks of harm, risks to confidentiality, and psychological risk. Cover both the likelihood of these things happening and their possible severity.*

**7. What are the benefits of taking part?**

*Give details of direct benefits to potential participants. If there are none, this should be made clear. Also include details of wider benefits to society, including publication/dissemination of findings.*

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

*State:*

* *that potential participants can ask questions about the study before deciding whether to take part*
* *that it is their choice whether to take part or not and this choice will not affect their clinical care*
* *that if they agree to take part, they can withdraw from the study without penalty at any time.*

**9. Has the study been reviewed by an ethics committee?**

*Who has approved the study? Give details of the ethics committee(s) that has/have approved your study.*

**10. What if I have any questions or want to raise a concern?**

*Make it clear that potential participants may ask questions/raise concerns at any time.*

*Give contact details for the study’s principal investigator or other member of the research team. Also give contact details for someone independent of the study staff, e.g. the secretary of the local ethics committee that has reviewed the study.*

**11. Data protection**

*This is the* ***preferred*** *data protection statement:*

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 is performed 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>

*If the study will involve illiterate participants or there are issues with translating the preferred statement into the local language, then you may consider using the simplified version below:*

The University of Oxford is responsible for ensuring the safe and proper use of any personal information you provide, solely for research purposes.