

Dental School Research Ethics Committee

PARTICIPANT INFORMATION SHEET

This document gives guidance on the information to be contained in information sheets for volunteers taking part in **non- clinical research**.

Potential recruits to your research study must be given sufficient information and time to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs.

1. **Study title**

Is the title self explanatory to a lay person? If not, a simplified title should be included.

2. **Invitation paragraph**

This should explain that the subject 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. 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.'

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

The background and aim of the study should be given here. Also mention the duration of the study.

4. **Why have I been chosen?**

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

5. **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'

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

You should say how long the subject will be involved in the research, how long the research will last (if this is different),

7. **What about confidentiality?**

Explain what arrangements are in place to ensure the confidentiality.

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8. **What will happen to my personal data?**

[Personal data, according to the General Data Protection Regulation (GDPR) means any information relating to an identifiable living person who can be directly or indirectly identified in particular by reference to an identifier. This may include information such as an individual's name, address, email address or date of birth. If your research project is using personal data (and note that any research project involving the use of written consent forms will be using personal data), describe the person data that will be collected/used and the arrangements for anonymising it (e.g. use of a research project number). If you are offering choices to the participants regarding anonymity/ identification, this should be made clear. Personal data is not anonymous where researchers have, or are likely to have in the future, access to a key, or other means, which would enable re-identification of the individual to which the personal data relates.]

9. **What do I have to do?**

Explain in simple terms what the participant is required to do.

10. **Are there any risks?**

Explain what, if any mechanisms are in place to compensate the participant in the event of an adverse event

11. **What will happen to the results of the research study?**

You should be able to tell the subjects 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.

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

You should say who is organising and funding the research.

13. **Will I be paid for taking part?**

Yes/No [If 'Yes', insert details of any payments that will be made for time and expenses.] You should understand that any [data/samples] you give will be as a gift and you will not benefit financially in the future should this research project lead to the development of a new treatment/method/test/assessment.

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

State any benefits to the participants that are reasonably expected. It is important not to exaggerate the potential benefits. If there is no intended benefit to the participant from taking part, this should be clearly stated e.g. there will be no direct advantages or benefits to you from taking part, but your contribution will help us understand.

15. **What if there is a problem?**

[Set out how complaints will be handled and what redress may be available (i.e. describe the process). In the first instance, notify participants which member of the research team they may contact (e.g. the Chief Investigator), should they wish to raise a complaint. Participants should be informed that, if they feel their complaint has not been handled to their satisfaction, they may contact someone independent from the research team (for example, the Chair of the School Research Ethics Committee).]

If you wish to complain or have grounds for concerns about any aspect of the manner in which you have been approached or treated during the course of this research, please contact [insert name of research team]. If your complaint is not managed to your satisfaction, please contact [insert name and contact details for the member of staff who handles complaints for your School.]

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16. **Contact for Further Information**

You should give the volunteer a contact point for further information.

It is important that all forms have a version number and date, included as a footnote.

Version:

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