Optional statements are highlighted turquoise – delete if not applicable to your research (then delete all advisory text – highlighted yellow)

[Study Title]

**PARTICIPANT INFORMATION SHEET**

Ethics Approval Reference: [Insert]

Thank you for considering taking part in our research project. This information sheet provides some information to help you decide whether to do so. Please take time to read this 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?

[To be completed appropriately for each study].

## Who can take part?

You can take part if you are normally healthy, aged between 25 and 65, and do not have any injuries (such as broken bones or large amounts of bruising) in your arms. If you have had an artery from your arm taken out to mend a blood vessel somewhere else in your body, you will not be able to take part. We need to measure people with different levels of blood pressure, so if you know that your blood pressure is normally high (hypertension), low (hypotension), or “normal”, you will be equally welcome to take part. {Each study should detail appropriate inclusion and exclusion criteria}

## Do I have to take part?

No. It is up to you to decide if you want to take part in this study. We will describe the study and go through this information sheet with you to answer any questions you may have. If you agree to take part, we will ask you to sign a consent form and will give you a copy for you to keep. However, you would still be free to withdraw from the study at any time, without needing to give a reason. This would not affect the standard of care you would receive.

## What will the study involve?

The study will take place at {location} in Oxford. The study will involve measuring the blood pressure in your arms.

You may have had your blood pressure measured before by a doctor or nurse. The machines we will be using work in the same way. An inflatable cuff will be wrapped around your upper arm or wrist, and will be blown up by the machine. The machine will measure your blood pressure and heart rate as the cuff deflates. You will also have some of your measurements taken using a manual monitor, where the cuff is inflated by the researcher, who then listens to through a stethoscope to measure your blood pressure. The test should not be painful, but may be uncomfortable when the cuff is blown up. {Delete appropriate sentences if only one type of measurement is to be used}.

We will take up to 14 measurements of your blood pressure. We will make measurements on both your right and left arms, so that no more than 7 measurements will be taken on one arm. This will take about 45 minutes. While the measurements are being made, we will ask you to sit in a chair with your arm on a table. We will also ask you not to cross your legs or talk during the measurements. You can ask for a break in the measurements at any time. {Each study should specify number of measurements and time required}

So that we can put the blood pressure cuff comfortably on your upper arm, you should wear sleeveless or short-sleeved clothing. You may wish to bring a cardigan or jacket if the weather is cold. If you are taking any medication to treat high blood pressure, we will ask you about this.

## Are there any risks in taking part in this study?

This way of measuring blood pressure is very safe, and is regularly used by doctors and nurses. You may feel uncomfortable when the cuff is inflated, and there is a small chance of bruising to the upper arm. We have designed the research to make this less likely, and we will stop the measurement if you find the measurement very uncomfortable, or your arm gets bruised. You can also choose to have a break or stop the measurement at any time, without having to give a reason.

At the end of the measurements, we will let you know what your blood pressure was. If your blood pressure is high during the measurement, this does not necessarily mean that you have high blood pressure, because blood pressure changes through the day, and can be raised by things like stress and nervousness. Because of this, the measurements we make are not a test for high blood pressure. However, if your blood pressure appears to be unusually high during the testing, we will advise you to discuss this with your GP, in case you need further tests or treatment.

If you are concerned about your blood pressure or any other aspect of your health, you should see your GP.

## Are there any benefits from taking part in this study?

If you have high blood pressure and do not know about it, we may see this during the study. This would allow you to receive appropriate treatment. However, this study is not a screening procedure, and is not a replacement for medical care.

## [Optional - Will my travel costs be reimbursed?]

[Optional – Yes. We will compensate you for reasonable travel costs to attend the measurement session.]

## Who has reviewed this study?

All research studies are checked by an ethics committee to ensure the research is conducted safely and to the best standards. This research has been reviewed by and received ethics clearance through the University of Oxford Central University Research Ethics Committee.

## Who is organising and funding the research?

[To be completed appropriately for each study].

## What happens to the data provided? [[1]](#footnote-1)

The information you provide as part of the study is the **research data**. Any research data from which you can be identified (eg. your name, date of birth, audio recording), is known as **personal data**. [If applicable to the study: this includes more sensitive categories of personal data (**sensitive data**) such as your racial or ethnic origin or data concerning your health]. It does not include data where the identity has been removed (anonymous data).

We will minimise our use of personal [if applicable: and sensitive] data in the study as much as possible.

The **research data** will be stored confidentially using…

Your responses will be [anonymised/ not anonymised]...

**Personal / sensitive data** will be stored confidentially using….

The [researcher and/or e.g. research team, supervisor, collaborator / translator / transcriber…] will have access to personal/sensitive data / research data. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the research.

*[Note: please encrypt electronic storage devices, especially if you deal with sensitive personal data. Please see* [*http://researchdata.ox.ac.uk/home/managing-your-data-at-oxford/storage-and-backup/*](http://researchdata.ox.ac.uk/home/managing-your-data-at-oxford/storage-and-backup/)*. Please also encrypt data and files before transferring or uploading these, see* [*https://www.youtube.com/channel/UC4FTuOgYsOYOGAbpfBZ\_7iw*](https://www.youtube.com/channel/UC4FTuOgYsOYOGAbpfBZ_7iw)*]*

[*If applicable*] We would like your permission to use direct quotes.

All research data will be stored for at least [x] years after publication or public release of the work of the research. *[Note that University policy stipulates a minimum of 3 years after publication, but certain funders may specify longer retention periods and additional data management requirements – see* [*http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/*](http://researchdata.ox.ac.uk/university-of-oxford-policy-on-the-management-of-research-data-and-records/)*].*  We may retain and store your personal data for an additional period of time as necessary for the purposes of the study, and for further research.

[*If applicable:* Your personal data may be transferred to, and stored at, a destination outside 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.

*[If applicable]* We would like your permission to use anonymised data in future studies, and to share data with other researchers (e.g. in online databases). All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

## What if there is a problem?

If you have a concern about any aspect of this project, please speak to the relevant researcher ([insert tel. no. here]) [or their supervisor ([insert tel. no. here]), where applicable] who will do his/her best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how he/she intends to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the chair of the Research Ethics Committee at the University of Oxford (Chair, Medical Sciences Inter-Divisional Research Ethics Committee; Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD).  The chair will seek to resolve the matter in a reasonably expeditious manner.

***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 <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>.

## What if I have further questions?

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

[Insert Researcher Name]

[Insert Department Name]

[Insert Department Address]

Tel: [Insert Number]

Email: [insert address]

1. Please refer to [CUREC’s Best Practice Guidance on Data Collection and Management](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/bpg) (BPG 09) [↑](#footnote-ref-1)