Note: this section **MUST** be completed if you are including *human participants* in your study

Please include here your participant information sheet, participant consent form plus any participant recruitment materials and permission letters.

Northumbria University NEWCASTLE

Faculty of Engineering and Environment

Participant Information Sheet

Study Title: Flatfeet classification using artificial intelligence.

Investigator: Mr Kamlesh Mistry

> You are invited to take part in this research study. Before you decide it is important for you to read this leaflet so you understand why the study is being carried out and what it will involve.
>
> Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether you would like to take part.

What is the purpose of the study?

The purpose of this study is to develop an artificial intelligence system that will help in suggesting the insoles to the person having flat feet by measuring the distance between the knees and ankles using the smartphone or laptop camera.

Why have I been invited to take part?

You have been invited to take part as you meet the following criteria:

- You are an adult aged 18+ years,

- You have a flat foot.
- You have normal foot or high arch.

Do I have to take part?

You are under no obligation to take part and you will not experience any loss of benefit or penalty if you choose not to participate.

What will I have to do?

You will be tested on our artificial intelligence system to take measurement of the distance between your knee and ankle joints. It will also measure the slope of the line joining ankle and knee joints. Only numerical measurement as data will be collected from the participants. This entire process usually takes 20-30 minutes.

What are the exclusion criteria (i.e., are there any reasons why I should not take part)?

You should not take part in this study if:

- Not applicable

What are the possible disadvantages/risks in taking part?

There will be no risk associated in participating in the study.

What are the possible benefits of taking part?

The participant will get to know about the adverse effects they faced in day-to-day life due to flatfeet which they might not be aware about. The results obtained from the study will then be utilized to further improve and work on the model to make it more accurate and easily accessible to the users.

Will my taking part be kept confidential and anonymous?

Yes. You will be allocated a unique participant code that will be used to identify any data that you provide. Your name and other personal details will not be associated with your data, for example any signed informed consent forms will be stored separately.

Only the research team will have access to any identifiable information; paper records will be stored in a locked filing cabinet and electronic information will be stored on the secure University network. This will be kept separate from any data and will be treated in accordance with the Data Protection Act.

How will my data be stored?

All data will be stored on the University's OneDrive network and where appropriate additionally protected with a password. Any paper data collected will be locked away in a secure folder.

What will happen to the results of the study?

The results will be used for an postgraduate project that will be examined as part of a MSc Data Science degree. Occasionally some results might be presented at a conference or published in a journal, but they will always remain anonymous. All information and data gathered during this research will be stored in line with the Data Protection Act and will be destroyed after a maximum of 3 years following the conclusion of the study. During that time the data may be used by members of the research team, only for purposes appropriate to the research question, but at no point will your personal information or data be revealed.

Who is organizing and funding the study?

The present research project has received no funding.

Who has reviewed the study?

The study and its protocol and its protocol has received full ethical approval from the Department of Computer and Information Sciences ethics committee. If you require confirmation of this, please contact the Departmental Ethics Lead using the details below and stating the full title and principal investigator of the study:

Name of relevant Department Ethics Lead: Dr. James Nicholson

Department: Computer and Information Sciences

Address: Ellison B113
Phone: 0191 227 4959

Email: james.nicholson@northumbria.ac.uk

How can I withdraw from the project?

The research you take part in will be most valuable if few people withdraw from it, so please discuss any concerns you might have with the investigators. During the study itself, if you do decide that you do not wish to take any further part then please inform one of the research team as soon as possible, and they will facilitate your withdrawal and discuss with you how you would like your data to be treated in the future. After you have completed the research, you can still withdraw your data by contacting one of the research team (their contact details are provided in the last section of the leaflet), give them your participant number, or if you have lost this, give them your name.

If for any reason, you wish to withdraw your data please contact the investigator within a month of your participation. After this date, it might not be possible to withdraw your individual data as the results might already have been published. As all data are anonymous, your individual data will not be identifiable in any way.

What happens if there is a problem?

If you are unhappy about anything during or after your participation, you should contact the principal investigator in the first instance. If you feel this is not appropriate, you should contact the Computer and Information Sciences Departmental Ethics Lead via the contact details given above.

Contact for further information:

Researcher email: sarthak.tyagi@northumbria.ac.uk

Supervisor email: k.mistry@northumbria.ac.uk

INFORMED CONSENT FORM

Project Title: Artificial intelligence model to minimize adverse effect of flatfoot on Lower back pain

Principal Investigator:

please tick or initial
where applicable

I have carefully read and understood the Participant Information Sheet.	☐
I have had an opportunity to ask questions and discuss this study and I have received satisfactory answers.	☐
I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice.	☐
I agree to take part in this study	☐

Signature of participant.. Date...………………

(NAME IN BLOCK LETTERS) ....……………………….

Signature of researcher: Date...……………….

(NAME IN BLOCK LETTERS):