PARTICIPANT CONSENT FORM

Study title - Comparing the effectiveness of computer-aided-design computer-aided-manufacture (CAD/CAM) insoles manufactured from foam-box cast vs direct scan on patient reported outcome measures: A double-blinded, randomised controlled trial.

Short title – Comparing clinical outcomes using two insole manufacture techniques.

Unique participant number: …..…… Initials: …… Month/Year of Birth: ……...

Participant initial each point

1. I confirm that I have read and understand the information sheet dated 08/09/2022 (version 2.0) for the above study and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. _____

2. I give permission for the research team to use my medical records for the purpose of this study _____

3. I understand that my medical records may be looked at by authorised individuals from the Sponsor for the study, the UK Regulatory Authority or the Independent Ethics Committee in order to check that the study is being carried out correctly. I give permission, provided that strict confidentiality is maintained, for these bodies to have access to my medical records for the above study and any further research that may be conducted in relation to it. _____

4. I understand that even if I withdraw from the above study, the data collected from me will be used in the analysis of the results of the trial, unless I specifically withdraw consent for this. I understand that my identity will remain anonymous. _____

5. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publications. _____

6. I agree for my anonymised data to be shared with members of the research team at NHS Greater Glasgow and Clyde and the University of Central Lancashire, who are undertaking this research. _____

7. I agree to be contacted about future opportunities to participate in research _____

8. I agree to take part in the study. _____

Name of the participant	Participant's signature and the date the participant signed the consent form
Name of the Investigator taking written consent	Investigator's signature and date the Investigator signed the consent form

Original to be retained and filed in the site file. 1 copy to participant, 1 copy to be filed in participant's notes