Appendix 1 – Participant Information Sheet (English Version)

Evaluation of the Imperial College Prosthetic Suspension Systems

We would like to invite you to join a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. This form gives detailed information about the research study and is yours to keep. Please take time to read the following information carefully and discuss it with others if you wish before you decide whether you wish to take part. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

Amputees walk and move differently to non-amputees, and the type of prosthesis being used affects the way that an amputee walks. The aim of this study is to research the movement patterns and satisfaction levels of amputees using two new types of prosthetic suspension system against your existing suspension system so that we can assess which system is better performing.

Why have I been chosen?

We are asking you to consider participating in this study because you are a lower limb amputee that is in good health, have been an amputee for longer than 24 months, and are already using a prosthetic limb provided by Exceed Cambodia/the DPO.

Do I have to take part?

No, this is entirely up to you. If you would like to take part, you will be asked to sign a consent form. Even after you have signed this consent form and agreed to join the study, you are free to withdraw from the study at any time. If you decide not to take part, or withdraw from the study, it will not affect any future interactions that you may have with any of the institutions involved in this project. If you choose to withdraw from the study at any time, the information collected up until that point will be retained and used in the study; unless you explicitly state that you wish your data to be removed from the study. No further data will be collected. Please inform any member of the research team if you no longer wish to participate in the study.

What will happen to me if I take part?

Once you have decided to take part in this research, you will be asked to come to the prosthetics clinic at Exceed Cambodia. You will be guided through the consent process and asked to sign the forms. You will be assigned an order for completing the trial, and you will complete the following over the course of 16 weeks:

Phase 1 – Recruitment and Fitting:

You will be contacted by a researcher from DPO to arrange for an initial casting appointment. At this first appointment, the research team will read you the participant information sheet (English version attached at Appendix 1), you will be given adequate time to ask for any additional information. Following the discussion and the explanation of consent, and only if you are willing to take part in the study, a form to obtain written consent will be given and described to you by the research team (English version attached at Appendix 2), and you will be asked to fill and sign it. You will be asked to answer a few questions about your amputation (English version attached at Appendix 3). You will then be asked to complete the PLUS-M and the SAT-PRO questionnaires regarding your mobility and satisfaction with your current prosthesis (English version attached at Appendix 4 and 5). These questions will be asked by the research team, and your responses recorded on the questionnaire.

Once consent has been received, you will have some basic measurements taken of your current prosthesis, photos and videos captured of donning/doffing, and you will have your residual limb cast. From the cast, two polypropylene sockets will be fabricated. One socket will be for the Imperial College suspension system using a locking liner (either pin lock or lanyard), and the other will be a cushion liner using the same suspension as your current leg. You will be provided with overnight accommodation if required and food and drink and return to DSP the following day for fitting and alignment of the Imperial College Suspension System and offered training and guidance on the use of the limbs. Basic measurements will be taken of the new limb, along with photos and videos of donning/doffing. Finally, you will be asked to complete questionnaires regarding mobility and satisfaction with the prosthesis

Phase 2 – Home Use 1:

Once fitted with the prostheses, you will then return to your residence with one of the new prostheses for a period of 2 months where you will use the new limb as your everyday prosthesis. You do not have to do any specific activities, just use the prosthesis as normal. During this period, check-ups will be performed over the phone by the researcher at 2 weeks and 4 weeks. In the unlikely event that the prosthesis breaks, we would ask that you inform the research team of how the device failed and what you were doing when the failure occurred, and then return to the clinic for repair or replacement.

Phase 3 - Return and User Satisfaction Evaluation 1:

After the 2-month user evaluation period, you will be asked to return to the prosthetic clinic with your new limb to complete the questionnaires regarding mobility and satisfaction with the prosthesis. The questions will be asked to you verbally by one of the research team. After completion of the questionnaires, basic measurements of the prosthesis will be taken, along with photos and videos of you donning and doffing the

limb. You will then be given the alternative leg as fitted in phase 1, and the leg you have been using in phase 2 will be removed. Basic measurements will be taken of the new limb, along with photos and videos of donning/doffing. Finally, you will be asked to complete questionnaires regarding mobility and satisfaction with the prosthesis.

Phase 4 – Home Use 2:

You will then return to your residence with the alternative new prosthesis for a further period of 2 months where you will use the new limb as your everyday prosthesis. You do not have to do any specific activities, just use the prosthesis as normal. During this period, check-ups will be performed over the phone by the researcher at 2 weeks and 4 weeks. In the unlikely event that the prosthesis breaks, we would ask that you inform the research team of how the device failed and what you were doing when the failure occurred, and then return to the clinic for repair or replacement.

Phase 5 - Return and User Satisfaction Evaluation 2:

After the second 2-month user evaluation period, you will be asked to return to the prosthetic clinic with your new limb to complete the questionnaires regarding mobility and satisfaction with the prosthesis. The questions will be asked to you verbally by one of the research team. After completion of the questionnaires, basic measurements of the prosthesis will be taken, along with photos and videos of you donning and doffing the limb. After completion of the study, the Imperial College Suspension Systems will be taken from you, and the setup of the cushion-liner based prosthesis as fitted during phase 1 will be checked and given to you, along with an additional cushion liner. You will then be discharged from the study with our compliments and a project completion bonus of $20.

What are the side effects, and are there any risks in taking part?

If you experience any abnormal muscle or joint pain and/or discomfort during the evaluation period please inform the researcher, and if you need to rest and/or want to stop, you can do so at any time. If there are problems with the prosthesis, the research team can be reached on XXX, and you should stop using the prosthesis and return to the clinic for repair/replacement.

What are the possible benefits of taking part?

Whilst there may be no immediate benefits to you as an individual this project aims to improve long-term outcome for amputees from which you may benefit in the longer term.

Will my taking part in this study be kept confidential?

Any information you give us will be kept confidential. If the study is published in a book or scientific journal, no individual will be identified in any way. Your personal details will be stored offline in a locked

cabinet. In order to protect your privacy under the Data Protection Act, after data has been collected it will go through a process called "Linked Anonymisation". This means that any identifiable information that you provide, such as your name or age, is kept securely separate from any information that is collected from you for use in the study, such as your height and amputation levels.

Any identifying information we collect from you will be stored in one place only, and this will be the physical consent form that you will be required to sign when you arrive for the study. This document links your name with the anonymous number that will be used in the collection and handling of your information for the remainder of the study. This will be kept in a locked cabinet in an access-restricted office in Cambodia.

What happens to the data you collect from me?

All data collected will be anonymised and stored on password protected computers in locked offices. As you may be aware, for this study there are several collaborating organisations. You will be given the option to give permission to share your data with other research organisations.

What will happen to the results of the research study?

The results of the study will be analysed by the research team and presented at biomechanical and clinical conferences and published in scientific journals. No individual participant will be identified in any report or presentation arising from the research. We are unable to provide you with your individual results; however, you can be provided with a summary report of our findings at the end of the study, upon your request.

Will I be paid for taking part in the study?

You will be awarded 10 USD for each day you spend at the clinic in recognition of the time committed to this study, as well as covered for all travel and subsistence costs incurred as a result of taking part in the study. You will also be provided with a new alternative prosthesis system. If you complete the whole trial, you will be offered an additional 20 USD project completion bonus.

Who has reviewed the study?

This study was reviewed by XXX.

What happens in case of withdrawal?

You will be informed of your right to withdraw from the study prior to giving your consent, and at each subsequent testing session. You do not have to give a reason, and you do not have to give any period of notice, but we would please ask that you make it clear to any member of the research team that you wish to withdraw. You can withdraw using the contact email, the contact telephone number you will be given, or

by speaking to any member of the research team in person. If you had already given your consent, the data gathered up until the point of your withdrawal will be stored, but no further information will be gathered. You may still have a copy of any information we may have gained from you should you so wish.