RESEARCH ETHICS APPROVAL COMMITTEE FOR HEALTH

Application form for full submission for research ethics approval

Staff		**PhD**	**x**	**Masters**		**UG**		**Other (e.g. MRes)**	

ESRC funded project or studentship	x	Knowledge Transfer Partnership		Consultancy	
Other funded or unfunded research project		Service evaluation/Audit		Other (Umbrella etc. please specify)	

Project Title	Deep learning for environmental state prediction and sensor fusion for intelligent wearable robots
Name of applicant/s	Frederick Sherratt
Email for applicant/s	Fs349@bath.ac.uk
Name & contact email for supervisor (for UG / Masters / PhD students)	Pejman Iravani Pi304@bath.ac.uk
Department	Mechanical Engineering
Proposed dates of study	Start: 10-02-2020 End: 19-05-2020

Secondary data analysis
Does this proposal involve secondary data analysis? This is when you are analysing data that has already been collected by somebody else, i.e. you will have no part in collecting the original data. YES ☐ NO **N.B.** Please attach evidence that of ethical approval for the original study. The Project Description should detail what you intend to do with the data, not how the data were originally collected. It is important to note whether the data you are using have already been anonymised.

Are there ethical implications concerned with the following general issues? If yes, please provide details below	
1. Funding source	No – EPSRC funded studentship
2. Freedom to publish the results	No – EPSRC funded studentship
3. Future use of findings	No
4. Conflicts of Interest	No

Information Classification Scheme
Confirm that you have completed the mandatory information security awareness online training module (available here: https://moodle.bath.ac.uk/course/view.php?id=56392) What category of data will you be collecting? (If you are unsure, please look at the guidance available on the REACH wiki) **Internal Use** **Restricted** **Highly Restricted**

Standard Operating Procedures (SOPs)
This link will take you to the SOPs for the Department for Health: http://www.bath.ac.uk/health/research/research-getting-started/sop.bho/index.html The SOP PDFs can be downloaded and printed, but before using a printed SOP please check this link to make sure oy have the most up to date version. The SOP for the creation and approval of all other SOPs can be found here: http://www.bath.ac.uk/health/research/research-getting-started/sop.bho/SOP_PDFs_/SOPs_SOP_V4.pdf

DESCRIPTION OF RESEARCH

1 Research Title	Deep learning for environmental state prediction and sensor fusion for intelligent wearable robots
2 Background and aims of the research (no more than 300 words)	It is estimated that 150,000 people per year will suffer a below knee amputation and this is increasing due to the rising prevalence of diabetes and related vascular disease. The loss of mobility that comes from loss of limb leads to decreased social and economic participation as well as further health issues. Advanced lower limb prosthetics are so far unable to adequately emulate lost muscle function. For lower prosthesis to emulate the lost limb, they must behave in a predictable manner that matches the users intent. The study will investigate the use of machine learning techniques in achieving this. Primarily it will look at mode selection based on time series sensor data.

3 Outline the study design and list the methods including any questionnaires/interview schedules (please attach). **How much time (roughly) will each method take and how long in total will participants be expected to take part in the study (maximum 300 words)**	This study will produce a large set of labelled activity data from able-bodies subjects is required. The data sets will be raw IMU (Inertial Measurment Unit) sensor readings along with contextual statistics on sample population Age and Sex. The data set will be fully anoynomised. Participants will be required for one 30 minutes session of; 15 minutes for briefing, consent and setup, 15 minutes for data collection. During data collection, participants will be required to perform ambulation around a natural built-up environment. The route will involve flats, stairs and ramps with participants guided by a researcher. Participants will wear a set of seven Movesense wireless IMU sensors. The Movesense is a watch sized device containing a 9 axis IMU providing accelerometers, gyroscopes and magnetometers readings. Data will be streamed over Bluetooth to a smartphone controlled by the researcher. The Movesense devices will be attached to the ankle, wrist, hip and chest using Velcro/elastic straps and clothes clips. This will be done in a non-invasive manner to minimise discomfort and its potential effects on movement. Sensors will be controller via the smartphone. The researcher will annotate activity of the incoming data using a custom smartphone app.
4 Who will be recruited to participate in the research?	A broad population is required to ensure adequate variation in the dataset. Adult students and staff member of the University population will be recruited.
5 How many participants will be recruited? Why is this number necessary?	The sample size will be from 25 to 50 participants. Machine learning requires large amounts of data set to produce a generalised solution. The larger the number of participants the higher quality the model.
6 How will participants be recruited?	Participants will be recruited from the general university population through personal contacts from the engineering department and sports teams. Care will be taken to ensure adequate variety in participants.
7 Are there any potential participants who will be excluded? If so, what are the exclusion criteria? Is there any specific inclusion criteria?	Underage participants and those unable to perfore the required activies unaided will be excluded. All participants must be able to provide written consent. There are no further inclusion/exclusion criteria. Exclusion/inculsion from the study will be determined by participant self-assesment as part of the brief and consent.
8 Where will the research take place?	Department of Mechanical Engineering and University of Bath Campus

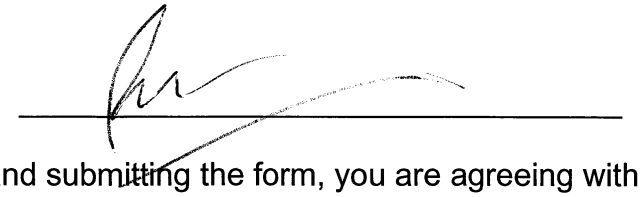
9 How will informed consent be obtained from all participants or their parents/guardians prior to individuals entering the study?	All participants will be required to read the full participant information sheet. Following verbal explanation of the aims, methods, objectives and potential risks of the study, written informed consent will be obtained from each volunteer. It will be made clear that participants are free to deny consent (withdraw) before, during, or immediately after data collection.
10 If the study aims to actively deceive the participants, please justify and briefly outline how this will be carried out	-
11 Will participants be made aware they can drop out of the research study at any time without having to give a reason for doing so? **Is it clear at what point participants can withdraw their data (e.g. before anonymization)?**	Yes, participants can drop out at any point during or immediately after data collection. Data will be anonymised immediately after the recording session.
12 Describe any potential risks to participants (physical, psychological, legal, social) arising from the study. *Explain how you will seek to resolve these.*	None, the study only requires participants to perform natural movements in a public environment. Sensors will be attached in a non-invasive, non-intimate manner.
13 Describe any potential benefits of the study for the participants	There are no immediate benefits to participation. The results of this project will generate a dataset from which to exploit future research opportunities in the field of amputee biomechanics.
14 Describe potential risks to researcher/s and *how these will be managed*.	None, all data collection will be performed in a public environment.
15 How will participants be debriefed? (i.e. feedback of results) **What aftercare will you provide?**	No debrief is required. No aftercare is required.
16 How will confidentiality and security of personal data relating to your participants be maintained?	Data is anonymized at collection. Personal information about the participants (Age, Sex) will not be linked to the anonymised data and only aggregated statistics will be published. All data will be stored in a restricted access folder on the X drive.

17 Will the participants be photographed, audio-taped or video-taped? If so, please justify	No audio/video is not required for the study. With participants permission photographs may be taken for use in subsequent reports. Participant anyominity will be maintained in any publication.
18 Is any reimbursement of expenses or other payment to be made to participants? Please explain.	None – it will be made clear this is a voluntary study.
19 Any other relevant information?	-
20 How long will you store *personal* data (including informed consent)? If you are retaining personal data longer than the end of the study, please justify	Once collected the data will be immediately anonymised. Consent forms will be held until the end of the study.

Attach the following (where relevant) <u>including version number and date</u>:

		Version	Date
1	Participant information sheets	V2	17/01/2020
2	Consent forms	V2.1	10/02/2020
3	Health history questionnaire	-	
4	Poster/promotional material	-	
5	Debrief	-	
6	Copy of questionnaire/ proposed data collection tool (questionnaire; interview schedule/ observation chart/ data record sheet/ participant record sheet)	-	
7	Data management plan	V1	18/12/2019

Signed by: Principal Investigator or Student Supervisor

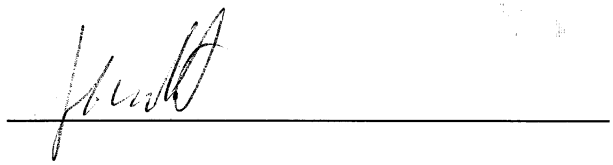


Date: 10/02/2020

By signing and submitting the form, you are agreeing with the following statement:

'I am familiar with the guidelines for ethical practices in research and I have discussed the ethical aspects of the proposed project with my supervisor(s) and/or the other researchers involved in the project. **I am also aware of and will comply with the university policies for storage and processing of human participant data.**'

Signed by: Student or other researchers



Date: 10/02/2020

By signing you are agreeing that you take joint responsibility for the application and conduct of the research.

PARTICIPANT INFORMATION SHEET

Deep learning for environmental state prediction and sensor fusion for intelligent wearable robots

Name of Researcher: Freddie Sherratt (PhD Student in Mechanical Engineering)
Contact details of Researcher: F.W.Sherratt@bath.ac.uk

Name of Supervisor: Dr Pejman Iravani (Senior Lecturer in Mechanical Engineering)
Contact details of Supervisor: P.Iravani@bath.ac.uk
Tel: +44 (0) 1225 384494

This information sheet forms part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. Please read this information sheet carefully and ask one of the researchers named above if you are not clear about any details of the project.

1. What is the purpose of the project:
This research is being carried out as part of PhD research looking into improvements in active lower-limb prosthetic control. This project aims to identify user intent from non-invasive wearable sensor data to enhance locomotion-mode selection.

The loss of mobility that comes from loss of limb leads to decreased social and economic participation as well as further health issues. Current lower-limb prosthetic do not adequately address lost muscle function leading to reduced mobility; falls and fractures; and damage to the spine and remaining leg due to asymmetric and high loading. Active prosthesis have the potential to restore near-natural behaviour but they must behave in a predictable manner that matches the users intent. The study will investigate the use of machine learning techniques in achieving this. Primarily it will look at locomotion-mode selection based on time series sensor data.

2. Who can be a participant?
A broad population is required to ensure adequate variation in the dataset so there are few restrictions on who can participate. The following criteria apply; you must be an adult and able to perform the activities listed in section 4 unaided.

3. Do I have to take part?
Participation in this study is entirely voluntary. Before you decide to take part we will describe the project and go through this information sheet with you. Please feel free to ask any questions you have about the procedures used in the study at any time.

If you agree to take part, we will then ask you to sign a consent form. However if at any time you decide you no longer wish to take part in this project you are free to

withdraw, without giving a reason. Your rights to withdraw shall be preserved over and above the goals of the study.

4. What will I be asked to do?
You will be asked to attend one 45 minute recording session. This will include i) a 15-minute brief and setup, ii) 2 x 10-minute recording session.

Participants will wear a set of seven Movesense wireless IMU sensors. See Figure 1. The Movesense device is a watch-sized device containing a 9 axis Inertial Measurment Unit and Heart rate sensor. Sensor data will be transmitted wirelessly over Bluetooth to a smartphone-controlled by the researcher.

Figure1: Movesense device [www.wearabletechnologyinsights.com/articles/13101/spotlight-on-suunto accessed: 18/12/2019]

The Movesense devices will be attached to the ankle, wrist, hip and chest using Velcro/elastic straps and clothes clips. This will be done in a non-invasive manner to minimise discomfort and its potential effects on movement.

The recording will be in two continuous sessions of approximatly 15 minutes. There will be a break between sessions. A typical recording session will be a walk around a pre-set route that includes the following environments:

- Flat indoor and outdoor paved surfaces
- Walking uphill and downhill
- Ascending and descending stairs
- Gentle and abrupt stopping

5. What are the exclusion criteria?
(are there reasons why I should not take part)?
Underage participants and those unable to perform the required activities unaided will be excluded. There are no further inclusion/exclusion criteria.

If you are comfortable performing the previously mentioned activities, there is no reason not the partake.

6. What are the possible benefits of taking part?
There are no immediate benefits to participation. You will be aiding in the generation of a new data set to aid research looking into Locomotion Mode Recognition.

7. What are the possible disadvantages and risks of taking part?
There are no disadvantages to you taking part in the project.

- The experimental trials will not require you to perform any other activity outside of those listed with all activities will be undertaken at your own pace.
- All measurments taken will be non-invasive and any attached instrumentation (Movesense wireless IMUs and associated attachments) will be external and non-obtrusive.
- Any testing session will stop should you report, or appear to be unduly stressed.

8. Will my participation involve any discomfort or embarrassment?
We do not expect you to feel any discomfort or embarrassment if you take part in the project. Testing sessions will be stopped should you wish too, or if you appear unduly stressed.

The experimental trials will not require you to perform any other activity outside of the required ones. All required sensors are designed to be comfortable for extended periods and will be attached external and non-obtrusive.

9. Who will have access to the information that I provide?
Only the research team will have access to the personal information that you provide. A research data set will be published in an anonymous form as per the University's Code of Practice – Research. This will be retained for a minimum of 10 years.

10. What will happen to the data collected and results of the project?
Data is collected in an anonymous and will be stored on password-protected PCs and only accessed by researchers directly involved in the study. There will be no links between persons involved in the study and the data they generate.

Participant anyominity will be maintained in any publication. In any manuscripts, reports or publications resulting from this study codes rather than names will be used. Any images published will not include faces.

Upon study completion, the anonymised data will be made publically available to aid other researchers in the field. This will be stored for a minimum of 10 years to comply with the University's Code of Practice – Research. No personal data will be released.

11. Who has reviewed the project?
This project has been given a favourable opinion by the University of Bath, Research Ethics Approval Committee for Health (REACH) [reference: EP 19/20 003].

12. How can I withdraw from the project?

You are free to deny consent (withdraw) before, during or immediately after data collection. Once data has been anonymized you will no longer be able to withdraw from the study.

Your rights to withdraw shall be preserved over and above the goals of the study.

13. University of Bath privacy notice

The University of Bath privacy notice can be found here: https://www.bath.ac.uk/corporate-information/university-of-bath-privacy-notice-for-research-participants/.

14. What happens if there is a problem?

If you have a concern about any aspect of the project you should ask to speak to the researchers who will do their best to answer any questions.

If they are unable to resolve your concern or you wish to make a complaint regarding the project, please contact the Chair of the Research Ethics Approval Committee for Health:

Professor James Betts
Email: j.betts@bath.ac.uk
Tel: +44 (0) 1225 383448

15. If I require further information who should I contact and how?

Thank you for expressing an interest in participating in this project. Please do not hesitate to get in touch with us if you would like some more information.

Name of Researcher: Freddie Sherratt (PhD Student in Mechanical Engineering)
Contact details of Researcher: F.W.Sherratt@bath.ac.uk

Name of Supervisor: Dr Pejman Iravani (Senior Lecturer in Mechanical Engineering)
Contact details of Supervisor: P.Iravani@bath.ac.uk
Tel: +44 (0) 1225 384494

CONSENT FORM

Deep learning for environmental state prediction and sensor fusion for intelligent wearable robots

Name of Researcher: Freddie Sherratt (PhD Student in Mechanical Engineering)
Contact details of Researcher: F.W.Sherratt@bath.ac.uk

Name of Supervisor: Dr Pejman Iravani (Senior Lecturer in Mechanical Engineering)
Contact details of Supervisor: P.Iravani@bath.ac.uk
Tel: +44 (0) 1225 384494

Please initial each box if you agree with the statement

1. I have been provided with information explaining what participation in this project involves. ☐

2. I have had an opportunity to ask questions and discuss this project. ☐

3. I have received satisfactory answers to all questions I have asked. ☐

4. I have received enough information about the project to make a decision about my participation. ☐

5. I understand that I am free to withdraw my consent to participate in the project at any time without having to give a reason for withdrawing. ☐

6. I understand that I can withdraw from the study at any time (up until immediately after the completion of the testing session). ☐

7. I understand the nature and purpose of the procedures involved in this project. These have been communicated to me on the information sheet accompanying this form. ☐

8. I understand that the University of Bath may use the data collected for this study in future research project(s) but that the conditions on this form under which I have provided the data will still apply ☐

9. I understand the data I provide will be treated as confidential, and that on completion of the project my name or other identifying information will not be disclosed in any presentation or publication of the research. ☐

10. I agree to the University of Bath keeping and processing the data that I provide during the course of this study and my consent is conditional upon the University complying with its duties and obligations under the Data Protection Act ☐

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11. I am capable of performing the required activities, described in the Participant Information Sheet, unaided and for the required duration ☐

12. I understand that all activities will take place at my own pace and can be stopped at any time if requested ☐

13. I give consent for the research team to take photographs of my person for written or oral presentations such as journal articles, conference presentation and reports. This is not a requirement to participate in the study. ☐

14. I understand that in any published photographs my anonymity will be preserved at all times. ☐

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15. I hereby fully and freely consent to my participation in this project. ☐

Participant's signature: _____ Date: _____

Participant name in BLOCK Letters: _____

Researcher's signature: _____ Date: _____

Researcher name in BLOCK Letters: _____

If you have any concerns or complaints related to your participation in this project please direct them to the Chair of the Research Ethics Approval Committee for Health, Dr James Betts (j.betts@bath.ac.uk, 01225 383448)

Doctoral Data Management Plan Template

1 Overview

1.1 Project title
Deep learning for environmental state prediction and sensor fusion for intelligent wearable robots
1.2 Student name and department
Frederick Sherratt – Mechanical Engineering
1.3 Supervisor(s)
Note: the main University of Bath supervisor is the Data Steward for the project.
Dr Pejman Iravani* – Department of Mechanical Engineering Prof Andrew Plummer – Department of Mechanical Engineering
1.4 Project description
The project aims to determine if machine-learning techniques can be used to improve performance of lower-limb prosthetics. This research focuses on locomotion-mode selection and as such a labelled data set of different locomotion-modes and transitions between is required.

2 Compliance

When you submit your DMP you are confirming that you have read and understood all of the legislative, policy and contractual requirements that apply to your project.

Information on additional University of Bath policies and UK/EU legislation that may apply to research can be found in our Data Management Plan Compliance Wiki page (this will require you to sign in with your University of Bath user account).

2.1 University policy requirements
Data must be stored securely in a manner that minimises the risk of loss of data and licenced in the as open a manner as possible. Sufficient meta data must be provided to allow others to use the data. All publication must include a data access statement.
University policy or guidance
University of Bath Research Data Policy
University of Bath Code of Good Practice in Research Integrity
University of Bath Electronic Information Systems Security Policy
University of Bath Intellectual Property Policy
University of Bath Code of Ethics
2.2 Legal requirements
Data collected from human subjects must comply with personal data protection regulations. Informed consent must be obtained from participants for data to be retained, shared, and used for new purposes.
UK Legislation or framework
General Data Protection Regulations

2.3 Contractual requirements	
EPSRC funding requires that all publicly funded research must publish any data collected into the public domain.	
Name of funder	**Data policy URL**
EPSRC	https://epsrc.ukri.org/about/standards/researchdata/

3 Gathering data

There is guidance and example wording for this section on the Data Management Plan Guidance Wiki page.

3.1 Description of the data

3.1.1 Types of data

The data will be raw accelerometer, gyroscope and magnetometer readings from seven IMUs along with timestamps of each sample recording, a set of timestamped activity labels is, and participant consent forms

3.1.2 Format and scale of the data

Original data will be in the form of .txt files containing hexadecimal representations of int16 fixed point numbers and associated uint32 millisecond timestamps. A second set of .txt files will contain millisecond timestamps and activity labels.A converted human-readable .csv form of this data will also be produced. Data will be less that 100Mb per participant.

Personal data will be paper consent forms and Sex and Gender information for each participant. These will have no link to the raw data files.

3.2 Data collection methods

Data will be collected using an android smartphone app that connects to the Movesense Bluetooth IMU sensors. The smartphone will save the data in its raw form to its internal storage.

3.3 Development of original software

Original software is required for all stages of data collection and processing.

Embedded C++ software has been developed to run on the Movesense devices transmitting their raw IMU data. A java Android app has been developed to connect to the sensors and save the raw data and activity labels to .txt files. Matlab scripts have been developed to convert the encoded raw data back to a human readable form.

The software has all developed specifically for this project and version controlled using Github. Associated documentation for their use is provided with the programs.

4 Working with data

There is guidance and example wording for this section on the Data Management Plan Guidance Wiki page.

4.1 Short- and medium-term data storage arrangements

In the short to medium term data will be stored in a X drive folder. All original data will be stored in a read-only format to prevent accidental overwrite.

Consent forms will be stored in a lock filing cupboard in my office until the end of the project when they will be securely destroyed.
4.2 Control of access to data and sharing with collaborators
The X drive folder will have access control restricted to myself and my research group.
4.3 File organisation and version control
Each participant's data will be stored in a separate folder with a random unique identifier to anonymise the data.
4.4 Documentation that will accompany the data
A readme file will accompany the data set explaining how to interpret the data and providing context.

5 Archiving data

There is guidance and example wording for this section on the Data Management Plan Guidance Wiki page.

5.1 Selection of data to be retained and deleted at the end of the project
Only processed data and aggregated population statistics will be retained after the end of the project. The original raw data and all consent forms will be destroyed
5.2 Data preservation strategy and retention period
As with other secondary data sources in the field data will be published in the University's Research Data Archive for a minimum of ten years.
5.3 Maintenance of original software
Scripts and software will not be maintained beyond the end of this project. Software will be archived with appropriate documentation for use again.

6 Sharing data

There is guidance and example wording for this section on the Data Management Plan Guidance Wiki page.

6.1 Justification for any restrictions on data sharing
No personal data will be included in published data set therefore there are no restrictions on data sharing.
6.2 Arrangements for data sharing
Data will be shared through the universities research archive with a data access statement provided in any publication based on it.

7 Implementation

There is guidance and example wording for this section on the Data Management Plan Guidance Wiki page.

7.1 Review of the Data Management Plan
The data management plan will be reviewed at the end of this experiment phase and before any subsequent experiments.
7.2 Special resources required for the project
No special resources required
7.3 Further training needs
I have attended data management and archiving courses and currently do no require further training.