***Department for Health***

***Research Ethics Approval Committee for Health***

**EIRA (Ethical Implications of Research Activity) 1 FORM**

This template must be completed for **all** research grant applications and should accompany the University’s Research Proposal form (RS1) for approval by the Head of Department.

Please note that this procedure is intended to help researchers consider ethical implications of research activity. Researchers are responsible for deciding, in conjunction with their departmental guidelines and professional disciplinary standards, whether a more extensive review is necessary.

***To be completed by Principal Investigator/Staff member:***

|  |  |
| --- | --- |
| **Brief Title of Project:**  | Neuromuscular, physiological and perceptual responses to linear vs. multidirectional high intensity running sessions in academy rugby union players. |
| **Names of PrincipaI/other Investigators:**  | Liam James Robinson (MSc Student & Main Researcher).Dr. Craig Twist (Main Supervisor - (External))Dr. Keith Stokes (Second Supervisor - (Internal - Bath)).Dr. Aaron Coutts (3rd Supporting Supervisor - (External)). |
| **Please state if this is Research or Consultancy work:**  | Research (As part of MSc Sports Physiotherapy)  |

**SECTION 1: COMPLETION FOR ALL RESEARCH**

|  |
| --- |
| ***Are there ethical implications concerned with the following general issues?*** ***If yes, please provide details below*** |
| **1. Data storage**  (eg Confidentiality, availability, length of storage, etc) | **YES -**  |
| **2. Are you free to publish the results?**  eg Are there any restrictions raised by contractual issues? | **YES – Nil Issues** |
| **3. Effect on/damage to the environment** eg Hazardous waste may be produced; water or air might be polluted; injurious pathogens might be released; damage to ecological systems/habitats. | **NO -**  |

|  |
| --- |
| ***Specific Issues*** |
| **4. Does the research involve human participants in any way? (**Please note if you are processing personal data you need to tick ‘Yes’.) | No  | Complete only Section 1 |
| **Yes** | **Complete Sections 1 and 2** |
| **5. Does the research involve animals in any way?** | **No** | Complete only Section 1 |
| Yes | Complete Sections 1 and 3 |

|  |  |  |
| --- | --- | --- |
|

|  |
| --- |
| **Demonstration of Ethical Considerations** |
| *Please outline the ethical issues which will need to be managed during the course of the activity.*  |

**\*Please also note: HRECs is also being applied for through the University of Technology, Sydney. This is being facilaited through Aaron Coutts (3rd assisting supervisor on this project & Professor in Sport & Exercise Science at University of Technology, Sydney).****Description of general ethical considerations:**Request for VolunteersConsent from VolunteersCollection and storage of the personal and experimental data being collected. Collection and storage of the Musculoskeletal Assessment information collected. Data Protection with regards to the above data being collected. Participants access to data & Confidentiality of collected data. Storing of all data, media type and retention of data in line with university policies. Collection of blood for Blood Lactate value and disposal of blood sample (Disposure of hazardous materials) Personnel who have access to data – assurances.  |

**SECTION 2: FOR COMPLETION IF YOUR RESEARCH INVOLVES**

**HUMAN PARTICIPANTS**

***If any of the answers to these questions are ‘yes’, please confirm in the space below how the ethical issues will be managed during the course of the activity.***

*Compulsory question for consideration by all disciplines:*

|  | **Yes** | **No** |
| --- | --- | --- |
| Will the study involve obtaining or processing personal data relating to living individuals, (eg involve recording interviews with subjects even if the findings will subsequently be made anonymous)? *Note: If the answer to this question is ‘yes’ you will need to ensure that the provisions of the Data Protection Act are complied with. In particular you will need to seek advice to ensure that the subjects provide sufficient consent and that the personal data will be properly stored, for an appropriate period of time). Information is available from the University Data Protection Website and* *dataprotection-queries@lists.bath.ac.uk* | **YES** |  |

***Departments may amend the following list to include topics of particular relevance to their discipline(s).***

|  | **Yes** | **No** |
| --- | --- | --- |
| 1. Does the study involve participants who are particularly vulnerable or unable to give informed consent? (eg children, people with learning disabilities) |  | **NO** |
| 2. Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited? (eg students at school, members of self-help group, residents of a nursing home) |  | **NO** |
| 3. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (eg covert observation of people in non-public places) |  | **NO** |
| 4. Will the study involve discussion of sensitive topics? (eg sexual activity, drug use) |  | **NO** |
| 5. Are drugs, placebos or other substances (eg food substances, vitamins) to be administered to the study participants and/or will the study involve invasive, intrusive or potentially harmful procedures of any kind? |  | **NO** |
| 6. Will blood or tissue samples be obtained from participants? *Note: If the answer to this question is ‘yes’ you will need to be aware of obligations under the Human Tissue Act, see further information at* [*http://www.bath.ac.uk/internal/ethics/committee/HTA.html*](http://www.bath.ac.uk/internal/ethics/committee/HTA.html) | **YES** |  |
| 7. Is pain or more than very mild discomfort likely to result from the study? |  | **NO** |
| 8. Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life? |  | **NO** |
| 9. Will the study involve prolonged or repetitive testing? |  | **NO** |
| 10. Will financial inducements (or other expenses and compensation for time) be offered to participants? |  | **NO** |
| 11. Will the study involve recruitment of patients through the NHS? Note: If the answer to this question is ‘yes’ you will need to submit an application to the NHS through IRAS, see: http://www.nres.npsa.nhs.uk/applications/integrated-research-application-system/ |  | **NO** |

|  |
| --- |
| **Section 2: Demonstration of Ethical Considerations***Please complete this section if any of the answers to the above questions are ‘yes’.*Type of data being handled:* Consent and Declarations to volunteer (written information and signature)
* Subject height, weight, age will be recorded at the familiarisation day. Address and phone number will need to be stored also to have correct contact details for the participant.
* All subjects will be recorded as numbers as to be de-identified within the project. This will enable better storage and better confidentiality of handling of the collected data. In addition, no personal data will be released outside of the research team of Liam James Robinson (LR), Keith Stokes (KS), Craig Twist (CT) and Aaron Coutts (AC) (Research Lead & Research Team).
* The numerical data, as will be collected from the tests of; neuromuscular assessment, blood lactate, GPS and Rate of Perceived Exertion will be stored initially in written form on the data recording sheets on the day of assessment (Protocols A and B). This is due to the stations (assessment zones) being separate from each other and differing personnel (study helpers) performing assessment at each station. Once a participant has completed all the stations, this written data will then be transferred by the research lead to an electronic copy of the data recording sheet alongside the participants designated participant number. This written data will then be destroyed via shredding and placed into confidential waste disposal at the lead researcher’s main place of clinical practice. Electronic data will then be stored as is discussed.
* Musculoskeletal (MSK) data will be collected during the initial musculoskeletal screening process. This data will be scanned and stored securely by the lead researcher via the media types discussed. The MSK data will be used only to assess suitability for participation. Those participants who do not meet the inclusion criteria after MSK assessment will have the MSK data destroyed by the lead researcher.
* GPS Data will be collected via the GPS units during all running drills in protocol A and protocol B, and this data will be stored alongside the participants designated participant number in the storage database.

Consent* Participants will be asked to volunteer for this project, and in turn will then be asked to give written consent via signing participant declaration (consent) forms if they wish to volunteer.
* In addition, participants will be given a full description of the project prior to the request for volunteers through both a short presentation by the lead researcher, and a fully disclosed participant information sheet.
* Data protection and confidentiality of any data will be stressed during the above, and will be also outlined as a guarantee on the delivered consent forms.

Media Type:* All data will be recorded primarily on a Microsoft© Surface 3 Pro tablet computer and will be maintained by the main researcher – Mr Liam James Robinson. This computer will be password protected.
* All collected data will be stored in individual files (Word/Excel) and will also be password protected.
* The only 4 people to have access to these files at all times will be the main author (LR) and supervisors (CT), (KS) & (AC). While the main author will password protect the main computer to be used, data discussion may be necessary between the research team.
* Any data interpreted by SPSS data will be maintained in a password protected SPSS file. This will be stored on password protected computers only and be discussed between the research team only.
* All raw data will be backed up and stored on an external password protected hard drive in case of system malfunction. One will be issued to LR and one to CT & KS in case of loss of data.

Data handling responsibilities/privileges:* The only 4 people to have access to these files at all times will be the main author (LR) and supervisors (CT), (KS) & (AC). While the main author will password protect the main computer to be used, data discussion may be necessary between the research team.

 Procedural:* All data will be de-identified at the time of collection and this raw data will be used up until the end of the project and submission of the research. The length of time for the study is likely to be 9-12 months after data capture.
* Data will then be stored for the length of time as required by the University of Bath and UTS Sydney where ethics will be requested from, this time in line with data protection requirements is 10 years.
* As a result, upon completion of the project, all data will then be moved to a secure unit for storage which can retain 10 year data. In accordance with university policies, data will be registered with a corresponding ‘Library Research Services’ and stored in an agreed position by both supervisor and student.
* GPS data will be accessible by the GPS co-ordinator only at the time of GPS data collection and once this data has been processed, it will be moved to the main computer for use by the main author. Once complete, the GPS data will then be deleted from the GPS host computer and the GPS units will be reset. Generated data will be stored alongside the numerical participant number.

Blood Sample:* Using the lactate analyser, participants will provide a 5µl capillary blood sample from a fingertip for analysis of blood lactate concentration ([BLa]) 3 min after completion of the running protocol.
* There is no other use of the blood sample (5µl) that will be taken.
* After collection, the blood sample will be placed on a lactate test strip, where it will be ready by a lactate analysis machine. The recorded value ([BLa]), will be stored on the data collection record sheet and any blood materials used will be disposed of in a correct hazardous material waste bin on the day of testing. At the close of the days testing, this hazardous material will be taken, by the lead researcher, to a hazardous waste disposal unit.
* The above procedure is thus in line with research obligations under the Human Tissue Act
 |

**N/A**

**SECTION 3: FOR COMPLETION IF YOUR RESEARCH INVOLVES ANIMALS**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes | No | In progress |
| 1. Has the project been submitted to and approved by the Ethical Review Committee for the purposes of Home Office approval under the Animals (Scientific Procedures) Act 1986? |  |  |  |
| 2. If the research is outside the scope of the Animals (Scientific Procedures) Act 1986 is it controlled by any other UK legislation? If so, please give details below. |  |  |  |
| 3.If the research is not controlled by UK legislation have the ethical implications of the project been considered by the Ethical Review Committee?[*http://www.bath.ac.uk/research/docs/nonlicencedthicareviewformfinalmay2010-2.doc*](http://www.bath.ac.uk/research/docs/nonlicencedthicareviewformfinalmay2010-2.doc) |  |  |  |

|  |
| --- |
| **Section 3: Demonstration of Ethical Considerations** |
| *This section is available for submission of further details relevant to Section 3.* |

Declarations:

I confirm that the statements in Sections 1-3 describe the ethical issues that will need to be managed during the course of this research activity.

|  |  |
| --- | --- |
| **Principal Investigator****Liam James Robinson** | **Signature:****Date:** |
| **Project Supervisor** **Dr Craig Twist** | **Signature:****Date:** |
| **3rd Project Supervisor (Australian Based)****Prof Aaron Coutts** | **Signature:****Date:** |
| **Head of Department**  | **Signature:****Date:** |

***Please return this form to the Secretary for the Research Ethics Approval Committee for Health (REACH). (Issues will be monitored for incorporation into an annual departmental report to be submitted to the University Ethics Committee.)***