**Application for Research Ethics Approval for Biosciences /BMRC, Food science and Sport and exercise Science (SHUREC2B)**

**SECTION A: Research Protocol**

**Important Note** - If you have already written a research proposal (e.g. for a funder) that answers the methodology questions in this section please include a copy of the proposal and leave those questions blank. You **MUST** however complete **ALL** of Section B and C (risk assessment).

**1. Name of principal investigator:**

**Faculty:**

**Email address:**

**2. Title of research:**

**3. Supervisor** (if applicable)**:**

**Email address:**

**4. CONVERIS Proposal Tracking number (applicable for externally funded research):**

**5. Other investigators (within or outside SHU)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Title** | **Name** | **Post** | **Division** | **Organisation** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**6. Proposed duration of project**

**Start date:** **End Date:**

**7. Location of research if outside SHU:**

**8.** **Main purpose of research:** ‏

Educational qualification

Publicly funded research

Staff research project

Other (Please supply details)

**9. Background to the study and scientific rationale** (500 -750 words approx.)

**10. Has the scientific / scholarly basis of this research been approved?** (For example by Research Degrees Subcommittee or an external funding body)

Yes

No - to be submitted

Currently undergoing an approval process

Irrelevant (e.g. there is no relevant committee governing this work)

**11.** **Main research questions**

**12. Summary of methods including proposed data analyses** (include outline of techniques to be used but do not include actual protocols).

**SECTION B**

**1. Describe the arrangements for recruiting, selecting/sampling potential participants.**

This should clearly indicate if participants with a particular health condition or healthy volunteers are being used, the inclusion and exclusion criteria, the sample sizes with power calculations if appropriate. Include copies of any advertisements for volunteers or letters to individuals/organisations inviting participation. The sample sizes with power calculations if appropriate should be included.

**2. Indicate the activities participants will be involved in** (tick and provide details as appropriate):

**i Providing biological samples:**

Yes

No

(If the answer is YES provide full details of samples including numbersand power calculation as appropriate, who is undertaking the sampling, location, procedures for collection, preservation and storage to ensure compliance with Human Tissue Act [www.hta.gov.uk](http://www.hta.gov.uk) ). Please refer to the SHU Human Tissue Subcommittee web pages and ensure SHU processes are followed for documentation of collection, storage and disposal of samples.

**ii Taking pharmacologically active substances or nutritional supplements:**

Yes

No

(If the answer is YES give full details of the preparation, dose, treatment duration, a route of administrations and relevant safeguards you will put in place to prevent harm to participants)

**iii Participating in diet or exercise programmes or activities:**

Yes

No

(If the answer is YES give full details of the programmes, their content and duration and the

relevant safeguards you will put in place to prevent harm to participants)

**3. What is the potential for participants to benefit from participation in the research?**

**4. Describe any possible negative consequences of participation in the research along with the ways in which these consequences will be limited.**

**5. Describe the arrangements for obtaining participants' consent.** This should include copies of the information that they will receive (participant information sheet) & participant written consent forms where appropriate. If children or vulnerable people are to be participants in the study details of the arrangements for obtaining consent from those acting in *loco parentis* or as advocates should be provided.

**6. Describe how participants will be made aware of their right to withdraw from the research.** This should also include information about participants' right to withhold information and a reasonable time span for withdrawal should be specified.

**7.** **If your project requires that you work with vulnerable participants describe how you will implement safeguarding procedures during data collection.**

**8. If Disclosure and Barring Service checks are required, please supply details**

**9. Describe the arrangements for debriefing the participants.** This should include copies of the information that participants will receive where appropriate.

**10. Describe the arrangements for ensuring participant confidentiality.** This should include details of:

* + how data will be stored to ensure compliance with data protection legislation
  + how results will be presented
  + exceptional circumstances where confidentiality may not be preserved
  + how and when confidential data will be disposed of
  + reference to the data management plan in relation to archiving etc.

**11. Are there any conflicts of interest in you undertaking this research?** (E.g. are you undertaking research on work colleagues or in an organisation where you are a consultant?) Please supply details of how this will be addressed.

**12. What are the expected outcomes, impacts and benefits of the research?**

**13. Please give details of any plans for dissemination of the results of the research. This includes your plans for preserving and sharing your data. You may refer to your attached Data Management Plan.**

**SECTION C**

**HEALTH AND SAFETY RISK ASSESSMENT FOR THE RESEARCHER**

1. **Will the proposed data collection take place on campus?**

Yes (Please answer questions 4, 6 and 7)

No (Please complete all questions)

1. **Where will the data collection take place?**

(Tick as many as apply if data collection will take place in multiple venues)

|  |  |  |
| --- | --- | --- |
|  | **Location** | **Please specify** |
|  | Researcher's Residence |  |
|  | Participant's Residence |  |
|  | Education Establishment |  |
|  | Other e.g. business/voluntary organisation, public venue |  |
|  | Outside UK |  |

1. **How will you travel to and from the data collection venue?**

 On foot  By car  Public Transport

Other (Please specify)

Please outline how you will ensure your personal safety when travelling to and from the data collection venue

1. **How will you ensure your own personal safety whilst at the research venue?**

1. **If you are carrying out research off-campus, you must ensure that each time you go out to collect data you ensure that someone you trust knows where you are going (without breaching the confidentiality of your participants), how you are getting there (preferably including your travel route), when you expect to get back, and what to do should you not return at the specified time.** (See Lone Working Guidelines). Please outline here the procedure you propose using to do this.
2. **Are there any potential risks to your health and wellbeing associated with either (a) the venue where the research will take place and/or (b) the research topic itself?**

 None that I am aware of

 Yes (Please outline below)

1. **Does this research project require a health and safety risk analysis for the procedures to be used?**

 Yes

 No

(If **YES** the completed Health and Safety Project Safety Plan for Procedures should be attached)

**Adherence to SHU policy and procedures**

|  |  |
| --- | --- |
| **Personal statement** | |
| I confirm that:   * this research will conform to the principles outlined in the Sheffield Hallam University Research Ethics policy * this application is accurate to the best of my knowledge | |
| **Principal Investigator** | |
| Signature |  |
| Date |  |
| **Supervisor (if applicable)** | |
| Signature |  |
| Date |  |
| **Other signature** | |
| Signature |  |
| Date |  |

**Please ensure the following are included with this form if applicable, tick box to indicate:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **N/A** |
| Research proposal if prepared previously |  |  |  |
| Any recruitment materials (e.g. posters, letters, etc.) |  |  |  |
| Participant information sheet |  |  |  |
| Participant consent form |  |  |  |
| Details of measures to be used (e.g. questionnaires, etc.) |  |  |  |
| Outline interview schedule / focus group schedule |  |  |  |
| Debriefing materials |  |  |  |
| Health and Safety Project Safety Plan for Procedures |  |  |  |
| Data Management Plan\* |  |  |  |

If you have not already done so, please send a copy of your Data management Plan to rdm@shu.ac.uk

It will be used to tailor support and make sure enough data storage will be available for your data.