UREC 4 Research ethics proforma FOR higher risk projects involving human PARTICIPANTS in research which involves the collection of biological samples, Food/NUTRITION supplementation, Sport SCIENCE evaluation at high intensity/stress or OTHERWISE intrusive research**.**

This form is designed to help students and their supervisors to complete an ethical scrutiny of proposed research. The University Research Ethics Policy ([www.shu.ac.uk/research/excellence/ethics-and-integrity/policies](https://www.shu.ac.uk/research/excellence/ethics-and-integrity/policies)) should be consulted before completing this form. The initial questions are there to check that completion of the UREC 4 is appropriate for this study. The final responsibility for ensuring that ethical research practices are followed rests with the supervisor for student research.

Note that students and staff are responsible for making suitable arrangements to ensure compliance with the General Data Protection Act (GDPR). This involves informing participants about the legal basis for the research, including a link to the University research data privacy statement and providing details of who to complain to if participants have issues about how their data was handled or how they were treated (full details in module handbooks). In addition, the act requires data to be kept securely and the identity of participants to be anonymised. They are also responsible for following SHU guidelines about data encryption and research data management. Guidance can be found on the SHU Ethics Website

<https://www.shu.ac.uk/research/excellence/ethics-and-integrity>

Please note that it is mandatory for all students to only store data on their allotted networked F drive space and not on individual hard drives or memory sticks etc.

The present form also enables the University and College to keep a record confirming that research conducted has been subjected to ethical scrutiny.

The form must be completed by the student and the supervisor and independently reviewed by a second reviewer or module leader (additional guidance can be obtained from your College Research Ethics Chair[[1]](#footnote-1)). In all cases, it should be counter-signed and kept as a record showing that ethical scrutiny has occurred. Some courses may require additional scrutiny. Students should retain a copy for inclusion in their research projects, and a copy should be uploaded to the relevant module Blackboard site.

Please note that it is also necessary to conduct a health and safety risk assessment for the proposed research in addition to the information included in **SECTION B**.

## Checklist Questions to ensure that External Approval for the research is not required:

| **Question** | **Yes/No** |
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| Does the research involve? |  |
| * Patients recruited because of their past or present use of the NHS
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| * Relatives/carers of patients recruited because of their past or present use of the NHS
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| * Access to NHS staff, premises or resources
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| * Access to data, organs, or other bodily material of past or present NHS patients
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| * Foetal material and IVF involving NHS patients
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| * The recently dead in NHS premises
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| * Prisoners or others within the criminal justice system recruited for health-related research
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| * Police, court officials, prisoners, or others within the criminal justice system
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| * Participants who are unable to provide informed consent due to their incapacity even if the project is not health related
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| * Is this an NHS research project, service evaluation or audit?

*For NHS definitions please see the following website*<http://www.hra.nhs.uk/documents/2013/09/defining-research.pdf> |  |

If you have answered **YES** to any of the above questions, then you **MUST consult with your supervisor** to obtain research ethics from the appropriate institution outside the university. This could be from the NHS or Her Majesty’s Prison and Probation Service (HMPPS) under their independent Research Governance schemes. Further information is provided below <https://www.myresearchproject.org.uk/>

## SECTION A: RESEARCH PROTOCOL

**1. Name of student:**

**College & Department:**

**Email address:**

**2. Title of research project:**

**3. Supervisor:**

**Supervisors email address:**

**4. Proposed duration of project:**

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

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

**6. Background to the study and scientific rationale/reasons for undertaking the research** (500 words approx.)

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**7.** **Main research questions and aims of research** (500 words)

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**8. Summary of methods including proposed data analyses (1000 words).**

Include:

* Outline of the study design
* Describe who are your participants, why are they included, and the numbers needed for the study
* Participant involvement and activities, samples collected, and measurements made.
* Techniques to be used (although detailed protocols are not required)
* Planned statistical analysis

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## SECTION B PARTICIPANT INVOLVEMENT

**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 recruited, the inclusion and exclusion criteria, the sample sizes with power calculations if appropriate. **You must** **include copies of any advertisements for participants or letters/emails to individuals or organisations inviting participation.**

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

1. **Providing biological samples:**

[ ]  Yes

 [ ]  No

If the answer is **YES,** provide full details about the type and number of samples you will collect. Please describe who will undertake sample collection, the location, and procedures for collection, preservation, and storage. Outline how you are compliant with the Human Tissue Act which regulates the storage and use of human biological samples ([www.hta.gov.uk](http://www.hta.gov.uk)) and university processes [www.shu.ac.uk/research/excellence/ethics-and-integrity/human-tissue](http://www.shu.ac.uk/research/excellence/ethics-and-integrity/human-tissue)

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1. **Taking pharmacologically active substances, nutritional supplements, foods or drink:**

[ ]  Yes

 [ ]  No

 If the answer is **YES,** please provide 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.

1. **Participating in a diet or physical activity intervention:**

[ ]  Yes

 [ ]  No

If the answer is **YES**, please provide full details of the programmes, their content and duration, and the relevant safeguards you will put in place to prevent harm to participants.

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

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**4. Describe any possible negative consequences of participation in the research along with the ways in which these consequences will be limited.** This includes the use of participants time, pain or discomfort both physical and psychological.

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**5. Describe the arrangements for obtaining participants' consent.** This should include copies of the participant information sheet and the consent forms that participants will receive. 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 also be provided.

*Note: Vulnerable people include children and young people, people with learning disabilities, people who may be limited by age or sickness, pregnancy, people researched because of a condition they have, etc. See full definition on ethics website in the document* [***Code of Practice for Researchers Working with Vulnerable Populations***](https://www.shu.ac.uk/research/excellence/ethics-and-integrity/guidance) *(under the Supplementary University Polices and Good Research Practice Guidance).*

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**6. Describe how participants will be made aware of their right to withdraw from the research project.** This should also be included in the participant information sheet. This should include all participants' right to withhold information, and a reasonable time span within which they may withdraw from the study, without a given reason.

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

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

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

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

* + How data will be stored to ensure compliance with general data protection legislation (GDPR)
	+ How results will be presented
	+ Exceptional circumstances where confidentiality may not be preserved
	+ How and when confidential data will be disposed of

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**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.

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

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**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.**

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## SECTION C

## HEALTH AND SAFETY RISK ASSESSMENT FOR THE RESEARCHER

1. **Do you have a health and safety risk analysis for the procedures to be used?** (Discuss this with your supervisor).

 [ ]  Yes

 [ ]  No (please complete this before you submit your ethics form)

If **YES** the completed Health and Safety Risk Assessment form should be attached. A standard risk assessment form can be generated through the Awaken system (<https://shu.awaken-be.com>). Alternatively if you require more specific risk assessment, e.g. a COSHH, attach that instead.

1. **Will the data be collected fully online (no face-to-face contact with participants)?**

[ ]  Yes (See the safety guidance for online research[[2]](#footnote-2) and **go to question 7b**).

[ ]  No (Go to question 3)

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

 [ ]  Yes (Please answer questions 5 to 8)

[ ]  No (Please complete all questions and consult with your supervisor)

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**  |
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| [ ]  | 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.

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

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1. **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 including steps taken to minimise risk)

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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.**

Please outline here the procedure you propose using to do this.

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**Insurance Check**

The University’s standard insurance cover will not automatically cover research involving any of the following:

i) Participants under 5 years old

ii) Pregnant women

iii) 5000 or more participants

iv) Research being conducted in an overseas country

v) Research involving aircraft and offshore oil rigs

vi) Nuclear research

vii) Any trials/medical research into Covid 19

If your proposals do involve any of the above, please contact the Insurance Manager directly (fin-insurancequeries-mb@exchange.shu.ac.uk) to discuss this element of your project.

## Adherence to SHU Policy and Procedures

| **Ethics sign-off** |
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| **Personal statement** |
| I can confirm that:* I have read the Sheffield Hallam University Research Ethics Policy and Procedures
* I agree to abide by its principles.
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| **Student**  |
| Name: | Date: |
| Signature: |
| **Supervisor ethical sign-off** |
| I can confirm that completion of this form has not identified the need for ethical approval by the TPREC/CREC or an NHS, Social Care, or other external REC. The research will not commence until any approvals required under Sections 4 & 5 have been received and any necessary health and safety measures are in place. |
| Name: | Date: |
| Signature: |
| **Independent Reviewer ethical sign-off** |
| Name: | Date: |
| Signature: |

**Please ensure that you have attached all relevant documents. Your supervisor must approve them before you start data collection:**

| **Documents** | **Yes** | **No** | **N/A** |
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| Research proposal if prepared previously | **[ ]**  | **[ ]**  | **[ ]**  |
| Any recruitment materials (e.g., posters, letters, emails, etc.) | **[ ]**  | **[ ]**  | **[ ]**  |
| Participant information sheet[[3]](#footnote-3)  | **[ ]**  | **[ ]**  | **[ ]**  |
| Participant consent form[[4]](#footnote-4) | **[ ]**  | **[ ]**  | **[ ]**  |
| Details of measures to be used (e.g., questionnaires, etc.) | **[ ]**  | **[ ]**  | **[ ]**  |
| Outline interview schedule / focus group schedule  | **[ ]**  | **[ ]**  | **[ ]**  |
| Debriefing materials  | **[ ]**  | **[ ]**  | **[ ]**  |
| Health and Safety Risk Assessment Form[[5]](#footnote-5)  | **[ ]**  | **[ ]**  | **[ ]**  |

1. College of Social Sciences and Arts - Dr. Antonia Ypsilanti (a.ypsilanti@shu.ac.uk )

 College of Business, Technology and Engineering - Dr. Tony Lynn (t.lynn@shu.ac.uk )

 College of Health, Wellbeing and Life Sciences - Dr. Nikki Jordan-Mahy (n.jordan-mahy@shu.ac.uk ) [↑](#footnote-ref-1)
2. Safety guidance for online research includes information on how to set up online surveys and/or conduct online interviews/focus groups. These guidelines can be found in BB. Please check with your supervisor/module leader. [↑](#footnote-ref-2)
3. It is mandatory to attach the Participant Information Sheet (PIS) [↑](#footnote-ref-3)
4. It is mandatory to attach a Participant Consent Form, unless it is embedded in an online survey, in which case your supervisor must approve it before you start data collection [↑](#footnote-ref-4)
5. It is mandatory to attach a Health and Safety Risk Assessment Form [↑](#footnote-ref-5)