# **UREC2 RESEARCH ETHICS PROFORMA FOR STUDENTS UNDERTAKING LOW RISK PROJECTS WITH HUMAN PARTICIPANTS**

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](http://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 2 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 [www.shu.ac.uk/research/excellence/ethics-and-integrity](http://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 UREC2 form must be completed by the student. Supervisors will review their students’ completed UREC forms and, if necessary, inform students of any required changes. For UREC2\* (Low Risk Research with Human Participants), the supervisor then signs off the form. Additional guidance can be obtained from your College Research Ethics Chair[[1]](#footnote-1)

\* If the supervisor thinks that the project is likely to result in a publication then the UREC2 form ***must*** be reviewed by an **independent reviewer**, drawn from the module teaching team, before data collection begins.

Students should retain a copy for inclusion in their research project, and a copy should be uploaded to the relevant module Blackboard site.

Please note that it may be necessary to conduct a health and safety risk assessment for the proposed research. Further information can be obtained from the University’s Health and Safety Website https://sheffieldhallam.sharepoint.com/sites/3069/SitePages/Risk-Assessment.aspx

## SECTION A

1. **Checklist questions to ensure that this is the correct form:**

Health Related Research within the NHS, or His Majesty’s Prison and Probation Service (HMPPS), or with participants unable to provide informed consent check list.

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

1. **Checks for Research with Human Participants**

| **Question** | **Yes/No** |
| --- | --- |
| 1. Will any of the participants be vulnerable?

*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)* |  |
| 1. Are drugs, placebos, or other substances (e.g., food substances, vitamins) to be administered to the study participants or will the study involve invasive, intrusive, or potentially harmful procedures of any kind?
 |  |
| 1. Will tissue samples (including blood) be obtained from participants?
 |  |
| 1. Is pain or more than mild discomfort likely to result from the study?
 |  |
| 1. Will the study involve prolonged or repetitive testing?
 |  |
| 1. Is there any reasonable and foreseeable risk of physical or emotional harm to any of the participants?

*Note: Harm may be caused by distressing or intrusive interview questions, uncomfortable procedures involving the participant, invasion of privacy, topics relating to highly personal information, topics relating to illegal activity, or topics that are anxiety provoking, etc.*   |  |
| 1. Will anyone be taking part without giving their informed consent?
 |  |
| 1. Is the research covert?

*Note: ‘Covert research’ refers to research that is conducted without the knowledge of participants.* |  |
| 1. Will the research output allow identification of any individual who has not given their express consent to be identified?
 |  |

If you have answered **YES** to any of these questions you are **REQUIRED** to complete and submit a UREC3 or UREC4 form. Your supervisor will advise. If you have answered **NO** to all these questions, then proceed with this form (UREC2).

1. **General Project Details**

| **Details** |  |
| --- | --- |
| Name of student |  |
| SHU email address |  |
| Department/College |  |
| Name of supervisor  |  |
| Supervisor’s email address |  |
| Title of proposed research |  |
| Proposed start date |  |
| Proposed end date |  |
| Background to the study and the rationale (reasons) for undertaking the research (500 words) |  |
| Aims & research question(s) |  |
| Methods to be used for:1. Recruitment of participants
2. Data collection
3. Data analysis
 |  |
| Outline the nature of the data held, details of anonymisation, storage and disposal procedures as required. |  |

**4. Research in External Organisations**

| **Question** | **Yes/No** |
| --- | --- |
| 1. Will the research involve working with/within an external organisation (e.g., school, business, charity, museum, government department, international agency, etc.)?
 |  |
| 1. If you answered YES to question 1, do you have granted access to conduct the research from the external organisation?

*If YES, students please show evidence to your supervisor. You should retain this evidence safely.* |  |
| 1. If you do not have permission for access is this because:
	1. you have not yet asked
	2. you have asked and not yet received an answer
	3. you have asked and been refused access

*Note: You will only be able to start the research when you have been granted access.* |  |

1. **Research with Products and Artefacts**

| **Question** | **Yes/No** |
| --- | --- |
| 1. Will the research involve working with copyrighted documents, films, broadcasts, photographs, artworks, designs, products, programs, databases, networks, processes, existing datasets, or secure data? |  |
| 2. If you answered YES to question 1, are the materials you intend to use in the public domain?*Notes: ‘In the public domain’ does not mean the same thing as ‘publicly accessible’.** *Information which is 'in the public domain' is no longer protected by copyright (i.e., copyright has either expired or been waived) and can be used without permission.*
* *Information which is 'publicly accessible' (e.g., TV broadcasts, websites, artworks, newspapers) is available for anyone to consult/view. It is still protected by copyright even if there is no copyright notice. In UK law, copyright protection is automatic and does not require a copyright statement, although it is always good practice to provide one. It is necessary to check the terms and conditions of use to find out exactly how the material may be reused etc.*

*If you answered YES to question 1, be aware that you may need to consider other ethics codes. For example, when conducting Internet research, consult the code of the Association of Internet Researchers; for educational research, consult the Code of Ethics of the British Educational Research Association.* |  |
| 3. If you answered NO to question 2, do you have explicit permission to use these materials as data?*If YES, please show evidence to your supervisor.* |  |
| 4. If you answered NO to question 3, is it because: A. you have not yet asked permissionB. you have asked and not yet received and answerC. you have asked and been refused access.*Note: You will only be able to start the research when you have been granted permission to use the specified material.* | **A/B/C** |

## SECTION B

## HEALTH AND SAFETY RISK ASSESSMENT FOR THE RESEARCHER

1. **Does this research project require a health and safety risk assessment for the procedures to be used?** (Discuss this with your supervisor)

 [ ]  Yes

 [ ]  No

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**  |
| --- | --- | --- |
| [ ]  | 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. **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)

|  |
| --- |
|  |

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.

|  |
| --- |
|  |

**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** |
| --- |
| **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.
 |
| **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** |
| --- | --- | --- | --- |
| 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  | **[ ]**  | **[ ]**  | **[ ]**  |

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)