

**STAGE 2 - RESEARCH ETHICS APPROVAL FORM**

All research carried out by students and staff at the University must receive ethical approval before any data collection commences.

**Notes**

* Applicants complete the Risk Checklist and Stage 1 - Research Ethics Approval Form prior to completing this Stage 2 - Research Ethics Approval Form. Following completion of the Risk Checklist and Stage 1 - Research Ethics Approval Form, if your research study was provisionally classified as Risk Category 2 or 3, you need to complete this form.
* Full details of the project are to be provided in this Stage 2. Where a question in the Risk Checklist was answered YES, please ensure that specific details are included in the appropriate box below.
* If a question does not apply to your project, insert ‘Not applicable’ or N/A.
* Help is provided for each question. Further help can be found in the Research Ethics Procedures document.
* You navigate through the form by using the tab keys. If you prefer to complete a normal Word document, you can unlock the form by selecting the ‘Restrict Editing’ button on the Developer tab, then click on ‘Stop Protection’. The boxes should expand to allow space for your text.
* Spellchecking is not available in Word forms, so you may find it helpful to prepare your responses in a Word document and then copy these to this form.
* Ensure the form is completed in sufficient detail to allow the reviewer to judge the ethical issues raised by the study. Remember that the reviewer will be considering the following questions when reviewing your application in order to be able to give ethical approval:
  + is it ethical to conduct the research project and is the proposed method of investigation appropriate, thorough and ethical?
  + does the research project meet the requirements of the relevant Research Ethics Principles (Research Ethics Policy A2.4)?

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| **TO BE COMPLETED FOR PROJECTS IN RISK CATEGORY 2 AND 3** | |
| **Your name** | Sandesh Paudel |
| **Project title** | Senior Shield- Next-Gen HealthCare App for Elderly |

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| **1** | **Project Overview** |
| **Please give a brief overview of your study, including a summary of your aims and objectives.**  Help: Describe the purpose of the research and what question(s) the project should answer. | |
| This project will recognize continuou vital sign, fall detection and medication management along with real time alerts to provide IoT-base Healthcare solution for the elderly.With the user-friendly interface, the project aims to enchance elderly care, offering a cost-effective solution for health and safety at home. Ensuration of the user authentication, location tracking, and integrates with brain games too for well being of the old ones are some of the features of the project. | |

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| **2** | **Methodology** |
| **Please give a description of your methodology, including any data collection and analysis methods.**  Help: Give an outline of your study here. If the project is complex, you can also submit your research proposal/protocol (no more than 2-3 A4 sides) if this would help the reviewer’s understanding of the project. Include details of your (or your Research Supervisor’s) appropriate skills and qualifications to carry out this research. | |
| The methodology consists of a literature review, followed by an examination of the IoT healthcare application, incorporating both qualitative and quantitative measures. Human testing will be central to real-world research. | |

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| **3** | **Main Ethical Considerations** |
| **Please give a brief description of the main ethical considerations involved in the study.**  Help: All research projects will have ethical issues, and you will be asked later in the process on recruitment, voluntary participation and the right to withdraw, but highlight here the main ethical considerations for your study (which may concern, e.g., the type of participants, the sensitive nature of the study, the data collection process, a lone researcher carrying out research off-campus, security-sensitive research) and advise how you will address the main issues. If the project is funded, give details here, and whether there are any potential conflicts of interest involved in the study. | |
| Ethical considerations focus on ensuring human trials, voluntary participation, informed consent, and the right to withdraw from the health app. Priority was given to maintaining confidentiality, anonymity, and adherence to ethical guidelines. | |

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| **4** | **Human Participants** |
| **If your study includes Human Participants (or their data), please give a description of who will be included.**  Help:   * Please note this should include sample size/number of participants, whether the project will focus on any particular groups/individuals, if it will include any at risk or vulnerable participants, participants aged 16 years or under, etc. Please also specify your rationale for including / excluding groups of participants. * If the research involves secondary data not in the public domain, give details in this section. | |
| As this is mainly focused on the Elder One, but the data collection of such age groups might be difficult.  So people above 30 yrs might be taken into considerations. | |

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| **5** | **Recruitment, Voluntary Participation, Consent and Right to Withdraw** |
| **If your study includes Human Participants, please give a brief description of the recruitment process, how you will ensure voluntary participation, if (and how) informed consent will be obtained prior to participants taking part in the study, and the right of withdrawal from the research process.**  Help:   * This should include clear information on how participants will be identified, approached and recruited; whether the study will include any covert research or deliberate deception; whether help is required from a third party/ gatekeeper to access participants; what information you will give participants, etc. * If expenses or any incentives are to be offered to participants, give full details. * If your research involves students, colleagues and/or other employees then you must specify the rationale for this and how you will address issues of coercion or feelings of obligation. * Regarding withdrawal from the study, discuss the different stages/dates a participant could withdraw or withdraw their data, and how they could do this. | |
| Participants will be recruited locally, within my immediate surroundings.The process ensures voluntary participation, and potential participants will be approached directly, provided with comprehensive information about the study's purpose, and informed about their right to withdraw at any stage without consequences.Withdrawal can occur at any stage before data analysis, and participant data will be promptly deleted upon withdrawal | |

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| **6** | **Risks and Benefits** |
| **Please give a brief description of how, when and where the research will take place and whether there are any risks and/or benefits involved.**  Help:   * This should include information on what participants will be required to do, the rationale for this and the level of risk involved. * When considering risks, please refer to risks to the participants (e.g., for research in sensitive areas), the researcher, any other parties to the research; and also any health and safety issues for anyone involved (e.g., for lone researchers carrying out fieldwork). * If participants will be exposed to ionising radiation, separate approval documentation must be submitted with this application. | |
| N/A | |

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| **7** | **Personal Data, Anonymity and Confidentiality** |
| **Please specify what type of information/data will be collected/analysed and the source(s). In addition, specify if and how you will ensure the anonymity of participants and keep information confidential.**  Help: This should include information on whether you are collecting new information/data or using that that is already in the public domain; whether the data you are using includes personal details; how the data will be processed and stored; who will have access to it; how and when it will be destroyed; the Data Protection requirements for any sensitive personal data, etc. In addition, include whether there may be any requirements for disclosure of information to other parties due to professional practice or legal reasons. If there are limits to confidentiality, explain clearly how the participants would be advised about these limits and possible outcomes. | |
| The study collects additional data from human testing of an IoT healthcare app. Personal descriptions will include user interactions and comments. The anonymity of the participants will be protected through anonymity, and confidentiality will be maintained by restricting only authorized personnel. After analysis, the data will be securely stored and destroyed. Disclosure to other parties is not required, and participants will be informed of confidentiality restrictions. The survey complies with data security requirements for sensitive personal data | |

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| **8** | **Reporting and Dissemination** |
| **Please give details of the planned dissemination and specify if the findings from the research will be published and whether any permission is required for this.**  Help: This should include information on the methods of dissemination (e.g., dissertation/thesis) and/or what will be published and where (research papers, conference presentations). Specify if any permission is needed (e.g., from participants, clients, gatekeepers, etc.) prior to publication, and whether there are any potential issues relating to Intellectual Property Rights when creating or using materials. | |
| N/A | |

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| **9** | **Location of research** |
| **Will the research take place outside of the country where you are enrolled as a student, or for staff, outside of the UK?** | |
| **YES  NO  If yes, give details below.**  Help: If yes, please specify where the research will take place and what will be involved. Research must comply with the laws of the country where it is taking place and also comply with local Data Protection and Intellectual Property legislation: you must confirm that your research is compliant with local requirements and how you have ascertained this. Advise if the project requires ethical approval in-country and how this has been ascertained. If approval is required, a copy of this should be included in the application or details of the process of how it will be obtained. Please make reference to insurance and indemnity cover for the project where relevant. | |
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| **10** | **Collaborative Projects** |
| **Is the research is a collaborative project (i.e., it involves more than one institution)?** | |
| **YES  NO  If yes, give details below.**  Help: If yes, please specify the other institutions involved and if ethical approval needs to be / has been given by them. Please also specify what procedures have been put in place to ensure ethical compliance from all partners. | |
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| **11** | **Any other permission or external ethical approval required to undertake the project** |
| **Please specify if the project requires any other ethical approval or permissions not mentioned previously in this application and how and when these will be obtained.**  Help:   * Other permissions: ethical approval does not give the right of access to the University’s students, staff or the use of University premises to carry out research, and you may need to contact an appropriate University gatekeeper for agreement to approach potential participants or for the use of premises, so please give details. * Gatekeepers: permission of a gatekeeper for initial access to participants may be required or to carry out data collection on their premises. * If your project requires approval from an external ethics committee, this should normally be obtained prior to submitting this application. * If a Disclosure and Barring Service check is required due to the specific participant group, give details. * Regarding insurance and indemnity cover, some projects will require individual confirmation of cover. See the Research Ethics Procedures document for more details. | |
| N/A | |

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| **FOR PROJECTS INVOLVING RISK CATEGORY 2 AND 3: DECLARATION AND SIGNATURE/S** | | | |
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| **APPLICANT (STUDENT/STAFF MEMBER/RESEARCHER)** | | | |
| *I confirm that I will undertake this project as detailed in stage one and stage two of the application. I understand that I must abide by the terms of this approval and that I may not make any substantial amendments to the project without further approval. I understand that research with human participants or their data must not commence without ethical approval.* | | | |
| I have read an appropriate professional or learned society code of ethical practice: | | Yes  N/A | |
| Where applicable, give the name of the professional or learned society: | | Sandesh Paudel | |
| *Signed* |  | *Date* | 30th Jan 2024 |

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| **RESEARCH SUPERVISOR/DIRECTOR OF STUDIES RECOMMENDATION FOR STUDENT PROJECTS** | | | | | |
| *I confirm that I have read stage one and stage two of the application. The project is viable and the student has appropriate skills to undertake the project. Where applicable, the Participant Information Sheet and recruitment procedures for obtaining informed consent are appropriate and the ethical issues arising from the project have been addressed in the application. I understand that research with human participants must not commence without ethical approval. I recommend this project for approval.* | | | | | |
| *Name* | Rohit Raj Pandey | *Signed* |  | *Date* | 30th Jan 2024 |

**Local Research Ethics Co-ordinators**

*Please complete EITHER* ***A*** *(giving ethical approval for the project) OR* ***B*** *(recommending the project to the School level group for approval)*

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| **A** | **LOCAL RESEARCH ETHICS CO-ORDINATOR APPROVAL**  *For projects approved by the Local Research Ethics Co-ordinator* | | | | | |
| *I confirm ethical approval for this project* | | | | | | |
| *LREC Name* | |  | *Signed* |  | *Date* |  |

**OR**

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| **B** | **LOCAL RESEARCH ETHICS CO-ORDINATOR’S RECOMMENDATION FOR SCHOOL APPROVAL**  *For projects that require School level approval* | | | | | |
| *I recommend this project for consideration at school level. It cannot be approved at local level due to the following reason(s)* | | | | | | |
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| *LREC Name* | |  | *Signed* |  | *Date* |  |

**School level group**

*For projects approved at School level please complete the box below.*

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| **PROJECTS APPROVED BY THE SCHOOL LEVEL GROUP** | | | | | |
| *I confirm that this project was considered by the School level group and has received ethical approval* | | | | | |
| *Group Lead* |  | *Signed* |  | *Date* |  |

**OR**

**University Research Ethics Sub-Committee**

*For projects approved by URESC please complete the box below.*

*Projects involving security-sensitive research do not need supervisor/LREC approval prior to being considered by the Chair of URESC.*

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| **PROJECTS APPROVED BY THE RESEARCH ETHICS SUB-COMMITTEE** | | | | | |
| *I confirm that this project was considered by the Research Ethics Sub-committee and has received ethical approval* | | | | | |
| *Chair* |  | *Signed* |  | *Date* |  |

*This form will be retained for the purposes of quality assurance of compliance and audit for THREE years*

**SUPPORTING DOCUMENTATION: what to submit with the application**

For projects involving human participants, you must submit, where appropriate, the Participant Information Sheet/s and consent form/s. You must also submit every communication a participant will see or receive. Failure to do so will cause delays to the application.

Below is a checklist reminder of what could be submitted, depending on the research project. Please tick the appropriate boxes for each attachment or give details of the document at the end of the checklist.

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| **SUBMISSION CHECKLIST** | **Tick box** |
| RISK CHECKLIST AND STAGE 1 – RESEARCH ETHICS APPROVAL FORM |  |
| STAGE 2 – RESEARCH ETHICS APPROVAL FORM |  |
| Participant Information Sheet(s) |  |
| Consent Form(s) |  |
| Assent Form (usually for children participants) |  |
| Recruitment documents  *eg, posters, flyers, advertisements, email invitations, letters, web pages if online research* |  |
| Measures to be used  *eg, questionnaires, surveys, interview schedules, psychological tests* |  |
| Screening questionnaire |  |
| Letters/communications to and from gatekeepers/third parties |  |
| Evidence of any other approvals or permissions  *eg, NHS research ethics approval, in-country approval* |  |
| Research proposal/protocol (no more than 2-3 A4 pages)  *It is not a requirement that this is included, however, if this would help the understanding of a complex project by the reviewer(s), please include* |  |
| Risk assessment form  *Some projects may require a risk assessment form: see the Procedures document for details (eg, projects involving a physical intervention, collecting data off-campus)* |  |
| Approval documentation for projects involving ionising radiation |  |
| Confirmation of insurance and indemnity cover where relevant  *Some projects need to be referred to the Insurance & Risk Officer: see the Procedures document* |  |
| Security-sensitive research form |  |
| Other: give details here: |  |
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**SUBMITTING YOUR FORMS**

* Students: email the typed forms (stage one and stage two) and supporting documentation to your Research Supervisor or Director of Studies.
* Staff: email the typed forms (stage one and stage two) and supporting documentation to your Local Research Ethics Co-ordinator.
* Security-sensitive research: the stage one form (and stage two form if applicable) should be submitted directly to the URESC Chair, Professor Karl Spracklen, [k.spracklen@leedsbeckett.ac.uk](mailto:k.spracklen@leedsbeckett.ac.uk) and include the Security-sensitive research form, available from the Research Ethics web page.