# UR Device Outlineethics review Application form

University Research Ethics Committee

To be used for School *or* University level review

Please append all relevant and supporting documentation to this project application form when submitting for School level (SREC) or University (UREC) review. Text boxes will expand as required and all language used to explain or justify the application should be comprehensible to a lay person.

Application form and all associated documents should be submitted electronically.

Submission deadline dates for UREC can be found on the [UREC webpage](https://www.reading.ac.uk/internal/academic-and-governance-services/research-ethics/RECcommitteedeadlines.aspx).

## Section 1: APPLICATION DETAILS

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| 1.1 Project and Dates | | | | |
| Title | Click here to enter text. | | | |
| Date of submission | Click here to enter a date. | | | |
| Start date | Click here to enter a date. | | | |
| End date | Click here to enter a date. | | | |
| 1.2 applicant details | | | | |
| Chief Investigator | Click here to enter text. | | | |
| Please note that an undergraduate or postgraduate student cannot be a named Chief Investigator for research ethics purposes. The supervisor must be declared as Chief Investigator. | | | | |
| Is the project being carried out in whole or in part to support a student degree?  Yes  Undergraduate  Masters  PhD  No | | | | |
| School | Click here to enter text. | | | |
| Department | Click here to enter text. | | | |
| Email | Choose an item. | | | |
| Telephone | Click here to enter text. | | | |
| All other Applicants | Name: | School | Position | Email |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

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| 1.3 what review is needed? | | | | | | |
| Please tick the appropriate box below to confirm which review your ethics application requires.  Please tick all that apply. | | | | | | |
| School Level Review and Approval (SREC) | | | External (for example, HRA) | | | |
| University Research Ethics Committee Review (UREC) | | |  | | | |
| Projects expected to require review by the University Research Ethics Committee (for example; research involving NHS patients, research involving potential for distress to participants) must be reviewed by the Chair of the School Ethics Committee or the Head of School before submission to UREC. For further information see Section 16 of the [UREC Guidance](https://www.reading.ac.uk/web/files/reas/EthicsGuidance_October_2012.pdf). | | | | | | |
| 1.4 external research Ethics committees | | | | | | |
| Please provide details of other external research ethics committees from whom a favourable ethics opinion will be required (for example; HRA REC) | | | | | | |
| Name of Committee | Date of submission / approval | | | Reference | | Status |
| Click here to enter text. | Click here to enter a date. | | | Click here to enter text. | | Click here to enter text. |
| 1.5 project submission declaration | | | | | | |
| On behalf of my co-applicants and myself,   * I confirm that to the best of my knowledge I have made known all information relevant to the appropriate Research Ethics Committee and I undertake to inform the Committee(s) of any such information which subsequently becomes available whether before or after the research has begun * I understand that it is a legal requirement that both staff and students undergo Disclosure and Barring Service checks when in a position of trust (for example; when working with children or vulnerable adults) * I confirm that if this project is an intervention study, a list of names and contact details of the participants in this project will be compiled and that this, together with a copy of the Consent Form, will be retained within the School for as long as necessary. * I confirm that I have given due consideration to equality and diversity in the management, design and conduct of the research project. * (For Chemistry, Food & Pharmacy (CFP) only) I confirm the Internal Review has been undertaken by Click here to enter text. and I have made the changes requested. | | | | | | |
| SIgned, chief investigator | | | | | | |
| Click here to enter a date. | | | | | | |
| Where required by the School’s Research Ethics Procedures, this ethics application should be signed off by the appropriate person to confirm the School Body are content for this application to be reviewed by UREC.  Chemistry, Food & Pharmacy – will require sign off from: Chair of SREC, Head of Department and School Ethics Administrator – insert rows below as required. | | | | | | |
| signed, authorising signatory | | | | | | |
| Signature: | | Position: | | | Date: | |
|  | | Choose an item. | | | Click here to enter a date. | |
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|  | | Choose an item. | | | Click here to enter a date. | |

## Section 2: PROJECT DETAILS

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| 2.1 LAY SUMMARY |
| Please provide a summary of the project in plain English that can be understood by a non-specialist audience, which includes a description of the background of the study (existing knowledge), the questions the project will address, the methods to be used and the key ethical issues.  Please note the lay summary should not contain references and be no more than 500 words. |
| Click here to enter text. |
| 2.2 PRIMARY RESEARCH QUESTION |
| Please detail the primary research question this project will answer. |
| Click here to enter text. |
| 2.3 SECONDARY RESEARCH QUESTION(S) |
| Please detail any secondary research question(s) this project will answer. |
| Click here to enter text. |
| 2.4 DESIGN AND PROCEDURE |
| Please describe concisely what the study will involve, how many times and in what order, for your participants and the procedures and methodology to be used.  Note: Any questionnaires or interview scripts should be appended to this application. |
| Click here to enter text. |

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| 2.5 LOCATION | | |
| Please describe where the research will take place. | | |
| Click here to enter text. | | |
| Please state whether an appropriate risk assessment/ local review has been undertaken. | | |
| Yes  No  Not required | | |
| Note:  - Ensure specific risk assessments have been undertaken for non-University locations (for example; schools or participant homes). Please consult either your School Ethics Contact or UREC for guidance. | | |
| If the project is to take place in Hugh Sinclair Unit of Human Nutrition, it must be reviewed by the Research Nurses and the Hugh Sinclair Manager also informed that the ethics application is being submitted for the study.’ Signatures are required below. | | |
|  | Hugh Sinclair Manager | Click here to enter a date. |
|  | Research Nurse  Click here to enter text. | Click here to enter a date. |
| 2.6 FUNDING | | |
| Is the research supported by funding from a research council or other external source (for example; charities, businesses)?  Yes  No | | |
| If “yes”, please,   1. Give details of the funding body; | | |
| Click here to enter text. | | |
| 1. Confirm if the funder specifically stipulates review by the University Research Ethics Committee.   Yes  No | | |
| 2.7 ETHICAL ISSUES | | |
| Please summarise the main ethical issues, including harms and risks, arising from your study and explain how you have addressed them. | | |
| Click here to enter text. | | |
| 2.8 DECEPTION | | |
| Will the research involve any element of intentional deception (for example; providing false or misleading information about the study)?  Yes  No  If “yes”, please justify and append a description of the debriefing procedure. | | |
| Click here to enter text. | | |
| 2.9 PAYMENT | | |
| Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?  Yes  No  If “yes”, please specify and justify the amount. | | |
| Click here to enter text. | | |
| 2.10 DATA PROTECTION | | |
| ***This section is required for applications reviewed at School (SREC) level only.***  ***For applications reviewed at UREC level, do not complete this section. Move onto section 2.11.***  What steps will be taken to ensure appropriate secure handling of personal data? Give comprehensive details on the collection, retention, sharing and disposal of participant personal data.  Personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.  For guidance on data protection please, see the [Data Protection for Researchers Guidance](http://www.reading.ac.uk/internal/academic-and-governance-services/research-ethics/RECwhatdoIneedtodo.aspx) document. | | |
| Click here to enter text. | | |
| 2.11 DATA MANAGEMENT PLAN | | |
| *Requirement for applications to be submitted to* ***UREC****, only.*  Applications submitted to UREC must be accompanied by a [Data Management Plan](https://www.reading.ac.uk/RES/rdm/planning/res-ethics-data-protection.aspx) (document available via link).  Please append the Data Management Plan. | | |
| N/A, application not to be submitted to UREC  Yes, appended\*  \*Please note; as the Data Management Plan is appended there is **no** requirement to complete section 2.10 Data Protection. | | |
| 2.12 DATA PROTECTION IMPACT ASSESSMENT (DPIA) | | |
| Will the research involve any activity that requires [a Data Protection Impact Assessment](http://www.reading.ac.uk/internal/imps/DataProtection/imps-d-p-dataprotectionbydesign.aspx) (DPIA)?  Yes  No  If “yes”, please append the “[Pre-Screening Questionnaire for Data Protection Impact Assessment](http://www.reading.ac.uk/internal/imps/DataProtection/imps-d-p-dataprotectionbydesign.aspx)”.  Please note; the Pre-Screening Questionnaire for a DPIA is only accessible with staff credentials and the Chief Investigator is responsible for its completion. | | |
| 2.13 INFORMED CONSENT | | |
| 1. Will you obtain informed consent from, or on behalf of, research participants?   Yes (go to question b)  No (go to question c)   1. If “yes”, please describe the process by which they will be informed about the nature of the study and the process by which you will obtain consent. 2. If “no”, you are not obtaining consent, please explain why (for example; ‘opt-out’ methodology without the acquisition of consent)?   Please append all relevant participant facing information documentation for participants, parents or guardians. Please note, age-appropriate information sheets must be supplied for all participants wherever possible, including children. Assent should be obtained from children, under 16 years, in addition to the consent required from parents, guardians or carers. | | |
| Click here to enter text. | | |
| 2.14 GENOTYPING | | |
| Are you intending to genotype the participants?  Yes  No  If “yes”, which genotypes will be determined? | | |
| **2.15 TISSUE SAMPLE MANAGEMENT** | | |
| What types of human tissue or other biological material will be included in this study?  HTA relevant  Non-HTA relevant  None | | |
| Please provide additional details here | | |
| Will the HTA relevant samples be stored for longer than 7 days?  Yes  No | | |
| How long will the samples be stored for?  \_\_\_\_\_Years \_\_\_\_\_\_\_Months | | |
| What will happen to the samples at the end of the research?  Retention  Disposal  Transfer | | |
| Please provide additional details here if applicable | | |
| NB: If HTA relevant samples are to be collected and stored by researchers in FNS the ethics application must be reviewed and signed by the Designated Individual for the Human Tissue Act (2004) licence | | |
| **SIGNED, AUTHORISING SIGNATORY** | | |

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| Signature: | Position: | Date: |
|  | Choose an item. | Click here to enter a date. |

## Section 3: PARTICIPANT DETAILS

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| 3.1 PARTICIPANT NUMBER |
| How many participants do you plan to recruit?  Please briefly explain why the number is appropriate to answer the study’s research question(s). |
| Click here to enter text. |
| 3.2 PARTICIPANT CHARACTERISATION |
| What age-range of participants will you recruit? |
| Click here to enter text. |
| Please list the principal inclusion and exclusion criteria. |
| Click here to enter text.  Click here to enter text. |
| 3.3 RECRUITMENT |
| Please describe the recruitment process and append any advertising if used. |
| Click here to enter text. |
| 3.4 NHS AND SOCIAL SERVICES INVOLVEMENT |
| Will participants be recruited because of their status as NHS patients or Social Services clients, or identified through those services’ records?  Yes  No  If “yes”, please give details of current status of the HRA REC review. |
| Click here to enter text. |
| Will the study involve adult participants unable to consent for themselves as defined by the Mental Capacity Act 2005 or other vulnerable adults?  Yes  No  If “yes”, please detail the associated procedures as set out in the HRA REC application. |
| Click here to enter text. |

# checklist

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| 1. The Application form has the appropriate signatories | | Choose an item. | |
| 2.The Participant Information Sheet includes a statement to the effect that the project has been reviewed by the appropriate Research Ethics Committee and has been given a favourable ethical opinion for conduct. | | Choose an item. | |
| 3. The Participant Information Sheet contains the relevant Data Protection information. | | Choose an item. | |
| 4. Where minors (under 18) and vulnerable adults are involved in the study/research, please confirm that all investigators have obtained a full enhanced DBS (Disclosure and Barring Service check). Please select ‘Not applicable’ if this does not apply to your research. | | Choose an item. | |
| 5. EITHER | a) The proposed research will not generate any information about the health of participants; | |  |
| OR | b) If the research could reveal adverse information regarding the health of participants, their consent to pass information on to their GP will be included in the consent form and in this circumstance I will inform the participant and their GP, providing a copy of the relevant details to each and identifying by date of birth. | |  |
| OR | c) I have explained within the application why (b) above is not appropriate. | |  |
| 6. EITHER | a) The proposed research does not involve children under the age of 5; | |  |
| OR | b) My Head of School (or authorised responsible person) has given details of the proposed research to the [University’s insurance officer](http://www.reading.ac.uk/internal/finance/Insurance/fcs-ins-travelandinsurance.aspx). | |  |
| 7. EITHER | a) The proposed research does not involve the taking of blood samples: | |  |
| OR | b) For anyone whose proximity to the blood samples brings a risk of Hepatitis B, documentary evidence of immunity prior to the risk of exposure will be retained by the Head of School or authorised responsible person. | |  |
| 8. EITHER | a) The proposed research does not involve the storage of human tissue, as defined by the [Human Tissue Act 2004](https://www.hta.gov.uk/policies/human-tissue-act-2004); | |  |
| OR | b) I have explained within the application how the requirements of the Human Tissue Act 2004 will be met. | |  |
| 9. EITHER | a) The proposed research does not involve the use of ionising radiation; | |  |
| OR | b) I am aware the proposed research will require [HRA REC review](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/ionising-radiation/). | |  |

# Version control

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| --- | --- | --- | --- | --- |
| Version | Keeper | Reviewed | Approved by | Approval date |
| 1.5 | UREC | Annually | UREC | September 2021 |
| 1.6 | UREC | Annually | UREC | February 2022 |