University of Reading

# University of Reading
# **Research Ethics Committee**

Policies, governance, procedures and guidance

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## Contents

## 1.0 Synopsis

This document sets out the policies and procedures by which the University of Reading Research Ethics Committee (UREC), established by Council, assesses the ethical propriety of all research conducted at, by, or on behalf of the University. It describes the steps to be taken to establish whether research falls within UREC's scope and the procedures to be followed to ensure that all such research secures the favourable opinion necessary for it to proceed. Explanation and guidance are provided on UREC's procedures for review and ongoing monitoring of human research and the role of in-School processes for the review of projects that do not – by exception – need to be referred to UREC. Guidance is given on the additional external ethical review needed for research activities that access NHS patients, patient records, samples, or data. The document signposts to useful supplementary resources, including template application forms and participant-facing documents.

## 2.0 Scope, purpose and terms of reference

a. to assess the ethical propriety of **all research** using human subjects, human samples (however obtained) or human personal data to be undertaken at, by, or under the auspices of the University, however funded. This encompasses both new research projects and requests to amend extant studies.

*UREC concerns itself exclusively with research. Teaching, service evaluation and audit activities are outwith its scope and do not require UREC approval. Guidance on categorisation is available **here.***

b. to have discretion on behalf of the University and, in the light of ethical considerations, to require such modifications as it may think fit before allowing the research to proceed. UREC decisions are binding on Heads of School and investigators but there is a right of appeal to the Strategy and Finance Committee.

*There is, therefore, an* ipso facto *requirement for all University research involving humans to secure 'approval' (a **Favourable Opinion**) from UREC before it commences.*

c. to offer advice to Heads of School and investigators on the ethical implications of proposed research and to encourage high standards of ethical behaviour in University research involving humans.

*Enquiries should be directed to the **UREC Secretary***

d. to monitor at its discretion the progress of research projects submitted to it by means of reports or in other ways and, if necessary, to suspend or terminate such research if required on ethical grounds.

## 3.0 Governance: Operations of the Committee

a. **Membership** UREC is established by Council, on the recommendation of Senate. Its membership comprises:

i. Eight members appointed by Senate:
ii. Up to two Lay members, appointed by Council
iii. Members appointed by UREC and reported to Senate
iv. A representative of RUSU

*Other than the Lay members and the RUSU representative, UREC members must be employees of the University of Reading.*

b. **Meetings** UREC holds an annual Plenary meeting for all its members and monthly Sub-group meetings to consider project applications.

i. **Annual Plenary Meeting**: One Plenary Meeting is held each academic year in the Autumn Term. At that meeting, the Committee shall consider the following standard agenda items, and any others its members wish to raise:

- Membership and Terms of Reference of the Committee
- A Review of the Committee's operation and procedures
- A draft Annual Report relating to the previous academic year, which includes a list of the projects which the Sub-Groups of the Committee have allowed to proceed, for approval and subsequent submission to the Senate
- An Annual Review of the Projects that Heads of School or University Department agreed be allowed in the previous academic year under the Committee's Exceptions procedure.

The Annual Plenary Meeting shall be quorate if seven members of the Committee are present, including at least four of the members of the Committee appointed by the Senate.

ii. **Sub-Group meetings (consideration of new applications)**: UREC delegates consideration of project submissions to Sub-Groups which normally meet on eleven timetabled occasions in each academic year. Sub-groups may also meet on further *ad hoc* occasions to expedite review of urgent or particularly challenging project applications.

Membership of the Sub-Groups shall be

- The/a Chair of UREC
- A Lay member of UREC (who may also be the Chair)
- At least two University members of UREC
- When required by the nature of the project under consideration, a medically qualified member of UREC
- The Secretary to the Research Ethics Committee (who may also be a member of UREC) shall be in attendance.

In addition, the Sub-Group shall seek the opinion of a further University member of UREC on each project and include this opinion in consideration of the project application when the Sub-group meets.

Sub-Group Meetings shall be deemed to be quorate if the views of the Chair, the Lay member (who may also be the Chair) and two other members of the Committee have been obtained on all projects under consideration.

The Sub-Group will deliver one of five possible outcomes on each project application it receives:

- **Favourable** The project may proceed
- **Favourable with conditions** The project may proceed when the conditions in the outcome letter have been met to the expressed satisfaction of the UREC Chair or their nominee.
- **Provisional** The project may not proceed until the matters raised in the outcome letter have been addressed, reviewed by the Chair (or their nominee, as appropriate) and given a Favourable opinion
- **Unfavourable** The project may not proceed (the application may be withdrawn and a replacement submitted)
- **No opinion** The project may not proceed. This outcome is given when the Sub-group cannot – based on the information presented in the application – form an opinion.

iii. **Voting at meetings**: Decisions at both the Annual Plenary and the Sub-Group meetings shall normally be reached by consensus amongst the members present. Should it be necessary to hold a vote on a particular issue, all members present shall have equal voting rights, the vote shall be decided by majority and in the event of a tie the Chair has the casting vote.

iv. **Chair's action:** Project submissions may be considered under Chair's (or their nominee's) action in exceptional circumstances.

c. **Amendments:** Applications for amendment to current projects which have already received a Favourable Opinion (*q.v.* Section 6.0 e.) will be reviewed, as received, in *ad hoc* fashion by the UREC Chair (or their nominee). Such applications will receive an outcome from the same suite as that available for initial project reviews (see Section 3.0 b. ii. Above).

d. **Community of Practice:** A UREC 'Community of Practice', hosted on MS Teams, is available to facilitate information exchange and to foster good research ethics practice across the University.

e. **Document version control:** The current version of this document ('University of Reading Research Ethics Committee: Policies, governance, procedures and guidance') is formally approved, biennially, by the University Board for Research and Innovation/Committee for Open Research and Research Integrity. Interim procedural and membership updates can be made and approved under the authority of the Chair of UREC.

## 4.0 Governance: Heads of School responsibilities

a. Heads of School are responsible for having procedures in place which identify all School projects that fall within UREC's terms of reference.

*Advice on all these responsibilities is available from the **UREC Secretary**.*

b. Heads of School are responsible for ensuring that all School projects that must be reviewed by UREC are submitted to the Committee in the manner prescribed in this guidance (*see* Section 6.0)

c. Heads of School are responsible for having in place procedures to identify School projects that fall within UREC's terms of reference, but which may be reviewed in-School via the 'exceptions' provisions (*see.* Section 5.0).

*The **Exceptions** provisions (Section 5.0) offer Heads of School the opportunity to review certain projects within School. There is, however, no obligation to exercise this freedom and UREC will review and give an opinion on any research project when asked.*

d. Heads of School are responsible for having procedures in place which ensure that all School projects that fall within UREC's terms of reference are not allowed to proceed until they have secured a favourable opinion from UREC (or the appropriate in-School body).

e. Heads of School are responsible for having procedures in place which identify all School projects requiring, in addition, review and approval by external bodies.

*A need for external review arises with research involving the NHS, when Health Research Authority REC review and approval are obligatory. For overseas research, approval from an in-country body is frequently needed.*

## 5.0 Governance: Exceptions – projects that may be reviewed in-School

a. A Head of School (or authorised Head of Department) **may** put in place procedures to undertake ethical review, and to allow, in-scope research projects within the School. Such in-School review may only be applied to research projects which, in the opinion of the Head of School (or authorised Head of Department):

*In-School review is an elective option. Heads of Schools in which research projects within UREC's scope are rare, are not obliged to create infrequently used in-School processes and may submit any application directly to UREC.*

i. do not involve participants, samples or data identified and accessed via the NHS. Such projects will necessarily require Health Research Authority REC review and approval, in addition to UREC review;

*Authoritative guidance on the requirement for HRA review can be found **here***

ii. do not involve subjects whose capacity to give informed consent may be impaired within the meaning of the Mental Capacity Act 2005;

*Authoritative guidance on the implementation of the Mental Capacity Act in research can be found **here***

iii. do not involve the storage of human tissue samples (in the absence of a research storage licence issued by the Human Tissue Authority). Such projects will necessarily require Health Research Authority REC review and approval in addition to UREC review;

*Guidance on the ethical review requirements for studies where human tissue will be stored without an HTA licence can be found **here***

iv. do not involve questions that might reasonably be considered to be impertinent or be likely to cause distress to the participants;

v. do not involve any significant risk of harm to the researchers or participants which cannot be mitigated by reliable measures;

vi. do not involve participants who could be considered 'vulnerable' in relation to the research procedures and interventions;

vii. do not involve participants who are in a special relationship with the investigator;

*The **UREC Secretary** is always available to give guidance on the categorisation of projects for REC review and to help decide whether a project may be reviewed in-School under these exception provisions*

viii. do not, on the insistence of the funding body, require review by UREC rather than by a devolved sub-committee.

b. If a project is reviewed in-School and is not submitted to the Committee, the Head of School (or authorized Head of Department) must be satisfied that the project conforms with the procedures in Section 6.0 below – including the requirement for annual reporting.

c. In the absence of any in-School alternative put in place by the Head of School (or authorised Head of Department), in-School applications should be made using the standard UREC application form

d. Heads of School (or authorised Heads of Department) who implement in-School procedures for the ethical review of research projects will be required to provide an annual report to the Committee. The report should:

*The request for this information is made annually in the Autumn Term to allow presentation of the information at the UREC Plenary meeting*

(i) Note any amendments made to the School's internal review procedures
(ii) List the research projects that were allowed (and any that were disallowed)
(iii) Note any projects involving research subjects under the age of 18
(iv) Note the number of human subjects who have participated.

## 6.0 Procedures: Applications to the Committee

a. All applications to UREC for the review of new projects should be made electronically, using the UREC application form and according to the published Sub-group meeting timetable whenever possible. They should be submitted via University email to UREC.

*Applications for review of planned alterations to projects which have previously been approved should also be made electronically to UREC (see Section 6.0 e. below)*

*b.* *In extremis,* UREC may consider applications in *ad hoc* fashion when the opinion is needed more swiftly than would be possible via the published meeting schedule.

*When this is necessary, the applicant should notify UREC promptly and provide as much notice as possible*

c. The UREC application form provides context-sensitive help and gives guidance to the applicant on the information that must be provided in the form and in the associated documentation that must be included in the application 'pack'. The application should therefore comprise:

i. In the form
- Project title and dates
- Applicant details
- Details of required reviews (including external)
- Appropriate in-School authorisation
- Lay summary (500 word limit)
- Research questions
- Design and procedures
- Location
- Funding source
- Ethical issues
- Deception
- Payment to participants
- Data protection and management
- Informed consent procedures
- Use of genotyping
- Participant details (number, characterisation, recruitment methods)

ii. As additional documents in the application pack
- Informed consent form
- Participant information sheet
- Any other participant-facing materials (procedural instructions, safety information etc)
- Advertising materials
- Questionnaires (or reference to standard/validated questionnaires)
- Protocol (not essential but include if available)
- A Data Management Plan (*q.v.)*

d. **Data Management Plan**. A clear and explicit understanding of the way human data will be managed (collected, used, stored, shared and disposed of) in a research project is an essential part of ethical review. UREC reassures itself of this important aspect by requiring that a Data Management Plan (DMP) be submitted as a component part of all applications to UREC. DMP guidance and templates are provided.

*For projects reviewed within Schools under the 'Exceptions' provisions (Section 5.0), a DMP is not required (although in-School review bodies and applicants are advised to make use of the online DMP guidance). Information on data management should be given in Sections 2.10, 2.11 and 2.12 of the application form.*

e. **NHS REC review, HRA approval and IRAS**. For applications which must also be submitted to the Health Research Authority (HRA) for NHS REC review and approval, the application to UREC may be made using the full suite of documentation required by the HRA

application process. This comprises the IRAS application form and a collection of associated documents similar to that specified in (c ii) above. This package should be augmented with an abbreviated UREC application form – comprising **only** Section 1.

f. **Collaborative research**. When research, that is in scope from a UREC perspective, is also being undertaken at or by a collaborating institution, agreement must be reached on which body/bodies will undertake the ethical review. The RECs of all collaborators will wish to declare themselves content. Researchers in this situation should seek advice from the UREC Secretary to determine the most pragmatic route to approval.

*Typically – and where the collaborating institution is 'leading' – the application and review may be done there first .A subsequent electronic application to UREC (comprising the original application to the collaborator's REC plus that REC's Favourable Opinion letter) would typically receive UREC endorsement by expedited review and Chair's Action.*

g. **Amendments**. For all in-scope research projects, there must always be in place a Favourable Opinion for the current, up to date, procedures and documentation. Thus, whenever any previously approved project procedures or documents are to change, an application must be made to UREC to review and give a favourable opinion to the proposed changes before these are implemented. The mechanism for review and approval of amendments is straightforward and succinct. Amendment applications should be made to UREC, comprising:

   i. A short email, identifying the UREC reference, project title and date of original ethical review/favourable opinion. The email should briefly summarise the changes that have been made, the reason(s) for making the changes now and the Chief Investigator's assessment of the ethical impact (if any) of their introduction.
   ii. Electronic copy of all amended and/or new materials (to include UREC application form, participant information sheets and any other altered documents. These must clearly show (by use of 'track changes' or highlighting) all the new and amended material.

h. **Monitoring**. UREC Monitors projects which it has reviewed and allowed to proceed by A. Requiring Chief Investigators to submit succinct annual reports on the progress of each active project that has received UREC approval (see Appendix 4). B. Undertaking an audit of the activities of a purposive selection of projects (determined by the Committee at its annual plenary meeting) each year..

University of Reading

# ETHICS REVIEW APPLICATION FORM

## 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.

## Section 1: APPLICATION DETAILS

| 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?<br>☐ Yes ☐ Undergraduate ☐ Masters ☐ PhD<br>☐ 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. |

## 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.

## 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. |
| | Choose an item. | Click here to enter a date. |
| | Choose an item. | Click here to enter a date. |
| | Choose an item. | Click here to enter a date. |

# Section 2: PROJECT DETAILS

| 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.<br><br>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.*

## 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<br><br>*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,

Give details of the funding body;

*Click here to enter text.*

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.

## 2.10 DATA PROTECTION

***For applications to be reviewed by UREC, or at the School level (SREC) in participating Schools (currently SPCLS and IoE) a Data Management Plan must be submitted. DO NOT complete this Section and move on to Section 2.11.***

**Otherwise:**

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 document.

*Click here to enter text.*

## 2.11 DATA MANAGEMENT PLAN

Applications submitted to UREC (and to SRECs in participating Schools – currently SPCLS and IoE) must be accompanied by a Data Management Plan (document available via link).

☐ Data Management Plan has been appended

## 2.12 DATA PROTECTION IMPACT ASSESSMENT (DPIA)

Will the research involve any activity that requires a Data Protection Impact Assessment (DPIA)?

☐ Yes
☐ No

If "yes", please append the "Pre-Screening Questionnaire for Data Protection Impact Assessment".

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

Will you obtain informed consent from, or on behalf of, research participants?

☐ Yes (go to question b)
☐ No (go to question c)

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.

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?<br><br>☐ HTA relevant<br>☐ Non-HTA relevant<br>☐ None |
| *Please provide additional details here* |
| Will the HTA relevant samples be stored for longer than 7 days?<br><br>☐ Yes<br>☐ No |
| How long will the samples be stored for?<br><br>_____Years _____Months |
| What will happen to the samples at the end of the research?<br><br>☐ Retention<br>☐ Disposal<br>☐ 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 | | |
|---|---|---|
| Signature: | Position: | Date: |
| | Choose an item. | Click here to enter a date. |

# Section 3: PARTICIPANT DETAILS

| 3.1 PARTICIPANT NUMBER |
|---|
| How many participants do you plan to recruit?<br><br>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.*<br>*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?<br><br>☐ Yes<br>☐ No<br><br>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?<br><br>☐ Yes<br>☐ No<br><br>If "yes", please detail the associated procedures as set out in the HRA REC application. |
| *Click here to enter text.* |

# CHECKLIST

| | | |
|---|---|---|
| 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. | ☐ |
| 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; | ☐ |
| 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. | ☐ |

# VERSION CONTROL

| VERSION | KEEPER | REVIEWED | APPROVED BY | APPROVAL DATE |
|---|---|---|---|---|
| **1.5** | UREC | Annually | UREC | September 2021 |
| **1.6** | UREC | Annually | UREC | February 2022 |
| **1.7** | UREC | Annually | UREC | June 2023 |

## 8.0 Appendix 2 Informed consent – Participant information sheet and Consent form guidance

a. Gaining and evidencing the informed consent of the participants is central to the ethical conduct of human-based research. An appropriate informed consent procedure is a pre-requisite to a favourable UREC opinion.

b. Conventionally, and most conveniently, this is done by providing prospective participants with a comprehensible (i.e. written in lay language) participant information sheet (PIS) and then requiring them to sign a consent form – indicating that they have received and understood the information and that they agree, on those terms, to take part. **Wherever this conventional approach can be adopted, it should be.** Note that *online* provision of information and acquisition of consent are perfectly acceptable in principle – provided the detailed mechanism/procedures give confidence that fully informed consent is being acquired from identified individuals.

c. Alternative informed consent models should not be discounted, however. There can be circumstances where – for example – information provision might, of necessity, be oral and consent might be signified in ways other than signing on a sheet of paper or electronic form. Always remember that the principle to be adhered to is 'evidenced informed consent'.

d. While it is not *directly* applicable, in full, to all forms of human research, the Health Research Authority's guidance on informed consent is definitive, has much that is relevant to ALL researchers - and is well worth consulting. A researcher adhering to the principles and practices advocated on the HRA website would – unavoidably (!) – produce informed consent materials that were fit for purpose.

e. The issue of **age** and the ability to give informed consent for participation in research in the UK is a nuanced one. The HRA gives helpful guidance. While there is no statute in England and Wales regarding a child's ability to consent to participate in research, UREC – in the interests of pragmatism – **requires** the following

   i. Informed consent must be obtained from all participants aged 16 and over.
   ii. Informed consent must be obtained from the parents or legal guardians on behalf of all participants aged under 16.
   iii. Assent (willingness to participate) must be obtained (or observed) all participants aged under 16.
   iv. Depending on circumstances, the 'assent' of parents or legal guardians of participants aged 16 and 17 should be obtained (in addition to the young participant's own consent).

f. Templates for participant information sheets and consent forms are given below.

a. This is not offered as a rigid template, but rather a flexible framework. We have suggested sub-headings which you may decide are appropriate to use or not, depending on the type of study you are planning and what is involved.

b. Although flexibility is encouraged, UREC usually finds that the sectionalised 'question and answer' format suggested below is accessible and palatable to participants – and provides UREC with reassurance that all necessary elements have been addressed.

c. The PIS is 'matched' with a consent form (see template example below), used to provide evidence that the participant has indeed been informed and has consented. Minor adaptation of the example provided will be necessary for online studies

d. The language used in the PIS should be clear, simple and readily understood by the target participant population. This applies not only for research involving children – where age-appropriateness of the material is important – but also more generally. Researchers must remember that the participant population is non-specialist and that no presumption should be made about their ability to read and understand complicated instructions and warnings. At the end of the informed consent process, the researcher must be absolutely confident that the participant fully understands what they have agreed to do. A comprehensive, readily comprehensible, PIS is a necessary element in having that confidence.

## Title

*A consistent study title, meaningful to the participant audience, should appear on all participant-facing documents. All documents should include the University of Reading logo.*

## Invitation and summary

*Remember – at this point you are inviting potential participants to take part, voluntarily, in a research project. Give them very brief information here – just enough to decide if they wish to read further. This is a good place to answer the question 'Why have I been invited to take part?'*

## Purpose and background

*What is the nature of what you are proposing? Why are you doing this research? What is already known? How many will be involved in the study? What alternatives are available to potential participants? If the research is contributing to an educational qualification (undergraduate OR postgraduate), this must be clearly stated here and the researcher(s) studying for qualifications should be identified.*

## What would taking part involve?

*This needs to be comprehensive and easy to understand from the participant's perspective so 'lay' language is important. Consider using simple diagrams to illustrate complicated timelines and long projects with multiple interventions and data acquisition periods.*

## What are the possible benefits of taking part?

*These are direct benefits to the participants – so be honest! Frequently, there are none. It is appropriate to say that there are no direct benefits, but that (say) participants frequently enjoy 'X', or enjoy knowing that their participation might contribute to 'Y'.*

## What are the possible disadvantages and risks of taking part?

*A 'fair and honest evaluation' is what's needed here. For much of the human intervention research conducted at the University the risks/disadvantages (beyond the time commitment) are very slight/minor but care – based on previous experience – should be taken to describe risks/disadvantages accurately.*

## What if something goes wrong?

*Effectively who to contact and what to do if something goes awry or the participant wishes to complain. They should always be provided with an 'escalation' route that goes beyond those directly involved in the prosecution of the study. Typically this will be someone in the School's management structure.*

## What will happen if I don't want to carry on with the study?

*The principle that any participant can withdraw at any time, without giving any reason - and with no disbenefit is very important. This position on withdrawal should be made clear here.*

## Will my information be kept confidential?

*Care needs to be taken to correctly explain the way confidential personal data will be handled. In addition to a simple, lay, description of the steps to be taken to ensure participant confidentiality, specific guidance on the data protection information that must be provided in Information Sheets is available online from the IMPS department. For UREC-reviewed projects, this will have been considered in the Data Management Plan.*

## What will happen to the samples I give?

*A simple description of storage, use, sharing and disposal. Mention of compliance with the Human Tissue Act, where appropriate, should be included here.*

## What will happen to the results of the study?

*Here, the storing/sharing/publication of results and data from the study – as will have been described in the Data Management Plan – is described in Lay terms to the participant. This is usually the best place to explain how participants can receive results/information themselves, if they are interested.*

## Who is organising and funding the study?

*A 'plain English' description of the School or Department which is organising and running the research is useful here. It should be made clear if the University of Reading is collaborating with any other organisations to deliver the research. All funding sources should be openly declared.*

## Who has reviewed this study?

*A standard declaration should always be included "This project has been reviewed by The University of Reading Research Ethics Committee (or substitute the relevant School body if the project has been reviewed via the Exceptions procedures) and given a Favourable Opinion for conduct"*

## Where can I get more information?

*The PIS should clearly identify the individual researchers (noting any who are undertaking the research as part of a qualification) and the Chief/Chief/Principal Investigator. Where the research is being performed as part of an educational*

*qualification (MSc or PhD, for example) the Supervisor (if different to the CI/PI) should be identified too.*

## Other points

*The Participant Information Sheet (whether hard copy or online) should be branded with the University logo.*
*Appropriate 'version control' measures should be in place so that the provenance and currency of the PIS can be assured.*
*To reiterate – the PIS and Consent Form should use simple, lay, language wherever possible since they are designed to be read and understood by a non-specialist audience.*

## Consent form template

| | | |
|---|---|---|
| **1.** | I have read and had explained to me by …… the accompanying Information Sheet relating to the project on: …….. | ☐ |
| **2.** | I have had explained to me the purposes of the project and what will be required of me. Any questions have been answered to my satisfaction. I agree to the arrangements described in the Information Sheet insofar as they relate to my participation. | ☐ |
| **3.** | I have had explained to me the information that will be collected about me, what it will be used for, who it may be shared with, how it will be kept safe, and my rights in relation to my personal data. | ☐ |
| **4.** | I understand that participation is entirely voluntary and that I have the right to withdraw from the project any time, without giving any reason, and that this will be without detriment. | ☐ |
| **5.** | I understand that the data collected from me in this study will be preserved and made available in anonymised form, so that they can be consulted and re-used by others.<br><br>*OR (delete whichever is inapplicable)*<br><br>I understand that the data collected from me in this study will be preserved, and subject to safeguards will be made available to other authenticated researchers. | ☐ |
| **6.** (*Optional*) | I authorise the Investigator to consult my General Practitioner<br><br>*OR (delete whichever is inapplicable)*<br><br>I authorise my General Practitioner to disclose any information which may be relevant to my proposed participation in the project. | ☐ |
| **7.** | I have received a copy of this Consent Form and of the accompanying Information Sheet. | ☐ |
| **8.** (*Optional*) | I am happy to be included on a register of research participants for the purposes of being contacted about further studies by……. | ☐ |

**Name:** ……

**Date of birth:** ……

**Signed:** ……

**Date:** ……

## Appendix 3 Membership of the University Research Ethics Committee (Session 2021-22)

**Appointed by Senate**

| | |
|---|---|
| Prof Sarah Brewer | International Study Language Institute |
| Dr Anastasia Christakou | School of Psychology and Clinical Language Sciences |
| Dr Kim Jackson | School of Chemistry, Food and Pharmacy |
| Dr Rosemary Lim | School of Chemistry, Food and Pharmacy |
| Professor Julie Lovegrove (*Co-Chair*) | School of Chemistry, Food and Pharmacy |
| Dr Eugene McSorley | School of Psychology and Clinical Language Sciences |
| Dr Anne Thies | School of Law |
| *Vacancy* | |

**Appointed by Council**

| | |
|---|---|
| Dr Geoff Botting (*Co-Chair*) | Lay member |
| *Vacancy* | |

**Appointed by UREC**

| | |
|---|---|
| Dr Tim Lincoln | Lay member |
| Dr Mike Proven (*Secretary*) | Academic and Governance Services |

***Ex officio***

| | |
|---|---|
| Bethany Nugus | Education Officer, Reading University Students' Union |

# University Research Ethics Committee - Annual update for ongoing UREC-approved studies

**Chief Investigators** should complete a **separate form for each research study** approved at any time by UREC (University Research Ethics Committee) and for which activity (including data analysis) was ongoing during the Academic Year 2022-2023 (i.e. since 1 October 2022)

* Required

* This form will record your name, please fill your name.

1. What is the Study Reference Number? (*please provide both the UREC reference and any separate School references)* *

2. What is the Study Title? *

3. Who is the Lead Applicant named in the study? *

4. Have any amendments to the originally approved project been granted? *

- ◯ Yes
- ◯ No

5. Please provide a one-line descriptor for each approved amendment *

6. Have any adverse incidents (as per SN59) been reported? *

- ◯ Yes
- ◯ No

7. Provide details of any adverse incidents (as per SN59) *

8. Have there been any other issues which did not require amendment or reporting but which resulted in material change from the originally approved study plan or protocol? *

- ◯ Yes
- ◯ No

9. Please give further information of the issue(s) *

10. Is the study ongoing? *

- ◯ Yes
- ◯ No

11. Please provide the date the study completed. *

Please input date (dd/MM/yyyy)

12. Please provide the date the study will end *

Please input date (dd/MM/yyyy)

13. Has anything been published following this study i.e. paper/conference etc *

- ◯ Yes
- ◯ No

14. Please provide further details of these publications *

15. If you have any comments to make regarding the Ethics review and approval process please do so here

**VERSION CONTROL**

(for the document 'UREC Policies, Governance, Procedures and Guidance')

| Version | Keeper | Approval | Effective from | Next review due | Notes |
|---|---|---|---|---|---|
| 1.1 | UREC Secretary | UBRI/CORRI | Nov 2021 | Nov 2023 | *First release in current form. Replaces 'UREC Notes for Guidance, Sept 2012'.* |
| 1.2 | UREC Secretary | UREC | March 2022 | Nov 2023 | *Minor updates to UREC application form, and update to UREC membership.* |
| 1.3 | UREC Secretary | UREC | June 2023 | June 2024 | *Minor updates to UREC application form, addition of annual review in appendix 4 and a few amendments to the guidance.* |