Researcher Checklist for Ethics self-assessment and/or Ethics Review Applications for research and KE activity involving human participants

1. Background

In order to facilitate best practice in research and KE and support researchers in doing so, the University has produced this guidance for researchers. The University must act transparently where there are expectations and requirements of researchers for ethical research, and this includes providing clarity on the role of an ethics review body.

This guidance should be read in conjunction with:

- The Introduction to Research Ethics Blackboard Training module, in particular the **section on Selection, Recruitment and Valid Consent.**
- Standard Operating Procedure: **UREC-SOP-002 Guidance for Reviewers.**
- Where researchers are working under the Human Tissue Authority's research licence, they must also refer to the **HTA Information and Resources Blackboard Site, including HTA SOP-009 Consent**.

2. Purpose and scope

To guide researchers to best practice in producing an ethics self-assessment or application for ethics review for research and KE activity involving human participants, and transparency around the remit and review parameters of the University's ethics review bodies and ad hoc ethics reviewers.

3. Guidance

3.1. Definition of Participants

This is wide and includes both primary and secondary data or material belonging to a participant. The definition of involving participants includes both direct and indirect contact with human participants. Examples of direct contact with human participants include interviewing people or taking measures from them. Indirect contact includes sending questionnaires to people in the post, obtaining data about people on-line including through social media forums, or accessing personal records or data. Both forms can have potential ethical implications.

An audience not directly involved in research and KE would not be seen as a set of participants.

Research using the internet; you should refer to the British Psychological Society's Internet Mediated Research Guidance and reference this in your ethics self-assessment form or ethics review application form, or supplementary documentation included with your form/s. For example, what people say online, such as in chat rooms on internet sites, may technically be in the public domain, this does not mean that it would be ethical to use it for research, as people may not expect their comments to be used in this way.

Dissemination of research may also identify individuals and this could potentially include risk to them or the researcher, and should be considered at the outset and recognized and risks reduced or eliminated as part of the ethics considerations when preparing your self-assessment/application form. Bearing in mind that even anonymous quotes can sometimes identify individuals. Information about this should be transparently provided during the consent process via suitable mediums for participant information.

3.2. An ethics self-assessment or ethics review application for a research or KE activity usually should contain information in addition to the forms used themselves:

To see what the remit and parameters of review are for a University ethics review body and/or ad hoc ethics reviewer, please see **UREC-SOP-002 Guidance for Reviewers,** which contains an indicative checklist for reviewers.

Ethics reviewers carry out reviews of the research and KE proposal itself, rather than the ethics form, though the submitted form should accurately reflect the proposal in summary and in lay person terms.

The ethics forms are designed to provide summary information around your proposal and its methodology and design so that perspective reviewers **1)** know the full breadth of what they are being asked to review for ethics implications (now or at later stages as the proposed project gets further developed). **2)** you yourself can carry out a self-assessment of potential ethics implications, recognize these, plan and mitigate in reducing or avoiding them and produce ethics research which protects potential participants and the research team from a risk of potential harm. **3)** a self-assessment acts as evidence of such consideration even if it is not a requirement for it to be reviewed.

Importantly, all the information included should be understandable by non-specialists and contain no complex technical terms. While ethics proposals are assessed by ethics committees/reviewers, others may do so as well to ensure that the research complies with ethical principles. These include institutions, sponsors, regulatory authorities, journal editors and publishers.

3.3. Participants

If your proposal contains participants or others you will work with, then this should be outlined in the ethics form too, and you will likely need to provide additional information to the ethics reviewers, **such as participant facing information (in any medium).** If such information will be provided verbally to participants, a transcript, in the English language should accompany your ethics form in most cases.

You will also need to ensure that participation is voluntary, in light of all information which may affect a decision to participate, and in light of the opportunity to withdraw at any stage (or specify limitations on withdrawal).

Consent forms are not a method for conveying information but a means to record participants' consent, if required. Regulated research will often require this to be recorded in a certain way.

Recruitment material should be included with your application form, and contain clear contacts for the study, affiliation, and funder if relevant, and any ethics review body reference number.

You can see the *Participant Information Medium (Guidance note)* for further details.

Don't forget that any selection criteria is part of the recruitment process and needs to be clearly articulated for both potential participants and ethics reviewers. Inclusion/exclusion exercises usually follow consent and should **not** be part of the consent process itself.

You are encouraged to complete the **Introduction to Research Ethics Blackboard Module**. If you wish to find specific information around participants and research and KE ethics, then the whole module is useful and particular detail is found in the **Recruitment, Selection and Valid Consent section** of the module.

3.4. See below information on general issues you *may* need to consider and provide either within or in addition to the ethics form:

Is the description of the project understandable?
Are the scientific end points clear?
Are the inclusion and exclusion criteria clear?
Has the research been adequately planned so it will be carried out in a timely manner?
Have the methods to collect and analyze data been outlined?
If relevant, is there an email or letter from the organization where the research is being undertaken agreeing that it can take place?
Are the sampling frame and the number of participants specified?
Are there issues of participant mental capacity to be considered and if so is the research design appropriate?
Is the recruitment process clearly described?
Is there a risk of coercion in the consent process?
Have potential participants been given adequate time to assess the information given about the research and their involvement?
Is it clearly stated that participation is voluntary and that there will be no adverse consequences of refusal?
Has the consent seeking process been adapted to cultural and local norms and expectations while respecting ethical standards?
Has the consent process been adapted to different cognitive or cohort needs for each participant set?
Are the process and time point(s) for withdrawal from the project detailed, as well as rights to request destruction of already collected data or tissue samples?

Does the research project involve deception and how will this be dealt with and justified to participants?
What provision is there for debriefing?
Does it detail and justify any inducements/rewards?
Is there detail of provision for benefit sharing?
What provision/ procedures are in place to assess risks and manage emergency situations/ unexpected findings/participant distress/disclosures?
Have the duration and security of storage of personal data, consent forms, transcripts, and audio and video recordings been specified and are they within recognized guidelines?

Have de-identification, data sharing and publication of the research been detailed?
Where participants wish to have their identity known and associated with their participation, is this adequately covered in the research design? Have risks in doing so been made clear to potential participants and recognized by the researcher (and mitigated or minimized).
Are there risks of stigmatization? If so, has a mitigation strategy been specified?
If relevant, how will participants will be able to access the final study report/ findings?
Does management of the research comply with international, national and institutional guidelines eg GDPR, the UK Data Protection Act 2018, Prevent, Disclosure and Barring Service regulations, institution lone worker policy, safeguarding policy?

Note: This guidance note covers non-regulated research and KE and also points researchers working under the Human Tissue Authority (HTA) licence to the University's HTA Standard Operating Procedures (SOPs), including Consent SOP.

For HTA, Health Research Authority (HRA), and other regulated research, researchers are required to be familiar with the legal and regulatory requirements. Where specific requirements are in place for both Participant Information Mediums and Consent Forms due to legal and regulatory requirements, the researcher must explain this within their ethics review application form.