School of Humanities

ETHICAL REVIEW OF STUDENT PROJECTS:
Guidance to Students

WHAT REQUIRES ETHICAL REVIEW

All student projects involving human participants require some form of ethical review. This includes interview and questionnaire studies, as well as the experimental work that one might find in (e.g.) Medicine or Psychology. The ethical review process provides additional safeguards for staff, students, and project participants and can contribute positively to teaching students about research methods and processes.

For the purposes of these guidelines, a 'project involving human participants' contains one or more of the following elements:

(a)   experimentation on human beings;

(b)   the observation of human beings for the purposes of a student project;

(c)   the recording, storage, or use of personal data for use in a student project; personal data for these purposes includes all information (excluding that already in the public domain) about existing individual people or about those who have died within living memory.

Purely documentary projects on sources that are already in the public domain will not normally require ethical review.

Purely historical, literary, and theoretical projects (*etc.*) will not normally require ethical review (unless it makes use of personal data, as defined above).

If students are uncertain whether a particular type of project requires ethical review, advice should be sought in the first instance from their supervisor. Students may also contact the Chair of the School of Humanities Student Project Ethics Committee for advice, Dr Mariangela Palladino, m.palladino@keele.ac.uk.

ACCESS TO AND/OR STORAGE OF MATERIAL THAT IS CONSIDERED TO BE SECURITY SENSITIVE

For the student's protection, if a research project involves access to and/or the storage of material that is considered to be security sensitive, whether it need ethical approval or not, these projects must be registered with the University before the research commences. More information about security sensitive research material and the registration process can be accessed via http://www.keele.ac.uk/researchsupport/researchgovernance/securitysensitiveresearchmaterial/

WHAT FORM SHOULD WILL ETHICAL REVIEW TAKE?

The processes outlined here apply only to projects undertaken by undergraduate students (UG) and students on postgraduate taught courses (i.e. PGT) and not PhD (PGR) students. Separate arrangements are in place for research students and for research undertaken by staff. Information about these can be found at: http://www.keele.ac.uk/researchsupport/researchethics/

If UG or PGT students are doing work which forms part of a research project led by Keele staff, or led by a Keele PGR, then the entire project should be treated as staff/PGR research and should similarly go through the process outlined at: http://www.keele.ac.uk/researchsupport/researchethics/

Special arrangements apply to research undertaken within health and social care. Any research project that involves NHS patients, their data and or tissues/samples must receive NHS Research Ethics Committee approval. Information about the process and the on-line application form can be accessed from: https://www.myresearchproject.org.uk/Signin.aspx. Furthermore, any research project undertaken within an NHS environment must have all the necessary governance approvals (eg NHS R&D or HRA approval and letter of access) in place at the NHS site(s) where the research is being undertaken before the research commences. Information regarding the process for ethical review of projects undertaken in social care can be accessed via http://www.hra.nhs.uk/resources/before-you-apply/non-nhs-recs/national-social-care-research-ethics-committee/

All other Undergraduate and Postgraduate Taught student projects involving human participants will be subject to ethical review and approval by a School-based Student Project Ethics Committee (S-SPEC) before any approach is made to prospective participants or subjects. Review by the School of Humanities SPEC may either be by expedited review or by the whole committee, depending on the nature of the project.

Submission

Please complete the ethical review application form subjoined and send it to the Chair of the School of Humanities Student Project Ethics Committee, Dr Mariangela Palladino, m.palladino@keele.ac.uk.

Deadlines

There are no deadlines for submitting applications to the School of Humanities S-SPEC, except that where ethical review is needed, you **MUST** obtain the approval of the School's SPEC **BEFORE** you begin the phase of research for which ethical approval is sought.

Student Non-Compliance with the Ethical review Process.

Point 11.5 of Regulation 8 Section 11 states 'Student projects which involve the participation of human subjects must not be undertaken without the prior

approval of a School Student Project Ethics Committee (or another Ethics Committee recognised for this purpose by the relevant School)'.

The University wide process for the investigation of alleged ethics offences at school level was approved by Senate in March 2014. Further information about the process can be accessed via http://www.keele.ac.uk/researchsupport/researchethics/ (section 4.1).

School of Humanities
School Student Project Ethical Review Committee (S-SPEC)
APPLICATION FORM (Undergraduate and PGT students)

Section A - Applicant's details

A1	**Project title**	
A2	**Name of researcher**	
A3	**School**	**Humanities**
A4	**Correspondence address**	
A5	**Keele E-mail address**	
A6	**Type of application**	**Undergraduate/Postgraduate Taught (please delete as appropriate)**
A7	**Please give supervisor name and contact details**	
A8	**Module Name and code**	
A9	**Project start date**	
A10	**Project end date**	

Section B - Project details

B1	In lay terms provide a brief summary of the project including the background and rationale for the proposed research and the hypotheses or research question(s) **(max 500 words).**

B2	In lay terms outline the type of procedure(s) and/or research methodology (eg observational, questionnaire, interviews, experimental) to be employed **(max 500 words).** Diagrams or flow charts that would aid clarification of the research should be attached if appropriate (these attachments will not be included in the word count).

B3	Describe the characteristics of the participant group, and the inclusion and exclusion criteria. Indicate the sample size, with an explanation of how this sample size was decided/calculated.

Section C - Ethically sensitive, challenging or issues of risk

C1	Will the research involve deceased persons, body parts or other human elements such as blood, hair or tissue samples (including saliva and waste products)? Yes ☐ No ☐

If yes, please discuss this project with Dr Alan Harper, Human Tissue Officer on 01782 674472 / 734654 or e-mail a.g.s.harper@keele.ac.uk. Please cite the reference number given by Dr Harper for this research project below;-

Reference number:

If yes, please give details with reference to the Human Tissue Act 2004.

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C2	Outline any potential risks to individuals, participants and researcher/members of the research team; the measures that will be taken to minimise risk; and the procedures that will be adopted in the event of an adverse event.

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C3	Will the research be undertaken overseas? Yes ☐ No ☐

If yes, have you consulted the Foreign and Commonwealth Office website for guidance/travel advice and is it safe to travel there?   Yes ☐   No ☐

Have you completed and submitted a risk assessment form?   Yes ☐   No ☐

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C4	Will the research include children or vulnerable adults such as individuals with a learning disability or individuals with cognitive impairment? Yes ☐ No ☐

C5	Will participants be deceived in any way about the study?	Yes ☐	No ☐
	If yes, describe the nature and extent of deception involved, including how and when this deception will be revealed and who will administer this feedback (debrief).		

SECTION D - Recruitment & consent process

D1	Indicate how potential participants will be identified, approached and recruited and outline any relationship between the researcher and potential participant.
	<mark>Remember to attach copies of posters, advertisements, invitation letters/e-mails to be used as part of the recruitment process with version numbers included in the footer.</mark>

D2	Describe the process that will be used to seek and obtain informed consent.
	If you answered yes to C4 (your participants are children or vulnerable adults) explain how you will ensure that individuals in these groups are competent to give consent to participate in this study.
	<mark>Remember to attach your information sheet and consent form with versions numbers & date included in the footer Templates available from http://www.keele.ac.uk/researchsupport/researchethics/</mark>

D3	Will consent be sought to use the data for other research?	Yes ☐	No ☐
	Will consent be sought to contact the individual to participate in future research?	Yes ☐	No ☐

D4	Can participants withdraw from the research?	Yes ☐	No ☐
	If yes, state up to what point participants are able to withdraw from the research		

	If **yes**, outline how participants will be informed of their right to withdraw, how they can do this and what will happen to their data if they withdraw.
	If **no**, explain why they cannot withdraw (eg anonymous survey).

SECTION E - Confidentiality and anonymity

E1	Outline the procedures that will be used to protect, as far as possible, the anonymity of participants and/or confidentiality of data during the conduct of the research and in the release of its findings.

SECTION F - Storage, access to, management of, and disposal of data

F1	Describe the research data that will be stored; where it will be stored and for how long; the measures that will be put in place to ensure the security of data; who will have access to the data; long term data management plans following completion of the project; and how/when data will be disposed of.
	If you are accessing or storing research material that is considered to security sensitive you will need to register your project with University. More information about security sensitive research material and the registration process can be accessed via http://www.keele.ac.uk/researchsupport/researchgovernance/securitysensitiveresearchmaterial/

SECTION G - Other ethical issues raised by the research

G1	Are there any other ethical issues that may be raised by the research?	Yes ☐	No ☐
	If yes, please give details.		

SECTION H - Other approvals required

H1	Does the project require researcher(s) to have a Disclosure and Barring Service (DBS) check?	Yes ☐	No ☐
	If yes, have you attached a confirmation of satisfactory DBS check memo?	Yes ☐	No ☐
	Does the project require National Offender Management Service (NOMS) approval?	Yes ☐	No ☐
	Does the project require NHS Research Development (R&D) Approval?	Yes ☐	No ☐
	Does the project require approval from another organisation?	Yes ☐	No ☐

SECTION I - Checklist

I1	Please list the documents attached to this application		
	Document	Version number	Date

Where appropriate, please attach the following
- Participant Information Sheet, which typically may include the following sections
    - why the participant has been chosen
    - what will happen to participants if they take part
    - a discussion of the possible disadvantages, risks and benefits of taking part
    - the procedures for ensuring confidentiality and anonymity
    - the proposed use of the research findings
    - contact details of the principal investigator plus details of additional support agencies (if necessary)
- Consent Form
- Copies of any questionnaire, interview schedules or topic guides.

Templates of Participant Information Sheet and Consent Forms for guidance can be obtained from
http://www.keele.ac.uk/researchsupport/researchgovernance/researchethics/

SECTION J - Declarations

J1	**Declaration by researcher** I confirm that:- - The form is accurate to the best of my knowledge - I will abide by the University's ethical requirements - I will inform the panel of any changes to the project - I am aware of my responsibility to be up to date and comply with the requirements of the law and any relevant professional guidelines
	Researcher name (in capitals)
	Researcher signature
	Date

J2	**Declaration by supervisor** I confirm that:- - I have read the application and am happy for it to proceed for ethical review - The application is accurate to the best of my knowledge - The project will comply with the University's ethical requirements - The applicant will inform the S-SPEC of any changes to the project - I am aware of my responsibility to ensure that the applicant is familiar with and complies with the requirements of the law and any relevant professional guidelines
	Supervisor name (in capitals)
	Supervisor signature
	Date

Please e-mail your completed application form and supporting documentation to the Chair of the
School of Humanities Student Project Ethics Committee, Dr Mariangela Palladino, m.palladino@keele.ac.uk.