This application form is for use by undergraduate / PGT students and must:

- Be completed for every project involving human participants/subjects/human tissues.
- Be accompanied by a project summary and where appropriate, participant information sheet(s), participant information letter(s) and consent form(s); please refer to templates and guidelines found at the end of this form.
- Provide both an electronic copy & hard copy of all documentation. The hard copy should be submitted to the William Smith Office, and the electronic copy should be submitted to spgs.spec@keele.ac.uk
- Signed by your supervisor (only hard copy).

APPROVAL MUST BE OBTAINED BEFORE potential participants are approached to take part in any research. Please note that the School Ethics Committee has a turnaround period of 3 weeks. Please also note that any cases which require resubmission would be subject to the same turnaround period, so do ensure you have planned sufficiently in advance to obtain full ethical clearance BEFORE you begin your research activities involving humans.

Please note that interview schedules, questionnaires, and other such material need to be authorised by your supervisor prior to commencing research, but are NOT required for submission with this form.

SECTION A

<table>
<thead>
<tr>
<th>Student Name:</th>
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<tr>
<td>Course:</td>
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<tr>
<td>Status:</td>
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<tr>
<td>Keele Email address:</td>
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<tr>
<td>Supervisor:</td>
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<tr>
<td>Title of Project:</td>
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<tr>
<td>Proposed start date:</td>
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<tr>
<td>Proposed end date for ‘field work’ (e.g. interviews):</td>
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Please note that it is your responsibility to follow the University’s Code of good research practice http://www.keele.ac.uk/researchsupport/researchgovernance/ and any relevant academic or professional guidelines in the conduct of your study. This includes ensuring confidentiality in the storage and use of data. Any significant change in the question, design or conduct over the course of the research should be notified to the Supervisor and may require a new application for ethics approval.

Participant information letter and consent form templates are available at the bottom of this form, and also from the Research & Enterprise Services website via the following link: http://www.keele.ac.uk/researchsupport/researchgovernance/researchethics/
### SECTION B

**ENSURING PARTICIPANTS’ VOLUNTARY AND INFORMED CONSENT**

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
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<tbody>
<tr>
<td><strong>1. Will the researchers inform participants of all aspects of the research that might reasonably be expected to influence their willingness to participate and in particular, any negative consequences that might occur?</strong></td>
<td>If <strong>YES</strong>, please give details:</td>
</tr>
<tr>
<td>If <strong>NO</strong>, please explain:</td>
<td></td>
</tr>
<tr>
<td><strong>2. Will all participants be provided with a written information sheet and be provided with an opportunity to provide (or withhold) written consent?</strong></td>
<td>If <strong>YES</strong>, please ensure that these documents are attached (see above). If <strong>NO</strong>, please explain why written consent &amp;/or information is not appropriate for this study.</td>
</tr>
<tr>
<td><strong>3. Is consent being sought for the information collected to be used for future research projects?</strong></td>
<td><strong>YES</strong> / <strong>NO</strong> (delete as appropriate)</td>
</tr>
<tr>
<td><strong>4. What are the exclusion/inclusion criteria for this study, and why?</strong> (i.e. explain who will be allowed to / not allowed to participate in your research project, and on what grounds you have chosen them, or deemed them suitable or otherwise).</td>
<td></td>
</tr>
<tr>
<td><strong>5. Will people who are vulnerable be allowed to take part in this study?</strong> For these purposes, vulnerable participants are those whose abilities to protect their own interests are impaired or reduced in comparison to the population as a whole. Vulnerability may arise from personal characteristics (such as mental or physical impairment) or from social context and disadvantage (e.g. lack of power, education, or resources). Prospective participants, who are at high risk of consenting under duress, or as a result of manipulation or coercion, should also be considered as vulnerable. All children and adults who lack mental capacity are presumed to be vulnerable.</td>
<td>If <strong>YES</strong>, what special arrangements (if any) are in place to protect vulnerable participants’ interests? If <strong>NO</strong>, please outline the rationale for excluding them:</td>
</tr>
</tbody>
</table>
6. Will the study involve participants who are unable to give valid (informed) consent (e.g. children and adults lacking mental capacity)?

YES / NO (delete as appropriate)

If YES, what procedures will be in place to ensure that informed consent is obtained, where appropriate, from third parties (e.g. parents or carers)? And what procedures will be in place (if any) to give the participants an opportunity to have their objections recognised and respected?

7. Will participants require any support to take part in the research (eg. disability support, interpreter)?

YES / NO (delete as appropriate)

If YES, what sort of support is required and how will it be delivered?

8. Does the investigation involve observing participants unawares?

YES / NO (delete as appropriate)

If YES, what efforts will be made to respect their privacy, values and well-being?

9. Will information and/or data from participants be kept confidential?

If YES, how?

If NO, please give rationale:

10. Does the research activity proposed require a Disclosure & Barring Scheme (DBS) disclosure? (Information concerning activities which require DBS checks are required can be accessed via https://www.gov.uk/government/publications/dbs-check-eligible-positions-guidance and http://www.keele.ac.uk/hr/policiesandprocedures/crbsafeguarding/ If you are unsure whether a DBS disclosure is required please contact Human Resources or Nicola Leighton prior to submission of this application form. If you answer YES please complete the relevant section below. If you answer NO please go to question 11.

HOME/EU STUDENTS ONLY

10a Have you (and other individuals who will be working on the research project) had a DBS Disclosure (or equivalent) initiated by Keele University?

10b If you have answered YES to question 10a please contact Nicola Leighton to obtain a confirmation note indicating that a DBS disclosure (or equivalent) has been previously initiated by Keele and that it was satisfactory. Is the confirmation note attached to this form?

If you have answered NO to question 10a please contact Nicola Leighton regarding the appropriate administrator immediately to arrange for a DBS disclosure (or equivalent) to be applied for.
You will still be able to apply for ethical approval in parallel to applying for a DBS disclosure. However, your project will not be approved by the ERP until you have forwarded the confirmation note from Nicola Leighton indicating that a DBS disclosure has been undertaken and is satisfactory.

INTERNATIONAL STUDENTS ONLY

Please contact Nicola Leighton on 01782 733306 or e-mail n.leighton@keele.ac.uk before completing this section

10c Have you (and other individuals who will be working on the research project) had a DBS Disclosure (or equivalent) initiated by Keele University?

10d If you have answered YES to question 10c please contact the appropriate person (as advised by Nicola Leighton) to obtain a confirmation note indicating that a DBS disclosure (or equivalent) has been previously initiated by Keele and that it was satisfactory. Is the confirmation note attached to this form?

If you have answered NO to question 10c please contact Nicola Leighton regarding the appropriate administrator immediately to arrange for a DBS disclosure (or equivalent) to be applied for. You will still be able to apply for ethical approval in parallel to applying for a DBS disclosure. However, your project will not be approved by the ERP until you have forwarded the confirmation note from Nicola Leighton indicating that a DBS disclosure has been undertaken and is satisfactory.

RESEARCH PROCESS

11. Will participants receive any reimbursements or other payments?

YES / NO (delete as appropriate)

If YES, please give details:

12. Does the research involve the analysis of data participants will not realise would be used by you for research purposes (e.g. confidential criminal, medical or financial records)?

YES / NO (delete as appropriate)

If YES, please give rationale:

13. Does the research involve the possible disclosure of confidential information to other participants (e.g. in focus groups)?

YES / NO (delete as appropriate)

If YES, please explain how this will be handled:
14. Will the researchers de-brief participants at the end of the research activity to ensure that they understand the nature of the research and to monitor possible misconceptions or negative effects? (De-briefing could involve providing participants the opportunity to raise questions and concerns, giving participants some preliminary feedback, reiterating some instructions or reassurances, etc.)

If YES, how will this be done?

If NO, please explain why not:

15. Are there any other ethical issues that you think might be raised by the research?

If YES, please provide details:

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**MEDICAL CONSIDERATIONS**

16. Does the research involve people being investigated for a condition or disorder which has received medical, psychiatric, clinical psychological or similar attention?

YES / NO (delete as appropriate)

If YES, please give details:

17. Are drugs, placebos or other substances (e.g. food substances, vitamins) to be administered to participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind?

YES / NO (delete as appropriate)

If YES, please give details and justify:

18. Will blood or other bodily fluids/tissues (including hair, nails, etc.) be obtained from participants?

YES / NO (delete as appropriate)

If YES, please give details and justify:
19. Is pain or more than mild discomfort likely to result from the study?

YES / NO (delete as appropriate)

If YES, please give details and justify:

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**HEALTH AND SAFETY**

20. Does the project have any health & safety implications with ethical dimensions for the researcher?

YES / NO (delete as appropriate)

If YES, please outline the arrangements which are in place to manage these risks:

21. Will any research take place outside the UK?

YES / NO (delete as appropriate)

If YES


YES / NO (delete as appropriate)

For international students - Have you also sought advice/guidance from the Foreign Office (or equivalent body) of your country?

YES / NO (delete as appropriate)

For all students - Will you be visiting any areas for which particular risks have been identified or for which the advice given is not to travel to this area?

YES / NO (delete as appropriate)

If YES

(a) Please give details

(b) Please outline the arrangements in place to manage these risks.
FINAL CHECKLIST:

Have you included?

☐ A project summary
☐ Participant information sheet(s) – if required
☐ Participant Invitation Letter(s) – if required
☐ Consent form(s) – if required – if required
☐ Student’s and Supervisor’s signatures

SECTION C

Signatures:

..............................................................................................................  Date: .........................
Student

..............................................................................................................  Date: .........................
Supervisor or Course/Module Tutor
PROJECT SUMMARY

Requirement: A summary of the proposal, between half a side to two sides of A4 paper, but no more.

Include a concise paragraph about the background to the study to place the work in context, include your aims/objectives/research question where applicable and give a clear account of methods considering the following:

- Be very clear about the 'process' – a flow chart can be very useful for reviewers
- What exactly are you doing?
- Who are you doing it with?
- Gatekeeping – do you need to get permission from anyone? If so, who?
- Who, how many and how are you recruiting? If numbers are flexible linked to methodology say so.
- When and how do ‘individuals’ get the information sheet or equivalent?
- When and how do ‘individuals’ give consent?
- When are things going to happen?
- Where do things take place etc.?
- How long (for example) are interviews (if this is flexible due to your methodology, say so); how long will it take to fill in questionnaires? How are questionnaires circulated to participants?
- Who sees the data? Consider password protection for computers
- How the data will be ‘looked after’ and stored and access by appropriate Keele staff ensured? Consider the University Guidelines for the storage of sensitive and confidential data on portable devices (2011) available from http://www.keele.ac.uk/media/keeleuniversity/fait/it/servicedeskinformation/policyandguidance/Portable%20Device%20Security-V2.pdf

GENERAL TIPS FOR CONSIDERATION ABOUT THE PROCESS/DOCUMENTATION

Use appropriate and consistent language for all letters, information sheet etc.

For all documents – consider your audience (lay, expert, research, practice, policy, etc)

Consider briefly introducing yourself first as a student/researcher in the invitation and information sheet – doesn’t need to be a biography, and does need to steer away from unduly influencing the would-be participant ahead of them reading the information

Information Sheets – is all the information there? Have you checked against the template Information Leaflet for content?

Be clear about confidentiality and anonymity – they are different.

Contact details – please use Keele contact details, NOT your personal ones, for your own safety.

BEFORE you hand in check thoroughly:

Have you filled in all the sections in the application form?

Be consistent – does everything you say in your application form -

- match everything you say in your summary?
- match everything you say in your information sheet?
- match everything you say in your consent form etc.?

Contact details: yours and if applicable your supervisor’s - are they where they should be? (Do not use personal telephone numbers)
Information Sheet

Study Title: <insert title>

Aims of the Research
Please state the aims of the research project.

Invitation
You are being invited to consider taking part in the research study <insert study title>. This project is being undertaken by <insert names of research team>.

Before you decide whether or not you wish to take part, it is important for you to understand why this research is being done and what it will involve. Please take time to read this information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is unclear or if you would like more information.

Why have I been invited?
Explain briefly why and how the participant was chosen and how many others will be in the study.

Do I have to take part?
You are free to decide whether you wish to take part or not. If you do decide to take part you will be asked to sign two consent forms, one is for you to keep and the other is for our records. You are free to withdraw from this study at any time and without giving reasons.

What will happen if I take part?
Explain what exactly will happen to participants (e.g. you will be given a questionnaire to complete)
Set down briefly and clearly what you will expect of participants

What are the benefits (if any) of taking part?
Explain the benefits, if any, of taking part

What are the risks (if any) of taking part?
Explain the risks, if any, of taking part

How will information about me be used?
Explain how their data will be collected and what the data will be used for. It must be clear whether the data collected will be retained for use in future research studies and whether further ethics approval will be sought.

Who will have access to information about me?
You should tell the participants how their confidentiality and/or anonymity will be safeguarded during and after the study.

You may wish to include the following statement in total or in part:-

I do however have to work within the confines of current legislation over such matters as privacy and confidentiality, data protection and human rights and so offers of confidentiality may sometimes be overridden by law. For example in circumstances whereby I am concerned over any actual or potential harm to yourself or others I must pass this information to the relevant authorities.

The participants should be told:-

- That data will be stored securely and where the data will be stored (e.g. in a locked filing cabinet, on a password protected computer)
- The level of identifiability (e.g. coded, unlinked-anonymous, fully identifiable)
- That the data will be stored in line with the sponsor’s guidelines (where there is a sponsor) and that the data will be retained by the principal investigator for at least five years.
- What the longer-term arrangements are for disposing of or keeping the data (e.g. that they will be securely disposed of, or placed in a repository)

Who is funding and organising the research?
State who is funding and organising the research.

What if there is a problem?
If you have a concern about any aspect of this study, you may wish to speak to the researcher(s) who will do their best to answer your questions. You should contact <insert researcher’s name> on <insert Keele contact number or Keele e-mail address>. Alternatively, if you do not wish to contact the researcher(s) you may contact <insert your supervisor’s contact details>

If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have been approached or treated during the course of the study please write to Nicola Leighton who is the University’s contact for complaints regarding research at the following address:-

Nicola Leighton
Research Governance Officer
Research & Enterprise Services
Dorothy Hodgkin Building
Keele University
ST5 5BG
E-mail: n.leighton@keele.ac.uk
Tel: 01782 733306

Contact for further information
Normally only Keele telephone numbers and e-mail addresses should be used in all study documentation. If there are reasons to depart from this then these must be explained in your Ethical Review Panel documentation.
CONSENT FORM

Title of Project: <insert title>
Name and contact details of Principal Investigator: <insert name, address, telephone, e-mail >

Please tick box if you agree with the statement

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions

2. I understand that my participation is voluntary and that I am free to withdraw at any time

3. I agree to take part in this study.

4. I understand that data collected about me during this study will/will not* be anonymised before it is submitted for publication.

5. I understand that although data will be anonymised because of my role it may be possible that I could be identified in reports and publications*

6. I agree to the interview/focus* group being audio/video recorded*

7. For focus groups*
   I agree to keep the issues discussed within the focus group confidential and in particular, to avoid identifying any of the participants in relation to these issues/individual comments made during the session

8. I agree to allow the dataset collected to be used for future research projects*

9. I agree to be contacted about possible participation in future research project*

10. I agree for my quotes to be used

________________________
Name of participant

___________________
Date

_____________________
Signature

________________________
Researcher

___________________
Date

_____________________
Signature

For Focus Groups/Interviews*
If you consent to participate in this study, it should be drawn to your attention that the researcher has a professional obligation to act upon any aspects of poor practice and/or unprofessional behaviour that may be disclosed during the research activity. Researchers should use the appropriate reporting mechanisms if they have witnessed or experienced poor practice and/or professional behaviour.