GUIDANCE FOR STUDENTS & SUPERVISORS

STUDENT RESEARCH PROJECT ETHICS REVIEW
Division of Psychiatry & Applied Psychology
(Version 21 Feb 2018)

The University of Nottingham’s Code of Research Conduct and Research Ethics (2016) underpins the University’s commitment to maintaining the highest standards of integrity, rigour and excellence in all aspects of its research and for all research to be conducted according to the appropriate ethical, legal and professional standards. This is consistent with the national framework published by Universities UK, The Concordat to Support Research Integrity (2012). Ethical review and approval is required for all projects where the research involves human participants.

The Division of Psychiatry & Applied Psychology (DPAP) Research Ethics Sub-Committee is authorised by the Faculty of Medicine & Health Sciences Research Ethics Committee to review certain research project proposals undertaken by its students.

Who is this guidance for?

This guidance is designed to help students describe their proposed research project in suitable and sufficient detail for it to be submitted for ethical review.

Before they begin, and for any type of project, all students must read and abide by the University of Nottingham’s Code of Research Conduct and Research Ethics 2016. This includes information about data storage and handling and the requirement to comply with data protection regulations. If undertaking internet-mediated research studies, students should read the British Psychological Society’s Ethics Guidelines for Internet-Mediated Research 2017 and the University’s Social Media Policy for Students 2015. Students may also be advised by their supervisors to read other guidance that is relevant to the topic or method of their research (e.g. on lone working, or safeguarding and obtaining consent in the case of research with vulnerable populations). Students may find The Research Ethics Guidebook: A Resource for Social Scientists useful background reading.

Students undertaking any type of project need to read the above mentioned guidance. This is an important part of their learning experience and should help alert them to ethical issues that may arise during the course of their project. Links are provided at the end of this document.

Who needs to submit their study for ethical review?

An on-line application for ethical review must be submitted for every student research project conducted in the Division.

PhD projects will be subject to review throughout the year. MSc and BMedSci projects may have required deadlines for ethical review: these will be detailed in Course handbooks or available from Course Directors. Course Directors will advise the Administrator to the DPAP Ethics Sub-Committee of those dates.
Supervisors may consider that ethical review by the DPAP Research Ethics Sub-Committee is not required if, for example, the study already has ethical permissions, or involves no data (e.g. literature review), is based solely on existing anonymised records (which have been anonymised prior to receipt by the student), documentary sources or data sets that exist in the public domain, or involves no fieldwork. If a student plans to use existing data sets that would allow individuals to be identified, the proposal must be submitted for ethical review.

For studies that do not require ethical review by the DPAP Research Ethics Sub-Committee, the student and supervisor should complete Sections 1, 2, 9 and 10 of the on-line application form, explaining why ethical review by the DPAP Research Ethics Sub-Committee is not required. The supervisor will submit it for approval by the Chair. A letter will be generated confirming that no (additional) ethical approval is required.

Training for students

All students are required to read this guidance carefully and take note of its requirements. They will be expected to consider ethical issues when they write up their research.

MSc and BMedSci students, as advised by their research project module convenor, should attend a face-to-face/on-line lecture on ethics, research integrity and the Division’s ethical review process. They should also attend a lecture on data protection and storage.

PhD students are required to take two University of Nottingham Graduate School courses (book on line) in the early stages of their research. These are:

[1] An online training course on Research Integrity. This requires one day and counts as two training points. This is a stand-alone online course designed to strengthen awareness of responsibilities and accountability when planning and conducting research. It provides guidance on what to do if things go wrong. For the majority of PhD students in the Division, the ‘Social Science’ course will be the most suitable, although supervisors may advise certain students to take the ‘Medical and Health Sciences’ course depending on the nature of their topic of study. Click here for more information.


Training for supervisors

Supervisors should be familiar with the Codes and guidance detailed above, attend Divisional or University training courses as advised, and note the regular updates on ethical review and data handling and storage presented at Academic Staff Meetings.
MAKING AN APPLICATION

The link to the on-line ethics review application form is available here.

When students first register, they only need insert their first and last names and their email address, ignoring the remaining requests for additional personal information such as home address. Please note - students will not gain instant access to the system as their registration needs to be approved by the system administrator. Thus, registrations at the weekend would not be processed until the following week. The administrator will send an email to confirm that registration is approved.

NB - only University of Nottingham email addresses should be used.

1 - APPLICANT DETAILS

This section asks for details of the supervisor/s and the student’s programme of study.

2 - TYPE OF STUDY

This identifies the type of project, and whether it is suitable for review by the DPAP Research Ethics Sub-Committee. Most projects will be subject to single review by one member of the Sub-Committee. Projects that involve sensitive topics or vulnerable populations, it will be subject to dual review.

The Sub-Committee is not authorised to approve studies that involve the recruitment of National Health Service (NHS), Her Majesty’s Prison and Probation Office Service (HMPPS) patients, premises, data, records or staff or studies involving care homes. For these studies students will be directed within the on-line application form to contact the University of Nottingham’s research governance team (the ‘Sponsor’) giving a brief outline of what and who the study involves. This will be reviewed by the research governance team and given approval to proceed to the next step, which may include an application for ethical review to the School of Medicine’s Faculty of Medicine and Health Sciences Research Ethics Committee or to the Health Research Authority (HRA) or other committees. These will require the completion of different forms. It can be a lengthy process so students and supervisors should allow plenty of time for this when planning their study.

For these studies, the student and supervisor should complete Sections 1, 2, 9 and 10 of the application form to explain why ethical review is not required by the DPAP Research Ethics Sub-Committee.

Disclosure and Barring Service (DBS) check

Where potential participants are vulnerable and/or aged under 18 years (and where there is any chance of students ever being alone with such participants) students will also be required to undergo a Disclosure and Barring Service (DBS) check to cover the period of study. The responsibility for completing this satisfactorily is the student’s and proof of successful completion
must be seen by the supervisor. Students should apply to Student Services, explaining clearly why a DBS check is required.

Projects undertaken in (or data gathered from) countries outside the UK

Students and supervisors are required to ensure that they are aware of any research ethical guidelines in the countries other than the UK that may apply to the study’s proposed participants. The student must agree to abide by the ethical guidelines provided in the UK (the University of Nottingham’s guidelines) or, in the case that the country in question has more stringent guidelines, by those that are the most stringent. Students and supervisors are also required to consider whether cultural sensitivities have been taken into account. Some issues which may not be sensitive in some countries and cultures may be regarded as sensitive in others.

Supervisors should conduct a risk assessment with their students on a case by case basis. Additional guidance and templates are available in the ‘Fieldwork’ section of the University Safety Office’s website.

Students who elect to undertake a research study outside the UK are not covered by the University of Nottingham’s travel insurance policy. They should make their own arrangements for travel insurance. The University will provide a list of insurance companies that they may like to try on the Financial and Business Services website. Any studies which give rise to concern should be discussed with the University’s Insurance Manager.

Supervisors should check the Insurance workspace and the FCO website to see if the travel destination has any warning notices. Any study that involves research in a high risk country will require additional approval from the University’s Insurance Manager.

3 - STUDY OUTLINE

A brief description of the study should be outlined in a pdf file of two or a maximum of three pages. It should be uploaded in this section by clicking on the button ‘Upload Document’. All documents to be uploaded must be written in Arial 11, single spaced and in pdf format. The title should indicate concisely the topic of study and nature of participants. Most projects will require following headings:

- Rationale (the scientific value of this study that justifies taking up participants’ time and effort, with reference to the existing scientific literature)
- Research question/s
- How access to participants will be gained (recruitment)
- Participants
- How data will be collected (eg. observation, interview, survey)
- Where data will be collected (eg. telephone, workplace, on-line)
- Justification of materials and measures (experimental tasks, interview guides, questionnaires, including if appropriate information on their reliability and validity)
- Justification of final sample size
- Key references (up to ten)

4 - PARTICIPANT INFORMATION

Approved templates for Participant Information and other forms, such as those required for Participant Consent, are available to download directly from the on-line application form and from the ‘Quick Downloads’ section of the Division’s Research Ethics Webpage. They provide
guidance about format and content and will need to be adapted for the study and its intended participants. If obtained from the webpage, students and supervisors should ensure they use the versions current at the time of application, not those that they have downloaded previously. Applications using old versions will be returned without review.

Participant information is designed to communicate with people who are not researchers, technical experts or scientists. Such outward-facing documents are challenging to write properly and require careful consideration. They should be concise and written in layperson’s language. Technical research terms should be replaced with words that laypersons will understand. Words like ‘mediated’, ‘organisational learning’, ‘negative relationship’ or ‘self-efficacy’ should not be used. Particular attention should be given to correct spelling and grammar. Students are advised to have these carefully proof read.

Participant Information should accurately describe all parts of the study that participants will be asked to be involved in and provide YES/NO options for each question posed. It should be explained why they are being asked to take part. The amount of time that participation will require should be clearly specified.

The voluntary nature of participation must be explained. Both implied and explicit coercion must be avoided. The latter may be a risk where potential participants are known to the researcher, for example, as friends. This may also be pertinent where there is an actual or perceived imbalance of power. For example, if potential participants are employees in an organisation managed by a member of the student’s family, they may feel obliged to participate. Such a third party is known as a ‘gatekeeper’: any person whose help is needed to recruit or gain access to participants. This could be a senior manager or company director. Care must be taken to ensure that a gatekeeper does not coerce potential participants nor be able to learn who has/has not agreed to participate.

At all stages of the study, and in its reporting, students must prioritise assuring both confidentiality (who has right of access to the data provided by participants) and anonymity (concealing the identities of participants in all outcomes resulting from the research, and assuring that they cannot be indirectly identified via location or demographic data). It is important where participants have been assured of anonymity that no-one (including a gatekeeper) can later identify participants or their responses, directly or indirectly, from any findings presented. For example, mentioning together country of origin, age, or gender might enable participants to be identified indirectly even though the findings from a questionnaire or interview are reported without names attached. Interview transcripts should never contain people or place names. The Participant Information and Study Outline (where participant recruitment is described) must make it clear how these risks can be avoided or minimised. If transcription services are provided by a third party they should sign the Transcriber Confidentiality Form, available on the Division’s Research Ethics website.

For sensitive topics, if concern or distress is possible, information must be provided about where participants can find advice and help. A list of examples is provided within an ‘information’ button in the on-line application form. If such help may require significant input from a particular source (for example, a counselling or occupational health service), it should be considered whether that source needs to be advised. A debriefing form after participation (in addition to Participant Information) is not necessary for most projects; supervisors will advise if they are needed.

As appropriate, this information may be translated into languages other than English and in other formats. It is the student’s responsibility to ensure this is done fairly and accurately.

Participant Information should also advise the participant that with anonymous, internet-mediated contributions, that it is not usually possible to withdraw data once submitted. Exceptions to this
are possible, where the student has set up procedures for so doing, for example by offering participants the opportunity to set their own unique identifying code for use in future correspondence to a given email address within a given period.

Details about sources of further information and complaints procedures should be given as detailed in the Participant Information template.

The supervisor may recommend that the participant information form explains to participants that the aim of the study is to help the student gain an academic qualification.

An Ethics Reference Number will be allocated once the project has successfully passed ethical review and will be available in the approval letter. This should be inserted on the participant information form in the space indicated.

5 - PARTICIPANT CONSENT

The approved Participant Consent template provides guidance about format. The guidance given in the Participant Information section above about writing clearly for a lay audience, also applies to the consent form.

The consent form should accurately describe all parts of the study that participants will be asked to be involved in and provide YES/NO options for each question. For example, if the participant is being asked to take part in an interview and answer a questionnaire, there should be YES/NO boxes to reflect their agreement to each component.

When a potential respondent declines to give consent, the researcher is allowed to offer further information or explanation about the research but must not apply any pressure.

The consent form may be translated into languages other than English and in other formats. It is the student’s responsibility to ensure this is done fairly and accurately.

For face to face studies, two copies of the consent form should be signed. One should be given to the participant. The other is securely retained by the researcher in a separate location from any resulting data. At the end of the project, scanned copies of all the student’s copies of consent forms must be securely deposited with the supervisor and the originals destroyed.

For on-line studies, it is sufficient to write at the bottom of the on-line consent form ‘By clicking this button I agree to participate’. The consent form should be placed AFTER the participant information form in an on-line study. Advice about obtaining consent for online studies can also be found in the British Psychological Society’s Ethics Guidelines for Internet-Mediated Research 2017.

Consent with vulnerable populations

When seeking consent, adults are assumed to be competent to do so unless the supervisor and student judge that they are unable to assess the information provided to make a decision. In such cases, additional consent forms are required for a relevant third party (for example parent, guardian or carer). The consent form will invite third parties to sign a statement that they have
read and understood the Participant Information, and agree that the potential participant can take part in the research. In the case of individuals under the age of 18 (young persons), they should be asked to assent to their parents’ signed consent forms. Templates for these are available on the DPAP Research Ethics webpage.

Under certain circumstances, opt-out consent is applicable. For example, where a Head Teacher considers that explicit parental consent is not required, the student (having obtained the written consent of the Head Teacher), provides parents with information explaining the proposed research project and gives them the opportunity to opt their children out by filling in and returning a form to the school. Supervisors should advise students accordingly and note BPS and other relevant guidance as appropriate.

6 - ORGANISATIONAL PERMISSIONS or EXTERNAL ETHICAL REVIEW

Students undertaking projects in outside organisations need to provide evidence (an email or headed letter) that the project has been approved by a suitably authorised person from that organisation. This may not be available at the time of application for ethical review. In which case, supervisors will undertake to check such permissions are in place before they permit the student to begin approaching potential participants. Supervisors should check that the letter of organisational permission accurately reflects the proposed study.

If the study is to be conducted in an outside organisation it also needs to be established whether that organisation has its own ethical scrutiny procedures.

7 - ADDITIONAL DOCUMENTATION

In this section, students upload materials such as questionnaires, interview guides, advertisements, posters, other marketing materials, initial email invitations to organisations or potential participants or cover letters.

8 - ETHICAL CONSIDERATIONS

Students and their supervisors should conduct their own initial ethical review, checking the list of ethical considerations to identify possible risks to ethical conduct. Ethics review is still required even if they deem none of these risks to apply. Risks are listed in order: issues relating to the topic of study, procedural issues, those that may occur before, during and after the process of data collection, and after completion of research. If students tick a box that indicates a potential risk, they must briefly explain, in the box that will pop up below, what procedures will be used to allay those risks. Consideration must be given about risks both to participants and the wider organisation in which the study takes place.

Supervisors should conduct a risk assessment for any possible personal risks to the health, wellbeing and safety of the student as researcher whilst undertaking the research. Lone working is strongly discouraged but if unavoidable, supervisors and students should consult the University’s Lone Working Policy. Any studies which give rise to concern should be discussed with the University’s Insurance Manager.
Supervisors should also discuss with their students how they will handle and store data securely in accordance with the requirements of the University’s *Code of Research Conduct and Research Ethics* (2016) and data protection regulations.

Even once ethical approval has been granted, students are advised to be constantly alert for potential ethical issues arising during their studies and undertake to discuss with their supervisor any emerging problems or unexpected developments (such as poor recruitment) that may arise.

If it is proposed that an approved project is subsequently subject to any significant change (for example to the date or place of data collection, or measures used), an Amendment Form should be submitted. This can be done in ‘Create Sub Form’ in the Actions Menu on the left hand side of the page on the on-line system: select ‘Amendment Form’.

9 - STUDENT DECLARATION

Students confirm their agreement to abide by the required codes of conduct.

10 - SUPERVISOR DECLARATION

Supervisors conduct a final review and explain that in their view EITHER the project does not require ethical review OR that it has their initial approval and can now be reviewed by the Committee. They then submit the form.

Supervisors and students will receive an email to inform them that their application has been successfully submitted and will be updated as to its progress. Decisions and feedback will be emailed to supervisors and students.

**ETHICAL REVIEW AND FEEDBACK**

The DPAP Research Ethics Sub-Committee aims to provide initial feedback to supervisors within 21 working days of receipt. Where a study is subject to dual review, comments from both reviewers will be combined into single set of feedback.

**Decision**

- Approval
- Conditional approval
- Revise and resubmit

**Feedback**

Reviewers will provide brief feedback where they consider ethical issues are unidentified or inadequately resolved, or where there is insufficient information for ethical issues to be revealed or discussed. Their aim is to comment on shortcomings, not to resolve them; the latter remains
the responsibility of the supervisor and student. Reviewers may advise on changes in any of the following sections of the application, as appropriate.

- Type of Study
- Study Outline
- Participant Information
- Participant Consent
- Organisational Permissions and/or External Ethical Review
- Additional Documentation
- Ethical Considerations

Reflective feedback for supervisor may also be offered. This constitutes suggestions from the reviewers that are offered for supervisors’ consideration. Making these changes is not compulsory.

**Action**

‘Approval’ means that there are no required changes and an approval letter will be automatically generated. ‘Conditional approval’ means that minor changes are required that can be oversee and signed off by the supervisor. The supervisor should upload the final version of the application. An approval letter will then be generated. ‘Revise and resubmit’ means that substantial changes are required. The supervisor should submit a revised version of the application and upload a ‘Letter of Revision’ explaining how (and where) the required changes have been made, or explaining why changes are not possible. Any changed documents should also be uploaded with any text that has been changed highlighted in yellow (not in track changes). Resubmissions are reviewed by the original reviewer/s.

Where an application has been resubmitted and stills fails to gain approval, the Chair of the Committee will be alerted.

**FURTHER READING & LINKS**

University of Nottingham’s Code of Research Conduct and Research Ethics (2016). Click here.
Universities UK (2012). The Concordat to support research integrity. Click here.
University of Nottingham (2012) Health and safety arrangements for lone working. Click here.
The research ethics guidebook: A resource for social scientists. Click here.