Module Level Approval Process in the Ethics Online System

This process applies to Undergraduate and Taught Postgraduate projects (group and individual) requiring Proportionate Review

The process covers broadly, generic study methods/designs that can be applied across a range of scenarios (for example, conducting focus groups, surveying etc.).

What is Module Level Approval?

Module Level Approval is an approval process that can be used to manage large cohorts of undergraduate and postgraduate taught projects. Projects should be managed within the scope of one approval, and supervisors are responsible for ensuring student projects remain within scope. In practice this means that students on the module do not submit individual ethics applications. Instead, their project is covered by the scope of the module level approval application. Students can still opt to undertake a project that require committee review, with the agreement of their supervisor, and they must make an individual ethics application.

Using Module Level Approval is appropriate when students taking the module will all be conducting the same type of low-risk or proportionate (previously medium)-risk research and will be using the same broad methods and procedures. Common aspects that should be included:

- Research methods and procedures (e.g. conducting interviews, surveys)
- Target populations
- The nature of the participants (N.B. no children or vulnerable adults)
- The type of method chosen to recruit and consent partisans
- The template for the information sheet, consent form, debrief sheet, covering letters (if applicable), written scripts (if applicable).
- Copies of data collection tools (e.g. questionnaire (ideally pre-validated, or adapted), interview schedule, observation tools etc.)

Module Level Approval applies only to low and proportionate (was medium) risk undergraduate and taught post graduate projects (group and individual). It cannot be assumed that all student projects will involve minimal risk. **Projects that require Full Review (high ethical risk as was) must be submitted for individual review via the Ethics Online System (EOS), a link to which can be found on the ethics and integrity web page: https://www.northumbria.ac.uk/research/ethics-and-integrity/**

How does Module Level Approval Work?

Each module should be reviewed annually by the relevant Module Tutor (MT) and where there are significant changes, a re-application for Module Level Approval should be made via the Ethics Online System (EOS).

1) MT writes the project brief for students (see examples provided in appendix A), ensuring ethical issues are contained by specifying:
    a. Range of primary data collection methods that can be used (e.g. interviews, questionnaires, street surveys etc.)
    b. Target populations from which students can sample
    c. Target sample size
    d. Risk assessments linked to the methods available to students
    e. The legal basis for processing data for Module Level Approval is consent based processing.

2) MT completes ethics submission for Module Level Approval on EOS for the module: refer to staff user guide on the ethics and integrity webpage under the New Ethics Online User Support and Guidance Tab. This should contain:
    a. The above framework for the research activities
    b. Approximate number of individual or group projects involved
    c. Department Ethics Lead (DEL) is assigned by Research and Innovation Service (RIS) to conduct the review of the ethics application for Module Level Approval in the Ethics Online System. Once approved, the MT must email the module code and ethical approval ID from the Ethics Online System to ethicssupport@northumbria.ac.uk. This will ensure RIS knows which modules have MLA and can mark any proportionate risk applications Approved. Any applications requiring Full Review and therefore outside of the MLA criteria will be assigned two Reviewers and Chair Review by RIS.
3) MT ensures all staff working on the module have completed the University Ethics Training module

Following ethical approval:

1) MT introduces students to the importance of ethical research including principles of data security and designing research within the approved framework
2) MT/Supervisor guides students in the design of their data collection instruments and sampling and the ethics approval process (see flowchart provided in appendix B)
3) Students complete project approval form (see example provided in appendix C)
4) Supervisor checks proposed data collection and sampling against the approved framework and negotiates with the student until the project meets the framework and is viable
5) To monitor student projects the Supervisor completes checkboxes on Student Project Approval Form, and sends to MT, stating that the student is approved to collect data. MT keeps a local record of approvals until projects are completed.
6) Proposed data collection that lies outside of the approved framework is referred to the MT who:
    a. Negotiates with the student/student group to align with the approved research framework, or
    b. Student submits an individual ethics application for specific non-aligned projects. If these projects are from a proportionate review category the MT may wish to consider adding them to the scope of the MLA.
7) At the end of the research project(s), MT must ensure students destroy the data they have collected.

Please refer to the Staff Applicant User Guide found here under the heading: New Ethics Online User Support and Guidance

Any queries should be directed to your Department Ethics Lead, details can be found here.

Appendix A: Example MLA application for questionnaire-based studies (this would be uploaded into Ethics Online System (EOS)

Introduction

Questionnaires can be used to evaluate a multitude of variables. These tend to be numerical/quantitative methods of measuring factors in larger sample groups (Gratton & Jones, 2015). The variables that may be measured using questionnaires or inventories are vast and range from psychological concepts (e.g. anxiety, motivation) to management/coaching styles. There are many pre-existing questionnaires that are deemed valid/reliable, and it is recommended that students use pre-existing questionnaires where possible or that they adapt them to their needs. It is good practice to comment on the validity and reliability of the questionnaire in the method section (Thomas, Nelson & Silverman, 2016).

Students may also design their own questionnaire if necessary, but should be mindful of language use and how questions are worded. Students should also consider the validity and reliability of self-designed single item questionnaires. As such, if students wish to design their own inventory, they should work very closely with their supervisor in the design phase.

This ethics application is to cover studies that aim to investigate non-sensitive topics within INSERT SUBJECT AREA. Sensitive topics that may be deemed high risk (and would require an individual ethics application) are those that may cause distress to a participant when completing the questionnaire (for example measurement of feelings following any form of abuse, assessing medical issues such as drug/substance misuse, eating disorders etc.). The diagnostic questions on EOS can help to determine this.

Method

Participants

This ethics application is relevant to participants that match the following:

- Aged 18 +
- Not classed as a vulnerable adult (e.g. learning disabilities)

Students should discuss their sample group with their supervisor. For 100% quantitative studies students should collect a minimum of 100 questionnaires. Mixed methods studies should be negotiated with supervisors in line with the guidance in the dissertation handbook. **departments should include their own specific criteria here**

Design and Procedures

The questionnaire(s) may be used as many times as necessary, but should not be too onerous for participants. Both within and between subjects designs can be conducted.

The questionnaire can be given out in person or via electronic means. Regardless of the medium, data must be kept confidential – this is particularly important if using online methods. Students should be clear on how the data will be kept secure. Only University approved online systems should be used to collect data.

All participants must give informed consent to take part - this can be done as part of the questionnaire and does not have to be on a separate sheet. All participants must receive an information sheet outlining the purpose of the study as well as a debrief. The legal basis for processing data for Module Level Approval is consent based processing

Qualitative data may also be collected via methods such as interviews or focus groups. The investigator must refer to the following risk assessments to ensure good practice is being applied:

- HL_RISK_173 (testing in an external environment)
- HL_RISK_378 (psychology testing)
- HL_RISK_722 (face to face interview)
- HL_RISK_727 (group interview)

  ** Departments should refer to their own specific, approved risk assessments here**

Data Analysis

The method of statistical analysis will be appropriate for the design of the study. Students have undergone training in the following types of analysis:

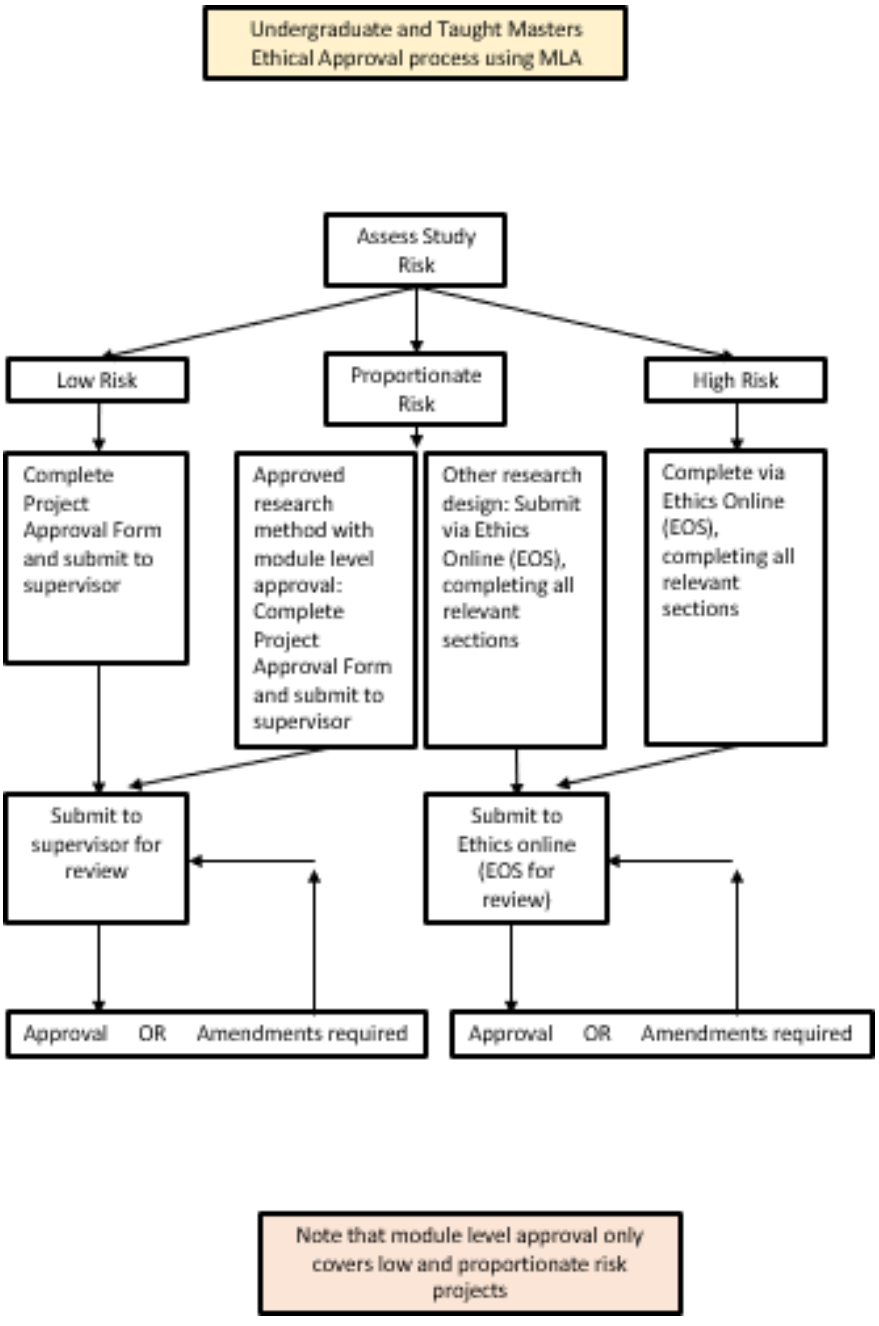
- Paired and independent t-tests
- One way ANOVA (within and between designs)
- Correlation analysis

Departments should refer to their own circumstances here

Recruitment

Recruitment may be done via word of mouth, posters, emails and social media. Students do not have access to email distribution lists. The text used in recruitment material should be submitted with the application. If a particular team/club/society are being targeted then proof of permission from the club coach/administrator/other must be provided. It is advised that students keep their recruitment more broad than a single club to assist take up.

Appendix B – Flowchart – Ethics process (UG and PGT)



NB High riskrequires Full Review

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Appendix C – Student Project Approval Form

Tutor sign off	
Ethics form complete	☐
Ethical concerns acknowledged	☐
Research tool(s) checked	☐
All relevant forms included (consent etc.)	☐
Is not high risk	☐

****Items highlighted green – module leader should insert, items highlighted yellow – student should insert****

MODULE CODE / TITLE: Student Project Approval Form

You should use this document if you intend to use one of the existing module level approval ethics applications. Please complete this document and discuss your study with your supervisor before you collect any data. *Failure to complete this document and have all aspects signed off and approved by your supervisor risks a notable deduction in your grade and may risk a case of Academic misconduct. Please see the module handbook for more details.*

Please ensure that your project meets the conditions of the existing ethics application (available on Blackboard). If it does not, then you will need to submit a full ethics application instead.

Student Name:	
Project Title:	
Supervisor Name:	
Ethics application you are amending (check box):	☐ Questionnaire Study ☐ Interview Study ☐ Low Risk Secondary Data Study

Introduction to the project: *Treat like an introduction to the study. Why is your proposed study important? What has already been done on the topic? How does your proposed study 'fit' with the current literature and what does it add? What is the aim of the proposed study? Make reference to appropriate studies.*

Methodology: *Please complete the table below, using the following info to guide you. Write this as a future tense method. Describe the **participants** that you will recruit, how many you are going to recruit, and indicate if you have any additional exclusion criteria. Include the **research design** (e.g. randomised/repeated measures/quantitative/qualitative/case study etc) and detail of your proposed **procedures** (i.e., how are you collecting the data?). Include information on all of the equipment you plan to use. If this is a low-risk study, outline how you will extract data and list the criteria you will use to do this. Somebody should be able to read this and replicate it. Describe all planned **data analysis** for both quantitative (e.g. t-tests, ANOVA, correlation etc.) and qualitative (content analysis, thematic analysis etc.) data. If doing a low-risk study explain how you intend to analyse the data you have collected. Use literature to justify your method.*

1. Is this a low-risk secondary data study? If Yes please go to questions 6 and 7.	☐ YES ☐ NO
2. Who are your participants and what is the inclusion criteria?	
3. How many will you recruit and from where?	

4. Are there any exclusion criteria (reasons why people should not participate)?	
5. Research design:	
6. Procedures (describe what you will do to collect data, include all equipment/methods you plan to use).	
7. Data analysis methods:	
8. Additional information:	

Health and Safety: *Relevant risk assessments are listed in the ethics application. If your project needs additional risk assessments, then you will need to submit a new ethics application. Please identify the elements of the listed risk assessment that are relevant for your study and the risk assessment(s) you are working with.*

Please check the relevant boxes* INSERT Risk assessments AS APPLICABLE TO YOUR DEPT e.g.:

☐ HL_RISK_173 Testing in an external environment

☐ HL_RISK_378 Psych testing

☐ HL_RISK_722 face to face interview

☐ HL_RISK_727 Group interview

Data Management *Standard phrases have been added to the ethics application. In rare instances, these may not be appropriate for your study. If not please describe below.*

Please check this box after you have read and understood ethics and health and safety information.

☐ I confirm I have read the University's health and safety policy and ethics policy. I have read and understood the requirement for the mandatory completion of risk assessments and that my study does not deviate from the module level approval ethics forms on Blackboard.

Further information (add below, if applicable)

- Consent forms
- Participant information sheet
- Debrief form
- Recruitment materials
- Permission letters
- Data collection tools

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Participant Information Sheet

Study Title:

Investigator:

You are being invited to take part in this research study. Before you decide it is important for you to read this leaflet so you understand why the study is being carried out and what it will involve.

Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether or not you would like to take part.

What is the purpose of the study?

Keep this simple. You need to give enough information so that the participant understands the purpose of this study, but do not include any complicated information and/or technical terms (e.g. 'test of personality' would be more suitable than 'big 5 trait test').

Why have I been invited to take part?

You have been invited to take part as you meet the following criteria

- List inclusion criteria.

Do I have to take part?

You are under no obligation to take part and you will not experience any loss of benefit or penalty if you choose not to participate.

What will I have to do?

Describe the method in simple terms. Give information on how much of their time it will take up (how many hours across how many days).

What are the exclusion criteria (i.e. are there any reasons why I should not take part)?

You should not take part in this study if:

- List exclusion criteria.

What are the possible disadvantages/risks in taking part?

Be honest – if the test may result in some discomfort then say so. But also say how this discomfort will be minimised.

What are the possible benefits of taking part?

Do the participants receive any free feedback e.g. questionnaire results etc. Will their results contribute to any future policies? Will they get to experience any contemporary research techniques?

Will my taking part be kept confidential and anonymous?

Yes. You will be allocated a unique participant code that will be used to identify any data that you provide. Your name and other personal details will not be associated with your data, for example any signed informed consent forms will be stored separately.

Only the research team will have access to any identifiable information; paper records will be stored in a locked filing cabinet and electronic information will be stored on a password protected computer. This will be kept separate from any data and will be treated in accordance with the Data Protection Act

How will my data be stored?

All data will be stored and transported using a password protected external hard-drive, the data will also be backed up on password protected file within the university network. Any paper data collected will be locked away in a secure folder.

What will happen to the results of the study?

The results will be used for an undergraduate dissertation that will be examined as part of a BSc/BA [insert name of degree] degree. Occasionally some results might be presented at a conference or published in a journal, but they will always remain anonymous. All information and data gathered during this research will be stored in line with the Data Protection Act and will be destroyed after a maximum of 3 years following the conclusion of the study. During that time the data may be used by members of the research team, only for purposes appropriate to the research question, but at no point will your personal information or data be revealed.

Who is organizing and funding the study?

The present research project has received no funding.

Who has reviewed the study?

The study and its protocol and its protocol has received full ethical approval from the Department of X postgraduate ethics system. If you require confirmation of this, please contact the chair of the undergraduate ethics using the details below and stating the full title and principal investigator of the study:

Name of relevant Department Ethics Lead:
Department:
Address:
Phone:
Email:

How can I withdraw from the project?

The research you take part in will be most valuable if few people withdraw from it, so please discuss any concerns you might have with the investigators. During the study itself, if you do decide that you do not wish to take any further part then please inform one of the research team as soon as possible, and they will facilitate your withdrawal and discuss with you how you would like your data to be treated in the future. After you have completed the research you can still withdraw your data by contacting one of the research team (their contact details are provided in the last section of the leaflet), give them your participant number, or if you have lost this, give them your name.

If for any reason, you wish to withdraw your data please contact the investigator within a month of your participation. After this date, it might not be possible to withdraw your individual data as the results might already have been published. As all data are anonymous, your individual data will not be identifiable in any way.

What happens if there is a problem?

If you are unhappy about anything during or after your participation, you should contact the principal investigator in the first instance. If you feel this is not appropriate, you should contact the Chair of ethics for Name of Department and name of Ethics Lead via the contact details given above.

Contact for further information:

Researcher email:

Supervisor email:

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INFORMED CONSENT FORM

Project Title:

Principal Investigator:

	please tick or initial where applicable
I have carefully read and understood the Participant Information Sheet.	
I have had an opportunity to ask questions and discuss this study and I have received satisfactory answers.	
I understand I am free to withdraw from the study at any time, without having to give a reason for withdrawing, and without prejudice.	
I agree to take part in this study.	

Signature of participant..... Date..... (NAME IN BLOCK LETTERS).....
Signature of researcher: Date..... (NAME IN BLOCK LETTERS) :

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Participant Debrief Sheet

Study Title:

Investigator:

Participant Code:

What was the purpose of the project?
Remind the participant why the study was completed.

How will I find out about the results?
Once the study has been completed, including the analysis of data (roughly ? weeks after the completion of your participation), the researcher will email you a general summary of the results upon request. If you would like to receive your own personal data, this can also be arranged via direct correspondence with the researcher.

If I change my mind and wish to withdraw the information I have provided, how do I do this?
If for any reason, you wish to withdraw your data please contact the investigator within a month of your participation. After this date, it might not be possible to withdraw your individual data as the results might already have been published. As all data are anonymous, your individual data will not be identifiable in any way.

The data collected in this study may also be published in scientific journals or presented at conferences. Information and data gathered during this research study will only be available to the research team identified in the information sheet. Should the research be presented or published in any form, all data will be anonymous (i.e. your personal information or data will not be identifiable).

All information and data gathered during this research will be stored in line with the Data Protection Act and will be destroyed 36 months following the conclusion of the study. If the research is published in a scientific journal it may be kept for longer before being destroyed. During that time the data may be used by members of the research team only for purposes appropriate to the research question, but at no point will your personal information or data be revealed. Insurance companies and employers will not be given any individual's personal information, nor any data provided by them, and nor will we allow access to the police, security services, social services, relatives or lawyers, unless forced to do so by the courts.

If you wish to receive feedback about the findings of this research study, then please contact the researcher at add email here

If as a result of your participation in this research you feel that it would be helpful to talk to a qualified professional you may wish to contact your GP, or advice on an appropriate counselling service can be provided.

This study and its protocol have received full ethical approval from the University Ethics Online System. If you require confirmation of this, or if you have any concerns or worries concerning this research, or if you wish to register a complaint, please contact the Ethics Lead or Ethics Director? (Insert relevant ethics lead name and email address), stating the title of the research project and the name of the researcher and project ID: *add your name here*

Thank you for participating

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Project Title:

Principle Investigator:

Audio Recording Consent Form

CONSENT TO AUDIO- RECORDING & TRANSCRIPTION

This study involves the audio recording of your interview with the researcher. Neither your name nor any other identifying information will be associated with the audio or audio recording or the transcript. Only the research team will be able to listen (view) to the recordings.

The recordings will be transcribed by the researcher and erased once the transcriptions are checked for accuracy. Transcripts of your interview may be reproduced in whole or in part for use in presentations or written products that result from this study. Neither your name nor any other identifying information (such as your voice or picture) will be used in presentations or in written products resulting from the study.

By signing this form, I am allowing the researcher to audio record me as part of this research. I also understand that this consent for recording is effective until the following date: ***ADD DATE HERE – date you will destroy recording***. On or before that date, the recordings will be destroyed.

Signature of participant…… Date……   (NAME IN BLOCK LETTERS)……
Signature of researcher: Date……   (NAME IN BLOCK LETTERS) :

REMEMBER TO ALSO INLCUDE YOUR DATA COLLECTION TOOLS HERE (copy of questionnaire and/or interview schedule). AND if applicable RECRUITMENT MATERIALS