

Block Ethics Approval for UG and PGT Levels - Guidance

This guidance introduces the Block Ethics Approval process for ethics review of student research at undergraduate and taught post-graduate levels. It should be read alongside DMU's <u>Research Ethics</u> <u>Code of Practice</u>.

All research involving human participants, or their data, requires ethics review. Whilst normally this review is done on a project-by-project basis, it is recognised that for UG/PGT level there are occasions where students may complete very similar or identical projects that are very low risk. In such cases it may be proportionate to approve research at a module level, rather than individually for each student.

Please note: Applications for dissertation modules at UG or PGT level are NOT suitable for the Block Ethics Approval process.

Block Ethics Approval applies when basic research is undertaken by students as part of a taught module on a routine basis or as part of a programme of work that is extremely low risk. Such cases will be typified by, for the most part, a consistency in practice and approach in terms of the research process, and where the research is assessed to be low risk. This will include projects where pedagogic research might be involved, and where students are engaged as co-producers of knowledge through the undertaking of research in their capacity as consultants.

Criteria for determining if the Block Ethics Approval process is appropriate:

- 1. The projects <u>do not involve high or medium-risk research topics</u> as defined by the <u>Research</u> <u>Ethics Code of Practice</u>, or where the ethical risks are static and well-understood;
- 2. The project design and methodologies are static (or subject to only minor change).
- 3. The risk of any unexpected ethics concerns arising is minimal, e.g. multisite, collaborative projects are at a higher risk of developing complications.
- 4. There is no requirement for the student to complete an ethics application as part of their academic development or professional body requirements.
- 5. The relevant supervisor(s) are aware and capable of discharging their responsibilities for the conduct and integrity of the project.

Guidance for module leaders:

- 1. A block application for exceptional ethics approval should be submitted by the module leader or the person responsible for coordinating research project ethics. A good module level application will be broad enough to encompass multiple projects over the approval period, but not so broad as to fail to highlight the methodologies and potential risks.
- 2. Modules must have in place mechanisms to ensure that research taking place under the auspices of an exceptional block approval adhere to the scope of the approval as defined in the approved application form.
- 3. Any project falling outside the defined scope of the application will not be covered and will therefore need a separate ethics application for review at the module level.
- 4. Those supervising research must be familiar with DMU's Research Ethics Code of Practice.



Process for application and approval

Applications for block approval must be made directly to the relevant Faculty Research Ethics Committee (FREC) following the procedures set out below:

- 1. The module leader should initially contact the FREC Chair to determine if the module concerned fulfil the criteria for Block Ethics Approval.
- 2. If it has been determined that a Block Application is suitable, the module leader should complete an 'Block Ethics Approval Screening Form' which can be found in Appendix 1.
- 3. If the screening questions determine that the module **IS** suitable for the exceptional block ethics application process, the module leader should create and submit an ethics application via the university's online ethics system, <u>Worktribe</u>, using their DMU Single Sign On credentials. (See 'Submitting a Worktribe block approval application' below)
- 4. If the screening questions determine that the module **is NOT** suitable for the block application process, students should submit individual applications for research ethics approval via Worktribe. A series of short demonstration videos and detailed step-by-step guides are available for UG/PGT students in the 'Help' section of Worktribe (<u>3. Ethics</u> Training for Worktribe).
- 5. When the application for Block Ethics Approval has been submitted to Worktribe, the application will follow the workstream process for review by the FREC, with feedback from the reviewer/s returned to the applicant (module lead) through the Worktribe system in due course.
- 6. Once approved, Block Ethics Approval is valid for a period of three years, after which a new application is required.
- 7. A summary of all projects conducted under the auspices of Block Ethics Approval must be submitted to the approving FREC (see contact details below) on an annual basis using the Annual Reporting Form in Appendix 2.
- 8. At the end of the three-year approval period, FRECs should complete an audit of research taking place under the auspices of that approval during against the original application. Any discrepancies will be taken into consideration by the Committee when deciding upon re-approval of future applications for the module.

Submitting a Worktribe block approval application:

- a. The responsible member of staff (e.g. module lead) should create a new ethics application within Worktribe. See the <u>Help section of Worktribe</u> for further general help on submitting an ethics application.
- b. You will then be asked to enter the following information.
 - Title enter the title to be used for the Block Ethics Application, please ensure you include your **module code**.
 - Project Dates these should span the next three academic years.
 - Project Description You may enter a brief description of the nature of the Block Ethics Approval project/s.
 - Applicant This should be pre-populated with your name.
 - Org Unit ensure your school is selected. This is usually pre-populated.



Note: do not select the module code in this field

- Tags Select 'Block Approval' from the drop-down list.
- For "Is this a student project?" select 'No'. Note: selecting anything other than 'No' will mark this application as a student project and will require you to identify a supervisor. Worktribe will not allow you to be both applicant and supervisor on an application and so you will be unable to submit.
- c. Complete the remaining mandatory fields in the Worktribe form. The form needs to provide enough information for the Ethics Committee to understand the nature of the projects that may take place under the Block Ethics Approval. It is expected that most projects will be of a similar nature, but where there is potential for some minor variance this should be made clear. The form should specify the number of participants that would likely be recruited to each individual project.

If you have any queries regarding the Block Ethics Approval process, please contact your relevant FREC:

- Arts, Design & Humanities (ADH): adhethics@dmu.ac.uk
- Business & Law (BAL): <u>BALResearchEthics@dmu.ac.uk</u>
- Computing, Engineering & Media (CEM): ethics.CEM@dmu.ac.uk
- Health & Life Sciences (HLS): <u>hlsfro@dmu.ac.uk</u>

Date	Responsible	Nature of Change	Version
26/11/2 4	William Knight	Form updated to advise applicants to select "No" to "is this a student project?" in line with changes to Worktribe process. Annual Reporting form has been significantly simplified, requiring only a summary of activities rather than a list of every student, their details and their project titles (pending approval from UREEC 051224)	V6



Appendix 1:

Block Ethics Approval - Application Form

This checklist should be completed for every module for which approval is being sought. This form will normally be submitted by the module lead.

It must be completed and approved by your Faculty Research Ethics Committee before potential participants are approached by students to take part in any research.

If approval has not been obtained, students should apply individually for research ethics approval prior to approaching potential research participants.

Section I: Screening Questions

Please answer each question by ticking the appropriate box. For further guidance, please refer to Appendix 2 of the Research Ethics Code of Practice.

		YES	NO
1.	Does the research involve participants who are particularly vulnerable or lack capacity to give informed consent (e.g. children, people with learning disabilities, your own students)?		
2.	Will the research require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited (e.g. students at school, members of self-help group, residents of nursing home)?		
3.	Is there a risk that the research topic might lead to disclosure from the participants concerning their beliefs, involvement in illegal actions or any other activities that may represent a threat to themselves or others?		
4.	Will the research involve collecting any personal special category information in a form that could allow the participant/ participants to be identified (e.g. identifiers relating to race, ethnic origin, politics, religion, trade union membership, philosophical beliefs, genetics, biometrics, health, sex life or sexual orientation)?		
5.	Will it be necessary for participants to take part in the research without their knowledge and consent at the time?		
6.	Will the research involve sensitive topics or fall under the remit of the sensitive research policy?		
7.	Are drugs, placebos or other substances (e.g. food substances, vitamins) to be administered to the research participants or will the research involve invasive, intrusive or potentially harmful procedures of any kind?		
8.	Will the research include research that involves animals or animal tissues?		
9.	Will blood or tissue samples that fall under the remit of the Human Tissue Authority		



be obtained from participants?

- 10. Is pain or more than mild discomfort likely to result from the research?
- 11. Could the research induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life to either a participant or the research themselves?
- 12. Will the research involve prolonged or repetitive testing?
- 13. Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?
- 14. Does the research fall under the definition of medium or high risk as defined in Appendix 2 of the Research Ethics Code of Practice?

If you have answered 'yes' to any of the questions in Section I the module is unsuited for block ethics approval, and you should look to utilise individual ethical approval for student research.

If you have answered 'no' to all questions, please continue to Section II.

Section II: Screening Questions

1. Do **all** students undertake common research tasks (e.g. do research on the same topic, using the same research methods, asking the same questions of participants)?

YES	NO

If Yes, proceed to Section III, if No continue below:

2. Do students undertake research tasks from a set range (e.g. do they select their research topic from a pre-set range of options; do they employ one of a set range of research methodologies; do they ask questions of a pre-set range of issues)?

YES NO	
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If Yes, please proceed to Section III and provide details of the range of research tasks they undertake within your Worktribe application.

If No to both questions 8 and 9: It appears unlikely that the module is suited for 'Block Approval' and you should be looking to utilise individual ethical approval.



Section III: Applicant Details

- 3. Name of Applicant:
- 4. Role/Job:
- 5. Email address:

Section IV: Module Details

- 6. Module Code:
- 7. Module Title:
- 8. Faculty/Centre:
- 9. Short Description of Research Component(s) of Module:

Section V: Research Activities

Please ensure your Worktribe application contains sufficient details of the following:

- Research questions/issues to be addressed.
- Research methods to be employed.
- Method of recruiting research participants.
- Criteria for selecting research participants.
- Expected number of research participants for each student project.

10. Do students use a common Participant Information and Informed Consent Form?

	YES	NO	
If YES, please upload a copy to your Worktribe application	tion.		
11. Is it intended that block approval will apply to all student	ts enrolled in the YES	e course of : NO	study?

12. Please outline how you will ensure a student's project proposal is compliant with the terms of the block approval. Remember that any project that is not within the terms of the block approval will require individual ethics approval.

Version:	5
Date:	10/09/2024
Review date:	10/09/2025
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Appendix 2:

Block Ethics Approval – Annual Reporting	; Form
Level of Study (UG/PGT):	
Course:	
Module Title:	
Ethics Lead:	
Worktribe Approval Reference No.	
Year of Study (i.e. 2024-25):	
year. Please also detail any potential devia	tails of the methodologies used, study populations and types of data collected by your students during the ations from the agreed Block Approval which you foresee for the coming year – be aware that if student the approved activity, you might need to amend your approved Worktribe application.