**Exceptional Block Ethics Approval - Guidance**

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

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 programme or module level, rather than individually for each student.

This applies to where 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.

**Where is exceptional block ethical approval most appropriate?**

Exceptional block approval is appropriate where:

1. The projects do not involve high or medium-risk research topics as defined by the Research Ethics Code of Practice, 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 ethics 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 to module / programme leaders**

1. A block application for exceptional ethics approval should be submitted by the programme / module leader or the person responsible for coordinating research project ethics. A good programme 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. Programmes must have in place mechanism to ensure 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 programme level.
4. Those supervising research must be familiar with DMU’s Research Ethics Code of Practice.
5. A summary of all projects conducted under the auspices of exceptional block approval must be submitted to the approving FREC on an annual basis using the form below.

**Application and approval**

1. Applications for exceptional block approval must be made directly to the relevant Faculty Research Ethics Committee following the procedures set out below.
2. An application form should be completed by the relevant programme/module ethics lead (such as the module lead). An ethics application should then be created within WorkTribe and the application form added as a supporting document (See below for further details).
3. Once approved, exceptional block approval is valid for a period of three years after which a new application is required.
4. At the end of the three-year approval period, Faculty Research Ethics Committees should complete an audit of research taking place under the auspices of that approval during against the original application. Any discrepancies may be taken into consideration by the Committee when deciding upon re-approval of future applications for the programme/module.

Submitting a WorkTribe block approval application:

* 1. The responsible member of staff (e.g. module lead) should create a new ethics application within WorkTribe. See the Help section of WorkTribe for further general help on submitting an ethics application.
  2. You will then be asked to enter the following information;
     + In ‘Org Unit’ ensure your school is selected. This is usually pre-populated. Note: do not select the module code in this field!
     + Project dates should span the next three academic years.
     + Select ‘Yes’ to ‘Is this a student project’
     + Enter the relevant module code in ‘module code’.
     + Select your name as both the applicant and supervisor.
  3. 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 approval. It is expected that most projects will be of a similar nature, but where there is the 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.

Please contact your Faculty Research Ethics Committee for further information.

**Exceptional 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 either the programme lead or research 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.

|  |  |  |
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|  | **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)? |  |  |
| 1. 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)? |  |  |
| 1. Is there a risk that the research topic might lead to disclosure from the participant concerning their beliefs, involvement in illegal actions or any other activities that may represent a threat to themselves or others? |  |  |
| 1. 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)? |  |  |
| 1. Will it be necessary for participants to take part in the research without their knowledge and consent at the time? |  |  |
| 1. Will the research involve sensitive topics or fall under the remit of the sensitive research policy? |  |  |
| 1. 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? |  |  |
| 1. Will the research include research that involves animals or animal tissues? |  |  |
| 1. Will blood or tissue samples that fall under the remit of the Human Tissue Authority be obtained from participants? |  |  |
| 1. Is pain or more than mild discomfort likely to result from the research? |  |  |
| 1. 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? |  |  |
| 1. Will the research involve prolonged or repetitive testing? |  |  |
| 1. Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants? |  |  |
| 1. 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 exceptional block 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:

1. 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**

*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 'Exceptional Block Approval' and you should be looking to utilise individual ethical approval.

**Section III: Applicant Details**

1. Name of Applicant:
2. Role/Job:
3. Email address:

**Section IV: Module Details**

1. Module Code:
2. Module Title:
3. Faculty/Centre:
4. 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.

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

**YES  NO**

*If YES,* please upload a copy to your WorkTribe application.

1. Is it intended that exceptional block approval will apply to all students enrolled in the course of study?

**YES  NO**

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

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| **Version:** | **2** |
| **Date:** | **28/09/2021** |
| **Review date:** | **28/09/2023** |
| **Author:** | **Dr Douglas Gray** |
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| **Owner:** | **Research Governance Team, Research Services Directorate** |

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| **Exceptional 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. 2021-22):** | | |  |
| **Student Name** | **Student P Number** | **Supervisor** | **Title of study** |
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