Ethical Approval Guidance and Process Policy 2020

North Warwickshire and South Leicestershire College

Vice Principal Quality
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Ethical Approval and Guidance and Process Policy 2020

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1. Application Form to Gain Approval For Activities Involving Research
1. **Introduction**

1.1 The procedures in this policy have been designed to assist with any applications or assessments that require Ethical Approval. This process policy will assist in the application of ethical approval requests, implementation of good conduct in research, ensure research is conducted at the highest quality and the prevention of misconduct.

1.2 The guidance and process policy are written for staff and students at North Warwickshire and South Leicestershire College - NWSLC (the college) who are planning to carry out a research project and/or any staff involved in assessing applications for ethical approval.

2. **What is Ethical Approval?**

2.1 Ethical approval is required for any research that involves human participants; their data and/or tissue to ensure the rights, safety, dignity and well-being of each participant is the primary consideration of the research project. By obtaining ethical approval the college can ensure that research is conducted to the highest ethical standard and that participants are treated open and fairly.

2.2 Any research that involves a collection and/or storage of sensitive data from human participants will require ethical approval before the research takes place.

3. **When is Ethical Approval Required?**

3.1 Ethical approval must be granted before any research has begun. It is your responsibility to ensure the correct forms are submitted and approved to avoid any possible delays in research.

3.2 NWSLC require ethical approval before an individual undertakes any:

   i. Research, product development, design studies, artistic studies or experiments involving human participants.
   
   ii. Interviews, questionnaires, surveys, focus groups or case studies, blood sampling involving human participants.
   
   iii. Research involving harmful, criminal, sensitive or extremist subject matters.
   
   iv. Research involving vulnerable groups - for example children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship.
   
   v. Research involving sensitive topics - for example participants’ sexual behaviour, their illegal or political behaviour, their experience with violence, their abuse or exploitation, their mental health, or their gender or ethnic status.
   
   vi. Research involving groups where permissions of a gatekeeper is normally required for initial access to members - for example ethnic or cultural groups, native peoples or indigenous communities.
   
   vii. Research involving deception or which is conducted without participants’ full and informed consent at the time the study is carried out.
   
   viii. Research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals.
   
   ix. Research which would induce psychological stress, anxiety or humiliation or cause more than minimal pain.
x. Research involving intrusive interventions – for example, the administration of drugs or other substances, vigorous physical exercise, or techniques such as hypnotherapy. Participants would not encounter such interventions, which may cause them to reveal information which causes concern, in the course of their everyday life.

3.3 NWSLC may require ethical approval for the following:
   i. Controversial or non-controversial literacy or artistic works.
   ii. Where the research project presents a significant risk to the environment or society.
   iii. Where the research project could bring the Colleges reputation into disrepute.
   iv. Where the research project raises any ethical issues that in the opinion of the Applicant or Tutor require further ethical review.

3.4 By obtaining ethical approval you are demonstrating that you are adhering to the ethical approval guidance and process policy 2020. Conducting research without ethical approval constitutes misconduct.

4. Applying for Ethical Approval - When can I Apply?
   4.1 Ethical approval can be applied for at any time. Ideally, this should be completed at the submission of the Research Proposal however occasionally the ethical dimensions of a project may become clear as it develops.

   4.2 In any case, ethical approval must be granted before any research has begun, it is the researcher’s responsibility to ensure the appropriate forms have been completed in full and submitted in a timely manner to avoid any delays.

   4.3 If a member of staff leaves NWSLC during a research programme they must reapply for approval for the continuation of their research.

   4.4 After approval, researchers may find that there are changes that need to be made to the application. In the case of any amendments or renewals the process is the same as for new applications. When renewing your application, you should refer to the original approval in your application.

5. Responsibilities of the Researcher

   5.1 Responsibility for the conduct of ethical research is ultimately the responsibility of researchers themselves. They will be expected to identify the relevant ethical principles, to operate within these principles, and be able to justify any research activity that does not comply with the following principles.

   5.2 Principle 1: Protection of the Participants’ Interests
      i. Gain informed consent from participants.
      ii. Protect the interests of vulnerable groups.
      iii. Assure the anonymity of participants.
      iv. Assure the confidentiality of information.
      v. Respect the privacy of participants.
      vi. Operate with transparency.
5.3 **Principle 2: Compliance with the Law**

i. All data collection, processing, security, ownership, and retention must be in accordance with the Data Protection Act 2018.

ii. All researchers must have a full understanding of participants’ rights under the Data Protection Act 2018.

iii. Identify legal (and moral) sensitivities surrounding the topic of research.

iv. Use legally acceptable methods of research.

5.4 **Principle 3: Scientific Integrity and Beneficence**

i. Demonstrate the value of conducting the research.

ii. Have the necessary credentials and skills.

iii. Use an appropriate research design with suitable strategies and methods.

iv. Be open and honest in dealing with colleagues and funding agencies.

5.5 **Respondents**

i. Respondents’ co-operation in a research project is entirely voluntary at all stages.

ii. Respondents must not be misled when being asked for co-operation.

iii. Respondents’ anonymity must be strictly preserved.

iv. If the Respondent on request from the Researcher has given permission for data to be passed on in a form which allows that Respondent to be identified personally:
   - The Respondent must first have been told to whom the information would be supplied and the purpose for which it will be used.
   - The Researcher must ensure that the information will not be used for any non-research purpose and that the recipient of the information has agreed to conform to the requirements of any relevant Code of Practice.

v. The Researcher must take all reasonable precautions to ensure that Respondents are in no way directly harmed or adversely affected as a result of their participation in a research project.

vi. The Researcher must take special care when interviewing children and young people.

vii. Respondents must be told (normally at the beginning of the interview) if observation techniques or recording equipment are used, except where these are used in a public place. If a respondent so wishes, the record or relevant section of it must be destroyed or deleted. Respondents’ anonymity must not be infringed by the use of such methods.

viii. Respondents must be enabled to check without difficulty the identity and bona fides of the Researcher.

6. **Procedures**

6.1 All staff and Higher Education students who wish to engage in research using participants must complete and submit an application form or approval for activities involving research.

6.2 The application should be accompanied by any relevant documentation that will allow an independent assessor to understand the nature of the project and the possible ethical issues.

6.3 **Staff:** completed forms should be signed and forwarded to the Vice Principal Quality for assessment and approval. Should there be any concerns the Vice Principal Quality will forward these to the Ethical Approval Committee for consideration and approval.

6.4 **Students:** completed forms should be discussed and signed by the tutor then forwarded to the HE Office (Ethical Approval Committee) for consideration and approval.
6.5 **The Ethical Approval Committee**: will convene weekly (on demand) in response to ethical approval concerns. Membership consists of:

i. Director for Higher Education

ii. HE Quality Manager

iii. HE Administration and Registry Officer;

iv. the nominated Learning and Skills Manager.

7. **Approval Form Submission Process**

8. **College Procedures**

8.1 The College requires that all research projects at Level 3 Undergraduate (Level 6 FHEQ) need to undergo ethical review. This includes:

i. undergraduate final year projects (BA);

ii. research grant applications made by research staff;

iii. contract research and consultancy.

8.2 **Students**: should complete the application form (Appendix 1) and discuss the research ethics implications with their tutor/module leader. The tutor/module leader should sign the form to acknowledge that this has been discussed with the student. A copy of the signed form should then be submitted to the HE Office for consideration by the Ethical Approval Committee.

8.3 **Research Staff**: all members of staff who plan a research project, whether funded by external funding bodies or the Colleges also need to seek ethical approval. The completed form should be submitted to the Vice Principal Quality.
8.4 Ethical scrutiny for Research conducted is primarily taken by the Ethical Approval Committee. The Chair will authorise the Ethical Approval Applications and will decide which outcome best describes the ethical status of the project and the proposed ways of addressing possible issues. These are:

i. no ethical issues;
ii. minor ethical issues which have been addressed and concerns resolved;
iii. major ethical issues which have been addressed and concerns resolved;
iv. ethical issues that have not been resolved.

8.5 Applicants (research students/research staff) are informed of the outcome of the approval process by email/letter.

9. Ethical Misconduct

9.1 Types of ethical misconduct include:

i. failure to obtain approval for an on-going research project;
ii. failure to observe the College’s Ethical Approval Guidance and Policy;
iii. breach of Ethical Approval conditions;
iv. failure to renew or apply for Ethical Approval when changes have incurred that have ethical implications.

9.2 The College takes a very serious view of anyone who brings the Institution into disrepute. Students who are found guilty of serious or repeated breaches of these ethical principles and or the Student Code of Conduct may be excluded from their course of study. Where there are concerns around potential ethical misconduct by a member of staff, or a member of staff has failed in their duty to supervise the ethical conduct of their students and researchers, consideration may be given to taking action under the College’s Disciplinary Policy and Procedure.
APPLICATION FOR ETHICAL APPROVAL OF A RESEARCH PROJECT

This application form is to be used by **STAFF** and **STUDENTS** seeking ethical approval for an individual research project where preliminary ethical assessment has indicated that full ethical review is required.

Guidance and support will be given by your tutor/module leader (for student research), the College’s Vice Principal Quality (for staff research). Queries arising out of this should be directed to the Vice Principal Quality.

*Applications must be completed on this form; attachments will not be accepted other than those requested on this form. This form has been designed to be completed electronically; no handwritten applications will be accepted.*

Research must NOT begin until approval has been received.
Failure to gain approval for your research project constitutes as misconduct and could result in disciplinary action being taken against you.

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**Section 1: Applicant Details**

<table>
<thead>
<tr>
<th>Applicant Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Email</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td></td>
</tr>
<tr>
<td>Applicant Type</td>
<td>□ Staff □ Student</td>
</tr>
</tbody>
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**Section 2: Project Details**

<table>
<thead>
<tr>
<th>Title of Research Project</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Programme (if relevant)</td>
<td></td>
</tr>
<tr>
<td>Proposed Start / End date (dd/mm/yyyy)</td>
<td>Start Date</td>
</tr>
<tr>
<td>Tutor / Module Leader (Student Research projects only)</td>
<td></td>
</tr>
<tr>
<td>Who is responsible for the overall management of the research?</td>
<td>Name</td>
</tr>
<tr>
<td>Are any other organisations involved?</td>
<td></td>
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</tbody>
</table>
Section 3: Project Outline & Proposed Research Methods
Briefly describe the aims of this research, including the anticipated benefits and risks. This description must be in everyday language. If any jargon, technical terms or discipline-specific phrases are used, these should be explained. Please do not exceed 500 words.

Section 4: Proposed Research Methods (Experimental Design)
Please provide an outline, in layman’s terms, of the proposed research methods. Specify where the research will take place and if it will involve the internet. Present an outline of the method in a step-by-step chronological order. Please avoid using jargon and technical terms as much as possible. Ensure you describe the key tasks including how data will be collected and used. Please do not exceed 500 words.

Section 5: Ethical Issues and Risks
Please provide a list of all ethical issues that have been identified and how they will be addressed. If there are any risks associated with the safety of the researcher and/or research subject have they been addressed? This may include personal safety issues, such as those related to lone or out of normal hours working or to visiting participants in their homes; travel arrangements, including overseas travel; and working in unfamiliar environments. Please do not exceed 500 words.

Section 6: Data Protection
Please list all data that will be taken from participants during the research project (E.g. Personal data or sensitive data). Will you seek consent for this data to be used for the duration of the research? How will the data be confidentially stored? Once the research project is complete how will you ensure the data is securely destroyed? How long will the data be retained for? How will you ensure the Data Protection Act 2018 is adhered to throughout the project?
Section 7: Participant Details

<table>
<thead>
<tr>
<th>Does this research specifically target any of the targets in this list (Select all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Students or staff of NWSLC</td>
</tr>
<tr>
<td>□ Adults (Over the age of 18 years and able to give consent)</td>
</tr>
<tr>
<td>□ Children/Legal minors (Anyone under the age of 18)</td>
</tr>
<tr>
<td>□ Persons incapable of giving informed consent</td>
</tr>
<tr>
<td>□ People from non-English speaking backgrounds</td>
</tr>
<tr>
<td>□ Welfare recipients</td>
</tr>
<tr>
<td>□ Prisoners or Parolee</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Does the study involve recruiting participants through a gatekeeper?</th>
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</table>

Section 8: Participant Information

<table>
<thead>
<tr>
<th>Will you inform participants that their participation is voluntary?</th>
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<tbody>
<tr>
<td>Will you inform participants that they may withdraw from the research at any time and for any reason?</td>
</tr>
<tr>
<td>Will you inform participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?</td>
</tr>
<tr>
<td>Will you provide an information sheet that will include the contact details of the researcher/team?</td>
</tr>
<tr>
<td>Will you obtain written consent for participation?</td>
</tr>
<tr>
<td>Will you debrief participants at the end of their participation (i.e., give them an explanation of the study and its aims)?</td>
</tr>
<tr>
<td>Will you provide participants with written debriefing (i.e., a sheet that they can keep that shows your contact details and explanations of the study)?</td>
</tr>
<tr>
<td>If using a questionnaire, will you give participants the option of omitting questions that they do not want to answer?</td>
</tr>
<tr>
<td>If an experiment, will you describe the main experimental procedures to participants in advance, so that they are informed about what to expect?</td>
</tr>
<tr>
<td>If the research is observational, will you ask participants for their consent to being observed?</td>
</tr>
</tbody>
</table>

Section 9: Participant Consent

Please describe the below in as much detail as possible.

1. What arrangements that you have put in place to ensure participants are informed of the nature of the research before they give their consent.
2. Are participants aware of what is involved when participating in your study and the use of identifiable data?

3. How will you ensure participants feel respected after the study and do not feel a significant level of unease or stress in relation to the research project?

4. Have any risks to the participants been identified? If yes, please list all potential risks and any procedures that will be put in place (please attach any support documentation)

<table>
<thead>
<tr>
<th>Section 10: Declaration</th>
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</thead>
<tbody>
<tr>
<td><strong>10.1 Staff Applications</strong></td>
</tr>
<tr>
<td>I certify that the information contained in this application is accurate. I have attempted to identify the risks that may arise in conducting this research and acknowledge my obligations and the rights of the participants. I confirm that the research will be conducted in line with all College, legal and local ethical standards.</td>
</tr>
<tr>
<td>Name of Researcher:</td>
</tr>
<tr>
<td>Signed:</td>
</tr>
<tr>
<td>Signature of Vice Principal Quality:</td>
</tr>
<tr>
<td>Signature of Ethical Approval Committee Member (if applicable)</td>
</tr>
</tbody>
</table>

| **10.2 Student Applications** |
| I certify that the information contained in this application is accurate. I have attempted to identify the risks that may arise in conducting this research and acknowledge my obligations and the rights of the participants. I confirm that the research will be conducted in line with all College, legal and local ethical standards. |
| Name of Student |  |
| Signed: | Date |
| Signature of Tutor / Module Leader: | Date |
| Signature of Ethical Approval Committee Member (if applicable) | Date |