RESEARCH ETHICS POLICY AND PROCEDURES
OPEN TRAINING COLLEGE

1. INTRODUCTION

The Open Training College (OTC) *Research Ethics Policy* presents an overview on how research ethics is managed in the college. It provides the basic principles of best practice in research for all research involving human research. The Policy is applicable to all OTC student researchers, and should be read in tandem with the *Code of Conduct for Researchers* (See Appendix 1). The Research Ethics Committee facilitates and promotes research in OTC based on internationally accepted ethical norms and with attention to the welfare and rights of study participants. The OTC supports research that reflects the professional obligations of student researchers and their research supervisors/tutors (OTC staff). College staff seeking approval for their own research purposes apply through the St. Michael's House (SMH) Research Ethics Committee.

2. PURPOSE & SCOPE

All research that involves people carried out by Open Training College (OTC) student researchers requires ethical review. Ethics review is a process whereby proposed research is reviewed by a team of reviewers in a related discipline to make sure that it conforms to a set of ethical standards. In applying this review process within the OTC, Research Ethics Committee (REC) members will be fully cognisant of:

a) ***HSE National Policy for Consent in Health and Social Care Research*** (2023), available here: https://hseresearch.ie/wp-content/uploads/2023/02/HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-compressed.pdf

b) CORU ***Social Care Workers Registration Board Code of Professional Conduct and Ethics*** (2019), available here: https://coru.ie/files-codes-of-conduct/scwrb-code-of-professional-conduct-and-ethics-for-social-care-workers.pdf

c) The ***National Disability Authority Ethical Guidance for Research with People with Disabilitie***s (2009), available here: https://nda.ie/publications/ethical-guidance-for-research-with-people-with-disabilities-report

The task of the REC is to review proposed research projects before they commence, to assess the ethical implications, and to provide College approval to student researchers on how they propose to best incorporate respect for dignity, rights and the welfare of research participants into their research design. This policy is intended to provide all student researchers and their research supervisors/tutors, who provide ongoing support/guidance, with an overview of research ethics in the OTC and the requirements of the REC regarding the research ethics approval process.

Retrospective ethics approvals will not be provided for any study conducted by OTC student researchers.

3. GENERAL PRINCIPLES

There are a number of key principles which underpin the OTC's commitment to achieving the highest standards of excellence and best practice in research ethics. This policy aims to provide student researchers with guidance on quality and best practice relating to seeking, obtaining and maintaining ethical approval. Student researchers are therefore required to seek ethical approval using the relevant application forms provided with this policy and on the OTC Learning Centre and to follow the submission instructions provided there. These principals are:

- Maintains ethical standards of practice in research, including truthfulness and honesty.
- Protects human subjects of research from harm.
- Ensures respect for participants, including confidentiality in research.
- Ensures that the practice of fully informed consent is observed, including the right to withdraw.
- Preserves the subjects' rights.
- Provides reassurance to the public and outside bodies that all the above are being done.
- Ensure Confidentiality/Anonymity.
- Adherence to OTC data protection policy and procedures.

4. ROLES & RESPONSIBILITIES

The REC is an AD Hoc sub-committee of the OTC Academic Council. The OTC requires that student researchers adhere to the policies and guidelines laid down by the Research Ethics Committee (REC) when obtaining ethical approval or exemption.

All OTC student researchers are required to know how to obtain ethical approval for their study.

Academic Supervisors/Tutors of student researchers are required to provide clear guidance as to the procedures involved in obtaining an ethical review in the OTC.

The role of the supervisor/tutor is to provide support and guidance to student throughout each step of the research process including advise on adherence to all OTC policies and OTC research ethics guidelines. The supervisor/tutor provides feedback to students throughout the process to support achievement of the learning outcomes of the Applied Research Methods module.

Academic Supervisors/Tutors are required to endorse their student's submissions for all reviews, prior to the application to the REC being submitted. All student researchers must be familiar with the policies and guidelines provided by the REC.

4.1 Research Involving Human Subjects: Ethical approval is required from the REC, and/or (if applicable) the appropriate human services agency research ethics committee as required by individual agencies/service providers.
Student Researchers should ensure that they have knowledge of any relevant disciplinary guidelines on research ethics including ***National Disability Authority Ethical Guidance for Research with People with Disabilitie***s (2009)

Any empirical research must have the required approval by the College's REC and also approval by any additional relevant Ethics Committees who might have responsibility in any other institution/organisation whose participants form part of the proposed research.

4.2 Risk ethical review:
An application for OTC research ethics approval must be made for any research proposals which involve:

- direct experimentation on individuals;
- gathering data from individuals;
- use of data derived from individual records where individuals might be identified.

Research conducted by student researchers may be of 'low risk' or 'no risk' standard i.e., research carrying little or no risks or discomfort greater than usually encountered during normal daily life, involving non vulnerable persons or their data.

A study that involves human subjects including vulnerable groups, sensitive topics, or exposing participants to risk or harm to a degree that is greater than they would normally be exposed to in everyday life, requires a review by the OTC REC.

The level of risk takes account of:

a) The profile of research participants and the extent to which participants can be considered vulnerable.
b) The sensitivity of the proposed research topic.
c) The proposed research methodology.

Vulnerable groups include:

• Children i.e., people under 18 years of age. **(Note: OTC student research will not include this group.)**

- Older people (certain groups over 65 but this depends on the nature of the research).
- Students.
- People with communication challenges/language difficulty.
- People with an intellectual or developmental disability.
- People with a mental health challenge.
- Relatives of people with intellectual or developmental disabilities, older people or people with mental health challenges who receive support from services.
- People who are confined to prison or residents of staffed care facilities
- People in dependent or unequal relationships (teacher/lecturer-student, therapist-client, employees as participants, care staff member/service user).
- Refugees, asylum seekers and migrants.
- Individuals on waiting lists for services.

4.3 Legal Considerations: Researchers are responsible for their own research and are therefore required to be aware of and comply with all applicable legal requirements and specifically required to be aware of the following:

4.3.1. Researchers must ensure that research fulfils any legal requirements including those of the Data Protection Acts (1988 – 2018 as may be amended) and the Freedom of Information Acts (1997 – 2014 as may be amended);

4.3.2 OTC requires that all research data stored electronically should use the OTC Google Drive only using two-factor authentication i.e., two separate, distinct forms of identification in order to access the research data. No hard copies of research material should be stored elsewhere. All student researchers must abide by the OTC GDPR policy and procedures in relation to data storage, sharing and disposal.

4.3.3 Human rights are protected by the Constitution of Ireland, the European Convention on Human Rights, and the European Convention on Human Rights Act, 2003. The United Nations Convention on the Rights of Persons with Disabilities protects the rights of people with disabilities and the Convention's General Principles are applicable in all research approved by the OTC REC.

4.3.4 Neither the OTC, the REC, nor individual members of the Committee accept any legal liability, or other liability whatsoever, for any advice or assistance offered to the researcher or to any third party in the processing of the application or for the subsequent supervision or conduct of the research.

RESEARCH ETHICS PROCEDURES:

Membership of the Research Ethics Committee (REC)

Membership:

Convenor (Chair):	Head of Department/Programme Director for Relevant Discipline/Suite of Programmes or Nominee
Members:	Programme Directors (Internal/College) from other disciplines (x2)
	Senior Lecturer from relevant discipline
	Senior Academic (External/Other HEI) recognised as having expertise in a cognate discipline and in research

Terms of Reference (ToR):

- The REC meets throughout the academic year in order to receive applications and conduct full reviews. Additional meetings will take place at times of peak demand, such as when a cohort of students are submitting their research proposals. Further meetings as required will be arranged on an Ad Hoc basis.

- A full list of meetings and application deadlines (usually at least 3 weeks before a meeting) is made available to relevant student cohorts at the start of each academic year.

- Research related to applications made to the REC must not be carried out until full and final approval has been given by the Committee. In particular, advertising, seeking participants to take part or data collection of any kind must not begin prior to a student receiving written approval from the OTC REC.

- The REC acts to safeguard the dignity, rights, safety, and well-being of actual or potential research participants, as well as the researchers.

- The REC ensures that research is conducted according to best practice and that the research adheres to the following values:
  - Maintains ethical standards of practice in research, including truthfulness and honesty.
  - Protects research participants from harm.
  - Ensures respect for participants, including confidentiality in research.
  - Ensures that the practice of fully informed consent is observed, including the right to withdraw from the study.

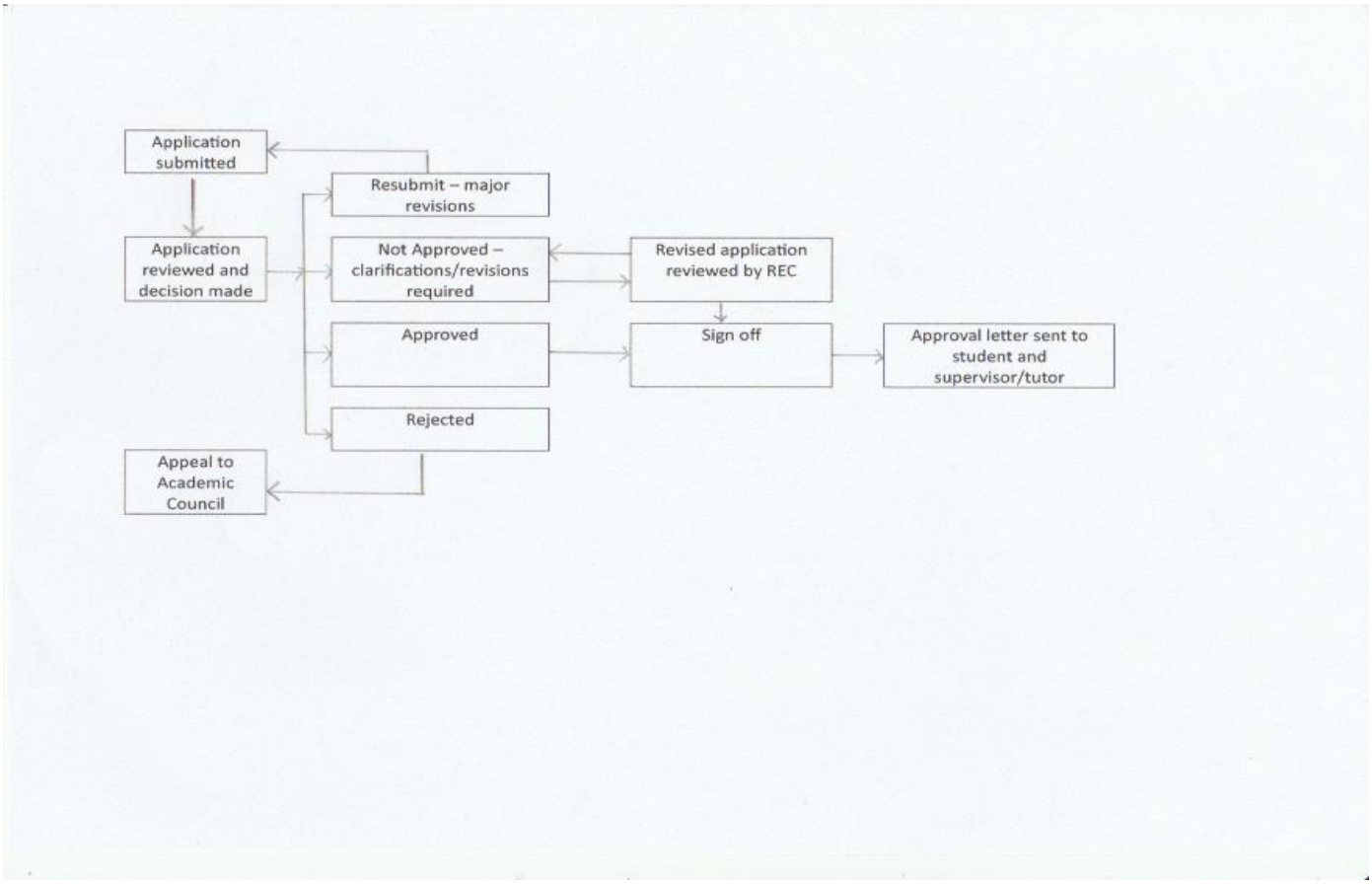
- Preserves the subjects' rights.
- Provides reassurance to the public and outside bodies that all the above are being done.
- Ensure Confidentiality/Anonymity.
- Adherence to OTC data protection policy and procedures.

- A minimum of three members must be present to be deemed quorate. The external member must be present. Each member of the committee has equal voting rights and a majority decision is required with any dissent being recorded. The Secretary to the Committee, as designated by the Chair, is required to record the proposals received, the decision reached and any conditions or dissenting opinions as appropriate. The REC Secretary will communicate by individual letter to each student applicant, with a copy to their research supervisor/tutor.

- The Committee is required to meet in a timely manner to facilitate students meeting deadlines, including allowance for resubmission of the proposal if required. Where ethical approval is not granted, the reasons for this will be provided to the researcher and their research supervisor/tutor, with an indication of whether a revised proposal would be welcomed by the Committee.

- The REC will make suggestions and recommendations on training and information for all parties involved in research processes within the College.

Research Ethics Approval Process



The function of the REC is to safeguard the health, welfare and rights of human participants and researchers in research studies. For any research proposal to gain ethical approval it must be designed to minimise predictable risk to both the research participant and the researcher.

Step	***Action(s)***
1	Student researchers are asked to liaise with their tutor/supervisor to ascertain the process for applying to the REC, if this is seen by the supervisor tutor as being a necessary step. In such cases, the Research Ethics Approval Application Form and Supporting Documentation are submitted at the same time as the research proposal. **Please note that in the academic year 2023/24 all students undertaking the Applied Research Methods module are required to submit a research ethics application to be reviewed by the REC.**

2	The tutor/supervisor reviews all research proposals to initially ascertain if they are either: **Exempt:** Deemed not to require ethical approval or **To be considered:** Deemed to need review by the REC. **Please note that in the academic year 2023/24 this step will not apply as all students undertaking the Applied Research Methods module are required to submit a research ethics application to be reviewed by the REC committee.**
3	Additional supporting documentation may be required and the applicant will be informed of and guided through these requirements where relevant.
4	Applicants are requested to submit their research ethics application and supporting documentation to Assessments at the time specified on the Course Calendar and in the ARM Assessment Guidelines. Assessments share the research ethics applications and supporting documentation with the members of the REC at least three weeks in advance of an REC meeting. Where the research involves interviewing or surveying people, the application also needs to be accompanied by: (i) A copy of the Participant Consent Form; (ii) A copy of the Participant Information Sheet (advising participants of what the research is for, how their role in it will work and what may/is to be done with the results) of the research; (iii) A copy of the paper advert for the study and/or a transcript of the script for a video advert (iv) A copy of the Questionnaire or list of questions to be used and details of the interview schedule for a qualitative interview; (V) Any other document that the research participant might be given. (vi) Confirmation that as a student researcher you meet the Garda vetting requirements of your employer for working with vulnerable groups. (vii) The applicant's signature on the application form. (viii) The student research supervisor's/tutor's signature on the application form. In cases where other research ethics committees have reviewed the application, copies of their responses must be provided as part of the application process.

5	The Application shared with the Supervisor/Tutor and the Year Coordinator and a reference number will be provided to the applicant by email.
6	The REC meeting is convened in a timely manner to review all applications.
7	The REC will consider the interest of the participants and in particular: • Ensure they are not negatively impacted as a result of participating and that specific consideration has been given to vulnerable groups. • Ensure that explicit informed consent in accordance with GDPR is included in the applicant's research design, including providing information on the appropriate storage and ultimate destruction of the data. • Include appropriate arrangements for research participants to withdraw from the research study. •Ensure the anonymity of participants and organisations and confidentiality regarding the information they may provide is included in the applicant's research design. In addition, researchers will ensure that participants are aware of the legal limits of confidentiality in relation to safeguarding children and vulnerable adults. • Consider whether the appropriate level of detail on intended research methodologies and rationale for the same is included in the research design • Consider the health and safety of the researcher and participants and how this will be ensured.
8	**Criteria for Approval:** To determine whether a research proposal meets the requirements for ethical approval the REC will consider: 1. Is the proposed research study design ethical? 2. Is the proposed method of investigation appropriate and ethical? Ethical approval will only be granted where the answer to both questions is positive. In addition, the REC will assess proposals using the following Research Ethics Principles: ● Maintains ethical standards of practice in research, including truthfulness and honesty. ● Protects research participants from harm. ● Ensures respect for participants, including confidentiality in research.

	● Ensures that the practice of fully informed consent is observed, including the right for research participants to withdraw. ● Preserves the subjects' rights. ● Provides reassurance to the public and outside bodies that all the above are being done. ● Ensure Confidentiality/Anonymity. ● Adherence to OTC data protection policy and procedures. The REC reserves the right to specify a more ethical methodology and approval of the proposal subject to the specified methodology being implemented. Other considerations may include the relevancy of the research to the investigation being carried out, and the timeframe of the proposed research.
9	Based on the criteria for approval, the REC may arrive at any of the following decisions with regard to the proposed research: 1. **Exempt:** Deemed as exempt from needing full ethical approval **Please note that in the academic year 2023/24 this decision will not apply as all students undertaking the Applied Research Methods module are required to submit a research ethics application to be reviewed by the REC committee.** 2. **Approval:** Approved as is with no conditions attached 3. **Not approved**: Application form to be resubmitted, with edits/revisions based on clarifications, additional information or changes to the supporting documents sought by the REC. All supplementary materials must be adjusted to reflect the student's revised application. 4. **Resubmit - major revisions.** Requires that the student prepare a fresh application involving an alternative research design. 5. **Rejected:** Written reasons for the decision will be provided to the student and resubmission will be possible.
10	Students will be informed of the decision by letter (sent as an email attachment) of the REC by the Programme Director (or Nominee), by email, within 3 working days of the REC meeting. Appeals may be made to the OTC Academic Council.

11	Students are advised that they cannot make substantial or significant changes to an approved research proposal. In particular, they must not change the research question(s), topic, focus, purpose advertising method, data collection method, data storage and proposed participant groups for the research. More minor changes may be permitted but only subject to supervisor/tutor approval (e.g., a smaller sample size than was originally intended). Researchers must at all times ensure the integrity of their research and not seek to influence research outcomes, falsify, sensationalise or distort their findings. If unexpected events occur that substantially affect the design of the research, the student, with support from their supervisor/tutor must communicate with the REC Secretary in a detailed letter that outlines the issue and any changes to the original research study proposed. The REC will reply promptly and will request further information as needed in each case.
12	Students will also be provided with the list of conditions relating to "Following Approval", as outlined below.

Following Approval:

- The research must be conducted in compliance with the approved protocol and any deviation from the original protocol must not be implemented without prior approval from the REC.
- Any unforeseen events that may affect the continued ethical acceptability of the research project must be reported immediately to the REC via the Secretary.
- The REC must be notified of, and approve, any changes to the original (approved) application.
- The REC must be notified of any changes in names of the student's supervisor/tutor.
- Research data arising from a research study must be in line with best practice and the OTC data protection policy and guidelines.
- Information for participants must include the name and contact details for both the researcher and of the academic supervisor/tutor.
- All materials (research study adverts, advertising videos, information sheets, consent forms, appointment letters, etc.) must display the OTC logo on Page 1.
- Approval is for the period stated on the letter of approval. Researchers must make a request for an extension should the collection of data exceed the study approval period.

- Research is carried out in full compliance with all regulatory and legal requirements currently in existence and in accordance with the ethical principles that have been outlined in the 'HSE National Policy for Consent in Health and Social Care Research'.

Any non-compliance with research approval may result in a range of sanctions including disciplinary action, termination of the research, allocation of a mark of zero and/or removal from the programme of study.

Appendix 1: Code of Conduct

Code of Conduct for Researchers

The CORU Social Care Workers Registration Board *Code of Professional Conduct and Ethics* (2019) outlines the following principles and best practice which Social Care Workers must adhere to:

Demonstrate ethical awareness.

You must:

- Carry out your duties and responsibilities in a professional and ethical way to protect the public.
- Always behave with integrity and honesty.
- Make sure you read, understand and comply with this Code of Professional Conduct and Ethics.
- Understand that if there is a conflict between this Code of Professional Conduct and Ethics and your work environment, your obligation is to this Code.

Respect the rights and dignity of service users.

You must:

- Always show, through your practice and conduct, respect for the rights and dignity of all individuals.

You must not:

- Discriminate, either directly or indirectly, against a person on the basis of: gender, family status, civil status, age, disability, sexual orientation, religion, race, colour, nationality or ethnic or national origins, or membership of the Traveller Community.
- Condone discrimination by others.

Avoid conflicts of interest

You must not:

- Accept inducements, financial or other incentives that could reasonably be perceived as affecting your professional judgement.
- For reasons of personal or commercial benefit, direct public service users to private practice.
- Enter into any agreement or contract that might cause you to breach this Code.

Undertake research in an ethical manner.

When you engage in research you **must**:

- Submit your research proposal to the relevant research ethics committee and get ethical approval before starting the research or, where there is no relevant research ethics committee in place, ensure that your research conforms to the current version of the Declaration of Helsinki.
- Follow guidance laid down in legislation and issued by relevant authorities.
- Obtain voluntary, informed consent from service users in line with the procedures laid down by the research ethics committee.
- Collect, protect, and destroy data in line with relevant legislation.
- Ensure that a service user's refusal to take part in research does not influence the delivery of service to that service user in any way.
- Make sure that, if you receive any payment or other financial benefit directly or indirectly from a pharmaceutical, medical device or other commercial organisation to conduct research, this does not influence the design or interpretation of your research.
- Address any potential conflict of interest and disclose any payment or benefit you have received from a pharmaceutical, medical device or other commercial organisation in any publication of research results.
- Follow accepted guidelines in scientific journals concerning intellectual property, copyright and acknowledging the work of others.
- Make sure you do not distort or misuse clinical or research findings.

(CORU Social Care Workers Registration Board *Code of Professional Conduct and Ethics* (2019), pp. 23-26) available at: https://coru.ie/files-codes-of-conduct/scwrb-code-of-professional-conduct-and-ethics-for-social-care-workers.pdf

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Audience:		Public – accessible to anyone
Reference(s)		HSE National Policy for Consent in Health and Social Care Research (2023 CORU Social Care Workers Registration Board Code of Professional Conduct and Ethics (2019 The National Disability Authority Ethical Guidance for Research with People with Disabilities (2009) Data Protection Acts (1988 – 2018 as may be amended) Freedom of Information Acts (1997 – 2014 as may be amended) Constitution of Ireland The European Convention on Human Rights European Convention on Human Rights Act, 2003 The United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) Declaration of Helsinki