Institute of Technology Carlow

Ethics in Research Policy

Policy Statement on Ethics in Research
**Policy & Procedure Title:**
Policy and procedures for Ethics in Research

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IT CARLOW

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RESEARCH ETHICS COMMITTEE: CONTEXTS AND FUNCTION

IT Carlow recognises that research ethics, ethical research design and a commitment to research integrity are fundamental to research activity. This policy, procedures and associated documentation are intended to provide an appropriate governance and management structure to:

- Ensure a robust ethical framework for all research led activity;
- Foster an appropriate research culture within the Institution;
- Align internal procedures with the proposed National Research Ethics Approval Framework that will be supervised by HIQA2.

The drafting and formulation of this policy and procedures has been informed by the following documents:

- The European Code of Research Integrity;3
- The Singapore Statement on Research Integrity;4
- The National Policy Statement on Ensuring Research Integrity in Ireland;5
- OECD Best Practice Guidelines for Ensuring Scientific Integrity and Preventing Misconduct.6

The IT Carlow Research Ethics Committee (REC) is the body tasked by the President of IT Carlow with responsibility for the oversight and supervision of the ethical review of all proposals for research activity carried out on institute premises or under its auspices.

This means that the REC has responsibility for the independent, ethical review of all research proposals and activity to be carried out by all learners, staff, collaborative and industry partners who are engaged in research activity, at whatever level.

As supervised learner research activity is conducted primarily for the purpose of educating learners in research techniques and methodologies, the REC shall carry out reviews of research protocols with the principal objective of contributing to the learner’s education concerning the scientific and ethical principles governing research.

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1 This policy and related procedures are designed to govern the management of ethical issues arising in research practice. For completeness this policy should be read in conjunction with the following IT Carlow policies and procedures:
- IT Carlow Policy and Procedures for Postgraduate Awards
- IT Carlow Policy and Procedure on Data Protection
- IT Carlow Policy and Procedure on Academic Integrity and Anti-Plagiarism

2 http://hiqa.ie/publications/international-review-research-ethics-structures.
The procedures relating to ethical review of a research proposal shall determine whether a proposal:

- Is eligible for exemption from review and approval
- Requires re-submission to apply for ethical approval
- Is granted ethical approval
- Requires redesign and resubmission in order to qualify for approval
- Is denied approval

Submissions of research proposals shall be made on the appropriate application forms set out in the procedures annexed to this policy statement.

The Ethics Committee shall have discretion on behalf of IT Carlow and taking account of relevant ethical considerations, to decline to approve any research proposal or to require such modifications as it may deem necessary. The REC shall advise the President on research projects having important ethical implications for IT Carlow.

In making a determination on a research proposal, the REC shall operate on a consensus basis. In the event that no consensus is reached a simple majority of those present and voting at a valid, quorate meeting of the REC shall determine the outcome.

**RESEARCH ETHICS COMMITTEE: COMPOSITION**

The Research Ethics Committee shall comprise fifteen members in total. The membership of the Committee shall reflect a range of core skills and expertise. Members shall have knowledge and experience of research methods and practice relevant to the strategic research priorities of IT Carlow. Specific skills represented across the membership shall include:

- Knowledge of and current experience in the sciences, biological and environmental science, health and social care, counselling or treatment of people;
- Knowledge of and training in ethical issues;
- Expertise in specific skill areas of statistics and data management.

It is necessary that the committee shall have the appropriate expertise, knowledge, experience and perspective to enable them to give adequate consideration to applications made and to address changes in legislation, compliance and standards as such arise. Therefore the committee may co-opt additional individuals with specific expertise to address such needs.

There shall be at least two members of the Research Ethics Committee drawn from outside of the Higher Education Sector.
In arriving at final membership of the committee, gender balance shall be considered as shall relevant and appropriate disciplinary spread and campus representation.

There shall be no substitution or delegation of membership on the committee.

**RESEARCH ETHICS COMMITTEE: APPOINTMENT AND TERM OF OFFICE**

The President of IT Carlow shall appoint the Chair of the REC. Other committee members drawn from staff of IT Carlow shall be appointed by a process of nomination as follows:

(a) **Representative members**

Nominations from the following constituent groups shall be made by the relevant Postgraduate Programme Stream Boards. The names of nominees shall then be conveyed to the chair for final approval and ratification.

- Faculty of Science 2
- Faculty of Business and Humanities 2
- Faculty of Engineering and Built Environment 2
- Wexford Campus 1
- Faculty of Lifelong Learning 1
- Externals 3

(b) **Ex-officio members**

- Chair of Research and Development Committee 1
- Head of Postgraduate Studies 1
- Vice President for Academic Affairs & Registrar (or nominee) 1

(c) **Presidential appointment**

- Chair 1

Representative Committee members shall be appointed for an initial term of two years. Members are eligible for re-appointment at the end of the first term. In circumstances where it would be beneficial to the work of the committee (and agreeable to the individual) a representative member may serve for a third (final) consecutive term.
Members are required to attend a minimum of two meetings in any one academic session. In circumstances where members are consistently unable to attend the Chair may exercise the right to request an alternative nomination from the relevant representative group.

**RESEARCH ETHICS COMMITTEE: SCHEDULE AND REMIT**

The Research Ethics Committee shall meet on a minimum of four occasions during an academic session (and more frequently if deemed necessary by the committee).

The quorum for a committee meeting shall be seven members. A valid quorate meeting must include the chairperson (or vice-chairperson) and an external member.

The business of the research committee shall be

- The review and approval of applications for research from learners undertaking programmes of research leading to awards at NFQ Level 9 (by research and dissertation) and NFQ level 10 programmes;

- The review and approval of research proposals from staff, post-doctoral researchers and from researchers associated with industry partners where the research is carried out under the aegis of IT Carlow or on its premises;

- The exercise of oversight of the Declaration of Ethical Consideration Process for research projects carried out across programmes at NFQ level 6, NFQ level 7, NFQ level 8 and NFQ level 9 (taught).

- Research proposals shall be submitted for review according to a published schedule of meetings. It is recommended that Principal Investigators/Research Supervisors shall be available at scheduled meetings of the committee to answer technical queries associated with any applications submitted under their name or with their approval.

**RESEARCH ETHICS COMMITTEE: DECLARATION OF ETHICAL CONSIDERATION (L6-9T)**

Documentation and guidelines for projects using this route are set out at Appendices I and II. In each case, completed forms shall be submitted by the learner to the supervisor for review and approval. The supervisor shall retain the forms until the research project is submitted for examination. At that stage the declaration forms shall be attached to the project as an integral part of the work for assessment. Forms shall
be available for inspection by the REC and may be requested at any stage in the research process. The REC shall exercise its oversight function by:

- Formal documentation, noting and recording of projects under Declaration of Ethical Consideration.
- Review and audit of projects under Declaration of Ethical Consideration. Working groups/ standing sub-committees of the REC shall carry out this function. It is anticipated that the review of project documentation shall be
  - A desk based review of copies of declarations
  - A random “depth test” or verification based on representative sampling (10%)
- Detailed terms of reference shall be issued by the REC to the sub-committee(s).

The REC shall exercise an appeals function by:

- (a) Reviewing cases referred by supervisors
- (b) Reviewing decisions appealed by applicants

**RESEARCH ETHICS COMMITTEE: APPEALS (L9R/L10)**

When the decision of the REC results in approval for a research proposal being declined or requiring specified modification, any person or persons with a material interest in that proposal (for example a supervisor or primary researcher) may appeal the decision to the President of IT Carlow. Such appeal shall be in writing and shall set out the basis of the appeal. The Appeal shall be received within one calendar month of the date that the original decision was communicated to the applicant.

On receipt of an appeal the President shall have discretion to proceed either by:

(a) Referring the appeal back to the REC for review and recommendation, or

(b) Empanelling a special review group of no less than three individuals to conduct a review and to make a recommendation. This review group shall include at least one external member. No member of a review group shall have had any involvement with either the original proposal or with the decision under review.

The President shall consider the recommendation of the review and shall either:

(a) Confirm the original REC decision, or
(b) Substitute a new decision with or without conditions attached.

That decision is final.

**RESEARCH ETHICS COMMITTEE: RECORDS**

The REC shall maintain:

- A Register of all decisions made in relation to research proposals submitted to it by learners at NFQ Level 9 (by Research), NFQ Level 10, by Staff or submitted on behalf of research groups, CORES or Campus companies;
- A noting that records all research projects considered under the Declaration route (Appendix II);
- A summary synopsis to record sample outcomes.

Records and Registers will be maintained in the office of the Vice President for Academic Affairs & Registrar.
RESEARCH ETHICS COMMITTEE: TRAINING

As part of its commitment to supporting research activity, IT Carlow, through the REC shall undertake to implement an information and training programme aimed at staff and learners across the institution. This shall be designed to embed inquiry based learning, research ethics, research design and research best practice as core elements of programme design and programme provision across all programmes at NFQ level 6 and above.

Within this training programme, specific provision shall be made to address procedural issues and developments in the area of research ethics as they impact on the functions of the REC and on the advisory functions of supervisors in respect of Declarations of Consideration of Research Ethics with respect to projects undertaken on programmes at NFQ Level 6 through 9 (Taught).

RESEARCH ETHICS COMMITTEE: POLICY REVIEW

The REC is responsible for the development and recommendation of policies and procedures in relation to ethics in research, which may from time to time become necessary.

In order to ensure that the Research Ethics Policy is up to date and fit for purpose this policy shall be subject to review in line with IT Carlow Policies and Procedures approved and adopted by Academic Council.
APPENDIX I

RESEARCH INVOLVING HUMAN PARTICIPANTS
GUIDELINES FOR RESEARCHERS AND SUPERVISORS
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A. Introduction

Ethics and a commitment to the application of “robust ethical principles” is one of the six core values of IT Carlow as stated in its Strategic Plan 2014-2018. While the value is phrased in the broadest sense to include strong governance, clear accountability and high values of integrity, ethics has a particular significance for research activities and especially where such research involves human participants. The purpose of this document is to provide ethical guidelines for all persons engaging in research involving human participants. This document is intended to supplement and be interpreted in accordance with the IT Carlow Research Ethics Policy Statement 2014.

Ethical Research - General Principles

Generally, ethical research incorporates the following:

- A commitment to the well-being, protection and safety of participants;
- A duty to respect the rights and wishes of those involved;
- An obligation to address the issue of who ought to receive the benefits of research and bear its burdens;
- A responsibility to conduct high-quality research;
- A commitment to communicate the results of research to relevant stakeholders and policy-makers.

These overarching principles apply to all stages of research which can be broken down into four stages:

- Collection;
- Use;
- Management;
- Storage

What is “research involving human participants”? Research involving human participants is to be understood broadly, to include the involvement of human beings either as active or passive subjects. Examples include, inter alia:

- Taking part in surveys, interviews or focus groups;
- Undergoing psychological, physiological or medical testing or treatment;
- Being observed by researchers;
- Researchers having access to their personal documents or other materials;
- The collection and use of their body organs, tissues or fluids (e.g. skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
- Access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.
In addition, the conduct of human research often has an impact on the lives of others who are not participants. When this impact is reasonably foreseeable, it may raise ethical questions for researchers and for those ethically reviewing research.

They may be collaborators or colleagues in the research process or they may simply be part of the context e.g. where learners are part of the context but not the subjects of a teacher’s research into his or her own professional practice.

What types of research involving human participants requires ethical consideration?

Most types of research involving human participants (see above) will involve ethical issues and will require consideration of these guidelines. Specific examples of these types of research are set out in the IT Carlow RE Policy.⁷

What are the main ethical considerations in research involving human participants?

The relationship between researchers and research participants is the ground on which human research is conducted and should be one of trust, mutual responsibility and ethical equality. Essentially there are four main considerations which constitute the “pillars” of ethical research. The design, review and conduct of research must reflect each of these values.

The Pillars of Ethical Research

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⁷ Essentially, the only types of human-related research that do not require ethical consideration are:

- Research utilising existing publicly available documents or data;
- Observational studies in public places in which the identity of the participants remains anonymous;
- Case study of one patient involving one participant only, with the proviso that written informed consent has been obtained from the relevant subject;
- Quality assurance studies;
- Audits.
B. General Guidelines: The Four Pillars of Ethical Research

1. Respect for Human Dignity

Researchers must operate within an ethic of respect for any persons involved in the research they are undertaking. This ethic of respect should apply to both the researchers themselves and any individuals participating in the research either directly or indirectly.

Researchers should ensure that taking into account the scope and objectives of the proposed research, the process of selection, exclusion and inclusion of categories of research participants is fair, and is accurately described in both the research proposal and the results of the research.

Individuals should be treated fairly, sensitively, with dignity, and within an ethic of respect and freedom from prejudice regardless of age, gender, sexuality, race, ethnicity, class, nationality, cultural identity, partnership status, faith, disability, political belief or any other significant difference. Researchers should avoid using designations that could give rise to unreasonable generalisation, resulting in possible stigmatisation of particular social groups.

No unfair burden of participation in research should be placed on particular groups (please refer to page 21 below).

Respect for human beings also involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.

Where participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary. Categories of otherwise qualified participants for a research project should not therefore be excluded merely because of their vulnerability or diminished capacity.

This value also requires that there is fair access to the benefits of the research and that the research outcomes should be made accessible to research participants in a way that is timely and clear.

For research with human-derived material the dignity of the donor must be respected.
2. **Voluntary Informed Consent**

This requires that all participants in research fully understand and fully and voluntarily agree to their participation in the research.

This includes the following elements:

**Openness and Disclosure**

Researchers must take the steps necessary to ensure that all participants in the research process are fully informed and understand *inter alia*:

- The objectives of the research;
- The research methods to be used;
- What exactly the participant will be required to do;
- Why their participation is necessary;
- Any possible risks to the participant and how they will be addressed;
- Expected benefits of research;
- The right to withdraw at any time;
- How the research findings will be used;
- How and to whom it will be reported.

A clear and detailed information leaflet setting out the above must be provided to participants prior to receiving consent and commencing the research\(^8\).

You must give sufficient and explicit detail, even in respect of information that may appear obvious to you. A separate informed consent form, for signature by or on behalf of the participant should also be provided.

**Appropriate language for your target participants must also be used.**

- Technical terms that are in common usage within your area of study/research must be clearly explained in ordinary language. You must assume that participants have no knowledge/experience of the area of study/research involved;
- Researchers should be reasonably aware of the sensitivities of participants and careful to avoid the use of words/terminology that some participants might find offensive.

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\(^8\) The securing of participants’ voluntary informed consent, before research gets underway, is considered a mandatory requirement for the conduct of research. Researchers must therefore avoid deception or subterfuge unless their research design specifically requires it to ensure that the appropriate data is collected or that the welfare of the researchers is not put in jeopardy. For example, this might include research involving the use of placebos and control groups. Decisions to use non-disclosure or subterfuge in research must be the subject of full deliberation and subsequent disclosure in reporting. Where such a course of action is envisaged, approval must first be obtained from the IT Carlow Research Ethics Committee.
Additional care should be taken where the target participants are children, persons with intellectual disabilities or persons with literacy issues to ensure that full understanding and proper consent is achieved.

In respect of on-line research involving human participants e.g. surveys etc., the above information may be supplied electronically (for example by e-mail when consent to participation is being sought). In such cases, researchers should append to their research proposal, a copy of the template correspondence to be sent to all such potential participants.

Social networking and other on-line activities, including video-based environments, present challenges for consideration of consent issues and the participants must be clearly informed that their participation and interactions are being monitored and analysed for research.

Researchers engaged in action research must reflect on and consider the extent to which their own research impinges on others, for example in the case of the dual role of teacher and researcher and the impact on learners and colleagues9. Dual roles may also introduce explicit tensions in areas such as confidentiality and must be addressed accordingly.

**Voluntary Participation**

This requires that all participants freely choose to participate without being subject to any duress or pressure either prior to or during the research in question.

**Right to Withdraw**

It follows that researchers must recognise the right of any participant to withdraw from the research for any or no reason, and at any time, and participants must be informed of this right from the outset.

**Incentives**

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9 The British BERA Charter for Research Staff in Education (2012)  
Use of incentives (e.g. payment or a promise of a donation to charitable cause conditional upon participation) in the design and reporting of research may be problematic as (i) it may put potential participants under implied pressure to participate and (ii) the potential to create a bias in sampling or in participant responses.

Consequently, it is recommended that researchers avoid the use of incentives to encourage participation. If in doubt researchers should seek advice from their supervisors.

3. Minimising Risk of Harm

Participants should not be exposed to risks greater than or additional to those encountered in their normal lifestyle.

Researchers must consider the risk of harm to participants and ensure that such risk is minimised.

Researchers are advised to consider carefully the various types of harm that participants could potentially be exposed to either during, or as a consequence of, the particular research activity in question.

Examples of the different types of potential harm include:

- Physical harms: including injury, illness, pain;
- Psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease;
- Devaluation of personal worth: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
- Social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;
- Economic harms: including the imposition of direct or indirect costs on participants;
- Legal harms: including discovery and prosecution of criminal conduct.

Researchers should also consider carefully minor discomfort such as, for example, minor side-effects of medication, the discomorts related to measuring blood pressure, and anxiety induced by an interview.

Where risk to participants does exist, researchers must ensure that adequate supports are available for participants to minimise any such risk e.g. immediate availability of first aid/ nurse/ doctor (if physical testing is involved), availability of counselling/ other supports etc.
Researchers must make known to the participants (or their guardians or responsible others) any predictable detriment arising from the process or findings of the research. Any unexpected detriment to participants, which arises during the research, must be brought immediately to their attention or to the attention of their guardians or responsible others as appropriate.

Researchers must also make it explicitly clear from the outset that all participants have the right to withdraw at any time.

Researchers must take steps to minimise the effects of designs that advantage or are perceived to advantage one group of participants over others. If researchers find during experimental design that their intervention is having perceived benefits and positive effects on participants over the control or comparison group, it is the obligation of the researcher to make these benefits available to the comparison group.

4. Protecting Privacy and Confidentiality

Researchers must ensure that adequate safeguards are in place to protect the privacy of individuals participating in the research and the confidentiality of their personal data.

Privacy

Researchers must recognise the participants’ entitlement to privacy and must accord them their rights to confidentiality and anonymity, unless they or their guardians or responsible others, specifically and willingly waive that right. In such circumstances it is a requirement that the researcher obtains such a waiver in writing.

Conversely, researchers must also recognise participants’ rights to be identified with any publication of their original works or other inputs, if they so wish. In some contexts researchers should be aware that it may be the expectation of participants to be so identified.

Data Protection

Researchers must comply with the legal requirements in relation to the storage and use of personal data as set down by the Data Protection Acts 1988-2003 and any subsequent applicable legislation. In essence people are entitled to know how and why their personal data is being stored, to what uses it is being put and to whom it may be made available.

Therefore, in the Information Sheet provided to participants, the following details should be addressed:

- That the data relating to each participant will be kept only for the purpose specified, will be relevant to the research and not excessive;
- How the data will be kept safe and secure e.g. if in manual form, where will the data be stored and how. If electronic information that it is password protected, encrypted as appropriate;
- If the information is to be seen by persons other than the researcher, who will that be and why;
- How long the information be retained for;
- How the data will be disposed of/ destroyed;
- Any plans to use the data in future studies, research or publications.

Researchers must also have participants’ permission to disclose personal information to third parties and are required to ensure that such parties are permitted to have access to the information. They are also required independently to confirm the identity of such persons and must keep a record of any disclosures. Disclosure may be written, electronic, verbal or any visual means.

The Data Protection Acts also give private citizens the right of access to any personal data that is stored in relation to them. Researchers seeking to exploit legal exclusions to such right must have a clear justification for so doing. 

**Limits on Confidentiality - Disclosure**

Certain categories of research, by their nature, may involve potential limits being placed on confidentiality (e.g. the need to report possible criminal conduct to relevant bodies/ authorities). In such cases, the researcher must inform all participants of this possibility in the Participant Information Sheet and research should only proceed once the consent of the participant to this has been obtained.

In other cases, researchers may judge that the effect of the agreements they have made with participants, on confidentiality and anonymity, will allow the continuation of illegal behaviour, which has come to light in the course of the research. In such circumstances they must carefully consider making disclosure to the appropriate authorities. If the behaviour is likely to be harmful to the participants or to others, the researchers must also consider disclosure. Insofar as it does not undermine or obviate the disclosure, researchers must apprise the participants or their guardians or responsible others of their intentions and reasons for disclosure.

At all times the decision to override agreements on confidentiality and anonymity must be taken after careful and thorough deliberation. In such circumstances it is in the researchers’ interests to make contemporaneous notes on decisions and the

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reasoning behind them, in case a misconduct complaint or other serious consequence arises.

Researchers should also debrief participants at the conclusion of the research and to provide them with copies of any reports or other publications arising from their participation. Where the scale of the research makes such a consideration impractical, alternative means such as a website and/ or abstract or summary sheet should be used to ensure participants are informed of the outcomes.
C. Specific Categories – Additional Guidelines

(i) Vulnerable Participants

Defining Vulnerable Participants for the purposes of Ethical Research

- Those with disabilities, cognitive or communicative difficulties;
- Child participants;
- Those who are institutionalised (prison, residential care etc.);
- Those with specific medical issues (for example mental health issues);
- Minority groups (e.g. members of the Travelling Community, non-English speaking persons).

General Guidelines

Prior to commencing work with vulnerable participant groups, researchers shall be compliant with the IT Carlow Garda Vetting Policy.

Consent should be obtained where possible from the participant depending on their needs.

Consent should also be obtained from key gatekeepers.

The researcher needs to assess and reassess the participants’ vulnerabilities and specific needs and take steps to protect participants (Rightmer, Yale University, 2014).

The capacity of the participant to give informed consent and participate in data collection methods should always be considered.

Researchers shall comply with the provisions of the Assisted Decision Making (Capacity) Act 2015 when seeking consent from persons who are regarded as lacking capacity under s. 3 of the Act.

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In the same document Vulnerable participants are also defined as those “vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons”. See also National Vetting Bureau (Children and Vulnerable Persons) Act 2012 and IT Carlow Code of Practice- Working with Learners, Children and Vulnerable Adults (November 2012).


13 As of 1st July 2017, this Act is yet to be fully commenced. However, once fully enacted, it will introduce assisted and co-decision making procedures across a range of decision making areas including research which will need to be followed. See: HSE https://www.hse.ie/eng/about/Who/QID/Other-Quality-Improvement-Programmes/assisteddecisionmaking/about-the-assisted-decision-making-act.html <accessed 26th
The methods of obtaining consent and data collection should meet the specific needs of the participant.

Total confidentiality should never be given in research with vulnerable groups. All participants and gatekeepers should be aware of the limits of confidentiality and the researcher must document the steps taken to make these limitations clear to those involved in the research and those giving consent. Should information of concern be disclosed during the research, researchers should inform a senior member of staff and follow the Children First: National Guidelines for the Protection and Welfare of Children (DCYA, 2011). The issues and the participants involved should be noted along with the decision making process. This should be kept in writing and clearly documented.

Researchers should conduct the research in a suitable setting, close to a central location where the participant and researcher can be seen by others (Children’s Research Centre, 2006).

All researchers should make provisions for their own personal safety when conducting their research.

In circumstances where research is carried out in a personal setting (e.g. a person’s home) it is recommended that a third party is present.

Researchers shall debrief and answer any questions participants have following the research process. Participants can withdraw from the research at any time without consequence and can view any information that is held by the researcher such as transcripts (NDA, 2009). Researchers are obliged to inform and make available to research participants the results and conclusions of the study and to make them aware of the valuable role that their participation has made to the generation of this knowledge. It is the researcher’s responsibility to redact transcripts and any other material to ensure that no other participants’ information is included in documentation before it is viewed.

Special Protection for those with Disabilities, Cognitive or Communicative Difficulties

Researchers should be aware that some societal groups feel that they have been overly researched. When selecting a research topic and group, researchers should question whether the particular topic chosen merits additional study or research. For example, in researching subject groups with cognitive learning difficulties or diminished responsibility, primary subject access will be limited and by default, much of the research will be confined to interaction with secondary subjects such as parents,

June 2017>; Inclusion Ireland http://www.inclusionireland.ie/sites/default/files/attach/basic-page/991/assisted-decision-making-act-factsheet.pdf <accessed 26th June 2017>
guardians and carers. Consideration should also be given to whether it adds value to the subject group or alternatively, it is likely to further stereotype it.

Written consent should be sought from key gatekeepers regardless of the age of the participant (Children’s Research Centre, 2006). Where possible, written consent must also be obtained from the participant. This may involve using creative methods of obtaining consent. For example, the use of handprints, clay mould handprints or use of translated consent forms for those where English is not their first language.

The research should be inclusive, accessible to those with disabilities and appreciate the diversity of the needs of the participants. Simple steps can be taken to ensure this. For example, using large print material for those with visual impairments or conducting interviews in a quiet location for those with hearing difficulties (NDA, 2009).

Consent should be ongoing and careful consideration should be given to the appropriateness to include this participant group prior to their selection (NDA, 2009).

Researchers should also consult with those with disabilities or special and additional needs or their representatives around the research topic, research questions and methods of data collection to ensure their appropriateness and inclusive research practice (NDA, 2009).

Researchers shall comply with the provisions of the Assisted Decision Making (Capacity) Act 2015 when seeking consent from persons who are regarded as lacking capacity under s. 3 of the Act.14

**Child Participants**

Knowledge of the *Children First: National Guidelines for the Protection and Welfare of Children* (DCYA, 2011)15 is essential and the procedures in this document must be adhered to. Researchers should familiarise themselves with the designated liaison person responsible for the implementation of this policy.

Research with children should be inclusive, have a firm commitment to children’s rights and be child-centred in its approach (Children’s Research Centre, 2006; Department of Children and Youth Affairs, 2012). Researchers should refer to the Guidance for developing ethical research projects involving children (2012) 16

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14 As of 14th July 2017, this Act is yet to be fully commenced. However, once fully enacted, it will introduce assisted and co-decision making procedures across a range of decision making areas including research which will need to be followed. See: HSE https://www.hse.ie/eng/about/Who/QID/Other-Quality-Improvement-Programmes/assisteddecisionmaking/about-the-assisted-decision-making-act.html <accessed 26th June 2017>; Inclusion Ireland http://www.inclusionireland.ie/sites/default/files/attach/basic-page/991/assisted-decision-making-act-factsheet.pdf <accessed 26th June 2017>

15 Elements of which have been placed on a statutory footing under the Children First Act 2015

In every case, written permission must be obtained from parent or legal guardian. If during the research project the child attains the age of 18, parental/guardian consent is negated and the researcher must seek the 18 year old’s permission directly in order to be able to continue the study (Spriggs, 2010).

Information describing the study should be presented to the child in an age appropriate manner e.g. puppets, child friendly leaflet, story etc.

Written consent should be obtained from children over 4 years of age. Creative methods can be used to ascertain consent (e.g. puppets, child friendly leaflet, story etc.). Verbal consent is sufficient for children under 4 years of age. Assent should be obtained from all children who are potential research subjects before they can be included as participants.

No incentives should be given to participate.

Findings must be disseminated to the children in a child friendly manner.

Methods of collecting data should be age appropriate and the length of time that children are involved in data collection should be kept to a minimum.

Researchers should consider the steps they need to take should children disclose sensitive information or if it is suspected that a child is at risk. This should be discussed with the designated person for the purposes of child protection prior to the commencement of the research.

Consent forms should refer to the fact that the researcher will adhere to the Children First Act 2015 and the Children First: National Guidelines for the Protection and Welfare of Children 2011, in the event of a disclosure.

A list of support services for children and their families should be drawn up prior to data collection should the research cause distress to the participants.

Researchers should always be mindful of the possible negative effects of their research.

Researchers should follow up on a concern about a child with the designated person for the purposes of child protection.

**Institutionalised Participants (prison, residential care etc.)**

Informed consent should clearly outline that consent is voluntary, without authority or incentives.
If required, the institution should not know the identity of those who chose to participate (Rightmer, Yale University, 2014).

Again, should the participant disclose sensitive information or information which is a cause of concern, the researchers should have considered this and have procedures in place to deal with this information.

**Participants with Specific Medical Issues**

Consent form should state the potential risks and benefits to being involved in the research.

Researchers should be particularly sensitive to the vulnerabilities of recently diagnosed individuals and/or people who have been informed that standard treatments have not been successful.

A patient advocate should be used in addition to the researcher obtaining written consent from the participant.

Consent needs to be monitored on an ongoing basis due to the needs of this particular participant (Rightmer, Yale University, 2014).
Minority Groups (e.g. Members of the Travelling Community, non-English speaking persons, impoverished communities)

All data collected should be kept confidential.

The researcher should consult with representatives of these groups to reduce the potential for stereotyping and stigmatisation.

Where communication issues emerge, the researcher must obtain consent using appropriate methods. For example, use of translator, verbal explanation of the research rather than written explanations.

Methods of data collection must be appropriate to the abilities of the participant. For example, it would inappropriate to use surveys with participants with literacy issues.

(ii) Qualitative Research

Qualitative research involves disciplined inquiry that examines people's lives, experiences and behaviours, and the stories and meanings individuals ascribe to them. It can also investigate organisational functioning, relationships between individuals and groups, and social environments. Qualitative research contributes to the development of new knowledge by enabling researchers to gain a better understanding of complex concepts of social processes and investigating how communities and individuals interpret and make sense of their experiences.

Data in qualitative research can be collected using a range of approaches such as:

- Interviews (including structured, semi-structured, unstructured, key-informant, sample informant);
- Life story or oral history;
- Focus groups;
- Observation of participant/s in their own environment, or in the environment being studied;
- Archival research;
- On-line research - on-line real-time group discussions using web-based chat-room technology (also known as E-groups) through the use of electronic bulletin boards and moderated email groups;
- Action research - community- or organisation-based carried out in the field.

Qualitative Research – Additional Ethical Considerations

A range of relationships between participants and researchers may develop as a result of the duration and nature of the interaction. Where such relationships threaten to compromise the research role, researchers must consider whether to modify those relationships, or to modify or even discontinue the research.
Researchers have a duty to inform participants whenever they are acting in a non-research professional role.

Research proposals that include sampling should clearly describe the recruitment strategy and criteria for selecting participants. Researchers should be able to justify such criteria.

Participants are often easily identifiable (for example, as members of small communities or groups, or as key informants), and the information they provide may be sensitive. For these reasons, care should be taken that participants are not identifiable by the information they provide, unless they have agreed to be identified. Special care should be taken to protect the identity of participants when disseminating information and storing material.

Where possible, participants should be informed about any potential to be identified in the results of research even if identifiers, such as name and address, are removed.

Qualitative research that explores sensitive topics in depth may involve emotional and other risks to both participant and researcher. Researchers must have clear protocols for dealing with distress that might be experienced by participants.

Predicting what topics are likely to lead to distress will not always be easy. Researchers should therefore carefully consider such likelihood in the planning of research aims and methodologies.

Qualitative research may involve methods of data collection that require the development of personal relationships with participants. Researchers should reflect on the impact that they may have on the participants and vice versa, and as far as possible should describe in the research proposal any anticipated impact of this nature.

Researchers should consider whether respect for the participants requires that the accuracy or completeness of each interview transcript should be verified by the relevant participant before analysis is complete.
### Research where participants undergo psychological, physiological or medical testing or treatment

<table>
<thead>
<tr>
<th>Issue</th>
<th>Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethical approval</td>
<td>Participant recruitment and testing not to commence until ethical approval granted.</td>
</tr>
<tr>
<td>Medical screening</td>
<td>Participants must complete in writing a medical screening form suitable for research in sport science and sports medicine and provide an oral explanation of what participation in a study will entail.</td>
</tr>
<tr>
<td>Consent</td>
<td>Participants should be given a participant information sheet explaining in simple terms the study background, procedures to be used, potential risks and possible benefits to be gained. Participants should be asked to sign a consent form. Appropriate guidelines for referral should also be in place.</td>
</tr>
<tr>
<td>Fainting, collapse, musculoskeletal injury</td>
<td>Researchers should hold current first aid certification or know how to access immediate first aid support including defibrillator equipment.</td>
</tr>
<tr>
<td>Placebo 'treatment'</td>
<td>Subjects will be made aware in advance that they may be randomly assigned to a treatment or a placebo/ control group.</td>
</tr>
<tr>
<td>Participants under the age of 18</td>
<td>Obtain written consent from child and parent or guardian. Separate participant information sheets to be provided for the child and parent or guardian.</td>
</tr>
</tbody>
</table>
Research involving the collection and use of body organs, tissue or fluids.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removal of tissue or body fluids from an individual: What needs to be considered/addressed in the information-consent letter for potential participants?</td>
<td>Information provided to the participant must be explicit about the range of intended uses of the tissue, and consent must be obtained for same</td>
</tr>
<tr>
<td>Risk of needlestick injury and cross infection between participant and researcher during collection of blood samples.</td>
<td>The researcher shall wear gloves. The puncture site should be sterilised before sampling and covered with a sterile swab afterwards. The sample should be collected according to standard procedures. New safety needles and devices should be used for each participant and should be disposed of immediately after use. Hepatitis B vaccination should be recommended to the researcher.</td>
</tr>
<tr>
<td>Storage and disposal of samples</td>
<td>Samples should be stored in appropriate containers, under appropriate conditions for a pre-determined duration. All samples should be disposed of according to Health and Safety guidelines</td>
</tr>
<tr>
<td>Ethical considerations when dealing with human biological material</td>
<td>Consideration should be given to (i) acceptable access to, and use of, the materials; (ii) potential privacy concerns arising from the handling of information derived from such materials; and (iii) the special status some individuals and religious groups accord to the human body and its parts.</td>
</tr>
</tbody>
</table>
| Information/ consent for potential participants.                    | • Specific type and amount of biological materials to be taken from study participants;  
• The manner in which biological materials will be taken and the safety and invasiveness of the procedures for acquisition;  
• The intended uses of the biological materials, including any commercial use;  
• The measures employed to protect the privacy of and minimize risks to participants;  
• The length of time the biological materials will be kept, how they will be preserved, location of storage, and process for disposal, if applicable;  
• Any anticipated linkage of biological materials with information about the participant, if applicable; |
Sample information consent letter should address:

- Right to withdraw the samples (or not) and what will happen to data already obtained or aggregated into the existing analysis;
- Prohibition of financial gain (i.e., researchers will not be able to sell the actual samples obtained for financial gain but may commercialise);
- The researchers’ plan for handling results and findings, including clinically relevant information and incidental findings;
- Rules governing transfer of samples to other laboratories;
- Any anticipated future use of this data for other research objectives (i.e., secondary use of data).

Any specimen(s) [specify type, e.g., tissue, blood, urine] obtained for the purposes of this study will become the property of the researchers/ sponsors and once you have provided the specimens you will not have access to them. They will be kept in [specify where and detail security and privacy controls] for [specify length of time]. The specimen(s) will be discarded or destroyed [and specify how] once they have been used for the purposes described in the protocol.

The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the researchers/sponsor. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.
D. Summary Checklist for Participant Information Sheet.

*Information sheets should make the following points of information explicitly clear to research participants:*

- What exactly the research involves (i.e. purpose and methodology);
- What the participants will be expected to do during the research process (including all known risks however slight associated with their participation);
- The full set of inclusionary and exclusionary criteria for participation in the research;
- What measures will be put in place to deal with any potential risks to participants;
- If the research involves the taking of samples (e.g. blood, tissue etc.), how those samples will be taken, how they will be stored and how and when they will be disposed of.
- The expected benefit/s of the research;
- For what purpose/ purposes the data provided by them will be used;
- Confirmation that the data relating to each participant will be kept only for the purpose/ purposes specified (and that it may be included in future publications where that possibility is envisaged by the researcher);
- Confirmation that data collected will be securely stored and electronic material will be password protected;
- Who will have access to the data and why;
- That all data relating to participants will be kept confidential and anonymity of participants will be preserved (apart from situations where limits of confidentiality and anonymity may apply);
- That any potential limits on confidentiality have been properly explained – (for example in circumstances where information is provided by a participant which must be disclosed to the Gardai and/ or other relevant authorities or where material is subject to a court order/ judicial ruling);
- How long the data will be retained by researcher;
- How the data will be disposed of (so as to preserve confidentiality);
- That participation is entirely voluntary and that participants have a right to a 'cooling off period' (where reasonably practicable) entitling them to a change of mind before commencing participation.
- That participants are otherwise free to withdraw from the research at any time.
- That feedback on research findings will be made available to participants and how this will be achieved.

E. IT Carlow Research Ethics Process
The IT Carlow Research Ethics Committee (REC) has responsibility for ensuring the ethical integrity of all research carried out under its auspices. In carrying out this task, a binary approach is adopted.

**IT Carlow Research Ethics Process**

**Binary System**

- L6-L9 Taught Masters
  - No application to REC
  - Self declaration process
  - Supervised annually by REC

- L9 Research Masters and L 10
  - Application directly to REC for exemption or clearance

**Level 9 Research Masters and Level 10**

For all proposed research to be carried out at Level 9 Research Masters or Level 10, an application must be made directly to the REC prior to commencement for exemption or clearance (see Appendices III and IV).

**Undergraduate and Level 9 Taught Masters**

An application to the REC is NOT required. Research at these levels is governed by the self-declaration of ethical consideration process detailed at Appendix II. The relevant forms in Appendix II shall be completed and signed PRIOR to any research commencing and shall be retained by the lead supervisor. The REC exercises a supervisory function over such research activity and may carry out an audit of compliance with the process at any time during the academic year. The self-declaration form contains three sections: Section A requires basic details of researcher and supervisor. Section B is essentially an ethics screening form. If there are no ethical issues involved in the proposed research (i.e. the answer to all questions on the form is NO) then that form shall be signed by researcher and supervisor and retained by the supervisor for records. In such a case, section C does not need to be filled out.

However, if the answer to any of the questions on section B is YES, then Section C shall also be completed and signed by the researcher, lead supervisor AND an independent second supervisor who certifies that all potential ethical issues in the research have been identified and that adequate control measures are proposed to address same. Sample participant information sheets and informed consent forms to be used in the research must be appended to this form and retained by lead supervisor.

N.B. The self-declaration forms (and associated documentation where required) must be completed and signed PRIOR to commencement of research activity.

**F. References.**
Guidance for Developing Ethical Research Projects Involving Children, published by the Department of Children & Youth Affairs, April 2012

Ethical Guidance for Research with People with Disabilities, published by National Disability Authority of Ireland, 2009 -

Australian National Statement on Ethical Research, published by the Australian Government National Health and Research Council, 2007 -
www.nhmrc.gov.au/guidelines/publications/e72


Children's Research Centre (2006). General Guidelines for Good Research Practice with Children:
http://www.tcd.ie/childrensresearchcentre/assets/pdf/CRC Ethical Doc.pdf


Department of Children and Youth Affairs (2011). Guidance for Developing Ethical Research Projects involving Children:

National Disability Authority (2009). NDA Ethical Guidelines for Disability Research:

National Disability Authority (2009). Ethical Guidance for Research with People with Disabilities:

Richtmer, T (2014). Introduction to the Human Investigation Committee and its processes:
http://www.yalecancercenter.org/research/trials/services/92962_Introduction%20to%20HIC.pdf

The British BERA Charter for Research Staff in Education (2012)

Guidelines for Ethics in Dual-Role Research for Teachers and Other Practitioners (2008)
http://www.uvic.ca/research/assets-old/docs/ors/forms/geidrr.pdf

Guidance for developing ethical research projects involving children.
Research with Children and Young People (2014)
http://ethics.grad.ucl.ac.uk/res_with_children.php

UK Economic and Research Council (ESRC) Framework for Research Ethics 2015
http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/

International Ethical Guidelines for Health-related Research Involving Humans Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) 2016


Children First Act 2015

Assisted Decision-Making (Capacity) Act 2015
Inclusion Ireland: Assisted Decision-Making - What does it mean?
http://www.inclusionireland.ie/sites/default/files/attach/basic-page/991/assisted-decision-making-act-factsheet.pdf <accessed 26th June 2017>
APPENDIX II

UNDERGRADUATE AND LEVEL 9 TAUGHT MASTERS PROGRAMMES
RESEARCH INVOLVING HUMAN PARTICIPANTS

FORM REC 1/L6-8/9T

DECLARATION OF ETHICAL CONSIDERATION
FORM REC 1/L6-8/9T

DECLARATION OF ETHICAL CONSIDERATION

NOTE: This form, (together with sample participant information sheet and sample informed consent form in the case of research to which Section C of this form applies) must be submitted to the supervisor with research proposal prior to commencement of research project.

This form (and additional documentation where Section C applies) shall be retained by the supervisor. The documentation shall be retained to be available for inspection by the REC as required and shall subsequently be attached to the completed research project once submitted for assessment.

In the case of research to which Section C of this form applies, the signature of a second supervisor is required to independently confirm that all relevant ethical issues have been adequately considered and addressed.

Research projects submitted for assessment which have not followed this procedure, shall not be assessed.

Section A

Learner Details:

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<th>Name</th>
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<tr>
<td>Email</td>
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<td>Department</td>
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<td>Year</td>
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<td>Module</td>
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Project Title:

Main Research Supervisor

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<th>Name</th>
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<td>Email</td>
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<tr>
<td>Department</td>
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Section B

TO BE COMPLETED PRIOR TO COMMENCEMENT OF RESEARCH

Does your proposed research project involve (circle as appropriate):

1. A requirement for participant information sheets and receipt of informed consent?
   
   YES ↑  NO↑

2. Management and retention of personal data of participants?
   
   YES ↑  NO↑

3. Vulnerable groups (e.g. children, prisoners, individuals who require assisted living or individuals for whom English is not the primary language)
   
   YES ↑  NO↑

4. Sensitive topics that may make subjects uncomfortable (e.g. sexual behaviour, illegal activities, racial bias or religious affiliation)
   
   YES ↑  NO↑

5. Use of Drugs
   
   YES ↑  NO↑

6. Invasive procedures (e.g. blood or tissue sampling)
   
   YES ↑  NO↑

7. Physical stress or discomfort
   
   YES ↑  NO↑

8. Psychological distress
   
   YES ↑  NO↑

9. Deception of, or withholding information from subjects
   
   YES ↑  NO↑

10. Access to data by individuals or organisations other than the researcher
    
    YES ↑  NO↑

11. Any conflict of interest relating to or arising from the research project
    
    YES ↑  NO↑

12. Any ethical dilemma relating to or arising from the research project.
If the answer to all of the above is NO, please sign this form and include it in your final project/thesis/dissertation.

If the answer to any of the above questions is YES, please proceed to complete Section C.

<table>
<thead>
<tr>
<th>Learner Signature</th>
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<tr>
<td>Date</td>
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<tr>
<td>Main Supervisor Signature</td>
<td></td>
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<tr>
<td>Date</td>
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</tbody>
</table>
Section C

To be completed PRIOR TO COMMENCEMENT OF RESEARCH where you do not qualify for an exemption under section B.

Please declare that the following control measures will be implemented in the case of your research thesis/ project/ dissertation:

I have assessed, identified and can demonstrate within the attachments to this document the potential risks associated with my research.

I confirm that the dignity and respect for participants will be adhered to at all times.

I confirm that I will communicate effectively to all potential participants that their participation in the research is voluntary and that all participants have the right to withdraw at any time

I have carefully considered the potential physical, psychological and emotional impact of my research on participants and will put in place appropriate safeguards in place to protect, support and minimise risk to those participating in the project

Where risks to the well-being of participants becomes apparent during the course of my research, where such risks were not foreseen at planning stage and/ or commencement of my research, I will immediately put appropriate safeguards in place to minimise such risks. (Details/ Examples/ Evidence of such safeguards shall be set out in an appendix to my completed project/thesis/dissertation)

I will not offer incentives to my research participants.

My methods are respectful and designed to fully consider the needs and vulnerabilities of my participants.

Every effort will be made to obtain full, voluntary and informed consent from all participants (including where appropriate, parents/ guardians/ gatekeepers)

I will provide a detailed information sheet to all participants. The information provided makes each of the following explicitly clear:

- What exactly the research involves (i.e. purpose and methodology);
- What the participants will be expected to do during the research process (including all known risks however slight associated with participation);
- The full set of inclusionary and exclusionary criteria for participation in the research
- What measures will be put in place to deal with any potential risks to participants;
- If the research involves the taking of samples (e.g. blood, tissue etc.), how those samples will be taken, how they will be stored and how and when they will be disposed of.
- The expected benefit/s of the research;
• For what purpose/purposes the data provided by them will be used;

• That the data relating to each participant will be kept only for the purpose/purposes specified (and that it may be included in future publications where that possibility is envisaged by the researcher);

• That data collected will be securely stored and electronic material will be password protected;

• Who will have access to the data and why;

• That all data relating to participants will be kept confidential and anonymity of participants will be preserved (apart from situations where limits of confidentiality and anonymity may apply);

• That any potential limits on confidentiality have been properly explained (for example in circumstances where information is provided by a participant which must be disclosed to the Gardai and/or other relevant authorities or where material is subject to a court order/judicial ruling);

• How long the data will be retained by researcher;

• How the data will be disposed of (so as to preserve confidentiality);

• That participation is entirely voluntary and that participants have a right to a ’cooling off period’ (where reasonably practicable) entitling them to a change of mind before commencing participation.

• That participants are otherwise free to withdraw from the research at any time.

• That feedback on research findings will be made available to participants and how this will be achieved.

I confirm that the information sheet detailing all of the above will be provided to the participants, (including, where appropriate parents/guardians/gatekeepers), and that it is drafted, in terms of the language used, in a manner that is appropriate to the participants involved

I have included a copy of the Participant Information Sheet I will use at Appendix I of this form

I have also included a copy of the template Informed Consent Form to be signed by participants at Appendix II of this form.

I confirm that I have read the IT Carlow Policy on Ethics in Research and the IT Carlow Guidelines on Research involving Human Participants prior to completion of this form.
Learner Declaration:

I hereby declare that the above measures have been taken by me in respect of my proposed research thesis/project/dissertation.

I understand that failure to comply with the above shall constitute a breach of the Institute’s policies and procedures regarding research conduct and ethics in research.

Learner Signature: __________________________________________

Date: ______________________________________________________

Supervisor 1 Declaration:

I declare that I have discussed with the learner the ethical considerations surrounding his/her proposed research and the operation of the control measures indicated above.

Supervisor Name (Printed): _________________________________

Supervisor Signature: ______________________________________

Date: ______________________________________________________

Supervisor 2 Declaration:

I declare that I have reviewed the documentation submitted and that all relevant ethical issues in the proposed research have been adequately considered and addressed.

Supervisor Name (Printed): _________________________________

Supervisor Signature: ______________________________________

Date: ______________________________________________________

PLEASE APPEND THE FOLLOWING TO THIS FORM

Appendix I

Sample Participant Information Sheet to be provided to participants

Appendix II

Sample Informed Consent Form/s to be signed by participants
APPENDIX III

LEVEL 9 RESEARCH MASTERS AND LEVEL 10 RESEARCH

Application to the IT Carlow Research Ethics Committee for

Ethical Exemption of a Research Project

(REC1 L9R/ L10)

Applicants are advised to submit any supporting documentation they may feel is relevant to support their application for Ethical Exemption for their research proposal.

When filling in applications for exemption or for ethical review please ensure that:

- All relevant sections are completed in typed text;
- All responses are placed within the spaces allocated;
- Bold type is not used;
- All sections are completed. Where a section or a question is not relevant to the proposed research project this should be indicated by entering N/A in the relevant section. Sections should not be left blank;
- Applicants shall ensure that responses to questions are not cross referenced to previous answers on the form. For example an answer which states “see above” or “see answer to question 3” is not an adequate response and a form bearing such a response shall be returned for satisfactory completion.
- Jargon or unexplained abbreviation is not used;
- All technical terms are explained in clear terms;
- All technical procedures are adequately described to enable assessors to determine the ethical implications of the proposed research project.

Application for ethical review exemption or for ethical clearance is an essential element in any research project. It represents a clear articulation of the research project, its methods, aims, objectives and outputs. Completed forms should be submitted (in the first instant) to the Head of Department or Faculty/Campus (or a designated staff member) for initial screening and endorsement. Forms which have not been completed satisfactorily or which are unclear or ambiguous shall be returned and shall not be tabled before the Research Ethics Committee for consideration.

Applicant Details

A.1 Researcher Details:
Name: ____________________________
Email: ____________________________
Telephone: _________________________

A.2 Principal Investigator / Research Supervisor(s):
Name: ____________________________
Email: ____________________________
Telephone: _________________________

A.3 Additional Expertise (if applicable)
Name: ____________________________
Email: ____________________________
Telephone: _________________________

A.4 Does this research form part of a programme of study? □ Yes □ No
If yes – please give details

A.5 I confirm that I have read and understood the following IT Carlow Policies:

Ethics Policy □ Yes □ No
Ethics Procedures and Guidance notes □ Yes □ No
On completing this form □ Yes □ No
Data Protection Policy □ Yes □ No
Anti-Plagiarism Policy □ Yes □ No
A. Research Proposal

B.1 Title of the proposed research project

B.2 To what extent has this topic already been researched and written about (e.g. is there a significant body of existing published work)?

B.3 From that, describe how this proposed research is contributing to what is known about the topic

B.4 Provide a brief description of research *(not more than 200 words in any section)*

a. The aims and objectives

b. The research design

(Note: This section can include an overview of methodology research design proposals regarding for example, evaluation and data gathering. In describing the research design, applicants are required to explain the reasoning behind their choice of method)

c. The size and composition of sample

d. Describe how the information is gathered and stored

e. Please state the location(s) the proposed research is to be conducted

f. The proposed starting date of research/study

B.5 Please list the investigators (including assistants) who will conduct the research. Please provide details of their qualifications and experience

B.6 Does this research proposal require any other form of Third Party Authority approval (e.g. licensing approval or access permission)? – If so please provide details of these and append copies where available
B.7 Outline the reasons that have led you to identify the proposal as qualifying for exemption from Ethical Approval.

Signed: ____________________________  Date: _________________
Researcher

Signed: ____________________________  Date: _________________
Principal Investigator
Supervisor)

REVIEWER COMMENT IF APPLICABLE FROM HEAD OF DEPARTMENT/ GROUP/ CORE/ INSTITUTE/ FACULTY/CAMPUS

Signed: ____________________________  Date: _________________
(Head of Department/Group/CORE/Institute/Faculty/Campus)
APPENDIX IV

LEVEL 9 RESEARCH MASTERS AND LEVEL 10 RESEARCH

APPLICATION FOR ETHICAL CLEARANCE FOR A RESEARCH PROJECT
(FORM REC2-L9(R)/L10)

Completing Forms

When filling in applications for exemption or for ethical review please ensure that:

- All relevant sections are completed in typed text;
- All responses are placed within the spaces allocated;
- Bold type is not used;
- All sections are completed. Where a section or a question is not relevant to the proposed research project this should be indicated by entering N/A in the relevant section. Sections should not be left blank;
- Applicants shall ensure that responses to questions are not cross referenced to previous answers on the form. For example an answer which states “see above” or “see answer to question 3” is not an adequate response and a form bearing such a response shall be returned for satisfactory completion.
- Jargon or unexplained abbreviation is not used;
- All technical terms are explained in clear terms;
- All technical procedures are adequately described to enable assessors to determine the ethical implications of the proposed research project.

Application for ethical review exemption or for ethical clearance is an essential element in any research project. It represents a clear articulation of the research project, its methods, aims, objectives and outputs. Completed forms should be submitted (in the first instant) to the Head of Department or Faculty/Campus (or a designated staff member) for initial screening and endorsement. Forms which have not been completed satisfactorily or which are unclear or ambiguous shall be returned and shall not be tabled before the Ethics Committee for consideration.
Application to the IT Carlow Research Ethics Committee for
Ethical Approval of a Research Project involving Human Participants or
samples donated by Human Participants (e.g. tissue or blood samples)
(FORM REC2-L9(R)/ L10)

Applicants are advised to submit any supporting documentation they may feel is
relevant to their research proposal (e.g. sample interview schedules, consent forms,
third party licenses or ethical approvals).

A. Applicant Details
A.1 Researcher Details:
Name: ______________________________
Email: ______________________________
Telephone: __________________________

A.2 Principal Investigator / Research Supervisor(s):
Name: ______________________________
Email: ______________________________
Telephone: __________________________

A.3 Additional Expertise (if applicable)
Name: ______________________________
Email: ______________________________
Telephone: __________________________
A.4  Does this research form part of a programme of study?  
☐ Yes  ☐ No
If yes – please give details

A.5  I confirm that I have read and understood the following IT Carlow Policies:
Ethics Policy  ☐ Yes  ☐ No
Ethics Procedures and Guidance notes
On completing this form  ☐ Yes  ☐ No
Data Protection Policy  ☐ Yes  ☐ No
Anti-Plagiarism Policy  ☐ Yes  ☐ No
B. Research Proposal

B.1 Title of the proposed research project

B.2 To what extent has this topic already been researched and written about (e.g. is there a significant body of existing published work)?

B.3 From that, describe how this proposed research is contributing to what is known about the topic

B.4 Provide a brief description of research *(not more than 200 words in any section)*

a) The aims and objectives

b) The research design

(Note: This section can include an overview of methodology research design proposals regarding for example, evaluation and data gathering. In describing the research design, applicants are required to explain the reasoning behind their choice of method)

c) The size and composition of sample

d) The method of how participants are expected to be selected, approached and recruited in conducting this proposed research?

(Note: The process of participant selection is required to be outlined clearly. If for example, participants are being contacted through an organisation, e.g. Faculty/Campus, an initial step would be to seek permission from the organisation to approach the participants. Any inclusion or exclusion criteria must also be specified.)

e) Describe the procedures that will be adopted to maintain the confidentiality of research subject(s).

f) Will any member of the intended group of research subjects, to your knowledge, be involved in other research projects or activities? If so, please give details and explain the nature of the engagement with other projects.

g) Describe how the information is gathered, stored, handled and anonymised.

h) Please state how long participant data is to be retained for before being destroyed and the proposed method of destruction.
i) If your research involves the taking of samples (e.g. blood, tissue etc.), please state clearly exactly how this is to be performed, how those samples will be stored, how and when they will be disposed of.

j) Please state whether participants are to be given the opportunity to access the results of the research and how this will be achieved.

k) Please state the location(s) the proposed research is to be conducted

l) The proposed starting date of research/ study

B.5 Has this research proposal received ethical approval from any other body? – if so please provide details.

B.6 Does this proposed research require licensing approval? – if so please provide details of licenses obtained.

B.7 Describe the research procedures as they affect the research subject and any other parties involved.

B.8 Describe (a) the ethical considerations of this proposal and (b) the steps to be taken to address these.

B.9 Please list the investigators (including assistants) who will conduct the research. Please provide details of their qualifications and experience

B.10 Are arrangements for the provision of clinical facilities to handle emergencies necessary? If so, briefly describe the arrangements made.

B.11 Specify whether research subjects include learners or others in a dependent relationship.

B.12 Specify whether the research will include primary respondents such as children, individuals with mental health issues, individuals deemed to be of diminished responsibility, individuals with a physical or intellectual disability. If so, please explain the rational for accessing these subjects for the proposed research. Please indicate alternative measures investigated to avoid the necessity for direct access to these primary respondents.
B.13 Please confirm that no payment will be made to any research subject.

B.14 Describe the procedures to be used in obtaining a valid consent from the subject. Please supply a copy of the information sheet provided to the individual subject(s).

B.15 Please indicate if there are any cultural, social, gender-based characteristics or sexual orientation, practices or behaviour of the subject(s) which have affected the design of the project or which may affect its outcomes.

Signed: ____________________________  Date:________________
Researcher

Signed: ____________________________  Date:________________
(Principal Investigator
Supervisor)

REVIEWER COMMENT IF APPLICABLE FROM HEAD OF DEPARTMENT/GROUP/
INSTITUTE/FACULTY/CAMPUS

Signed: ____________________________  Date:________________
(Head of Department/Group/CORE/Institute/Faculty/Campus)
APPENDIX V, ANNEX A:
TEMPLATE FOR ANONYMOUS SURVEY

DATE

TITLE OF RESEARCH STUDY
(The title may need to be shortened. The title does not have to appear in a cover letter, but it should appear at the beginning of the questionnaire.)

You are being invited to participate in a research study about explain the study’s purpose in a few words. This study is being conducted by insert name of Researcher and name of Principal Investigator / Research Supervisor (if Researcher is a learner), from the insert department affiliation at Institute of Technology Carlow (herein referred to as IT Carlow). If Researcher is a learner, indicate that the study is being conducted as part of an undergraduate project, graduate learner project, thesis, or dissertation. If funded, identify the funding agency.

OPTIONAL: You were selected as a possible participant in this study because explain succinctly and simply why the prospective subject is eligible to participate, if applicable.

There are no known risks if you decide to participate in this research study. There are no costs to you for participating in the study. The information you provide will briefly explain what the information is being used for. The questionnaire will take about indicate approximate amount of time to complete. The information collected may not benefit you directly, but the information learned in this study should provide more general benefits.

This survey is anonymous. Do not write your name on the survey. If this is a web-based survey, indicate how you will provide anonymity (e.g., not collect addresses). Also, indicate that absolute anonymity cannot be guaranteed over the Internet. No one will be able to identify you or your answers, and no one will know whether or not you participated in the study. Individuals from give name of the funding agency, if any, and the Institutional Review Board may inspect these records. Should the data be published, no individual information will be disclosed.

Your participation in this study is voluntary. By completing and doing whatever the respondent should do with the completed survey (e.g. post, email, put in a box in a specific location), you are voluntarily agreeing to participate. You are free to decline to answer any particular question you do not wish to answer for any reason.

If you have any questions about the study, please contact Name, mailing address, phone number, and email address of the Researcher (and supervisor if Researcher is a learner).

IT Carlow’s Research Ethics Committee has reviewed and approved my request to conduct this project. If you have any concerns about your rights in this study, please contact the Chair of the Research Ethics Committee.
APPENDIX V, ANNEX B:

EXAMPLE CONSENT FOR ANONYMOUS SURVEY

RESEARCH PROJECT TITLE

DATE

You are being invited to participate in a research study about (e.g.) employee turnover. This research project is being conducted by Dr. Name Surname of Institute of Technology Carlow and is funded by the Department of Jobs, Enterprise and Innovation. The objective of this research project is to attempt to understand why people leave their jobs. It is being conducted in over 20 companies throughout Ireland. The survey is being given to current and former employees of all of these companies.

There are no known risks if you decide to participate in this research study, nor are there any costs for participating in the study. The information you provide will help to understand how best to satisfy the needs of organisations and the needs of employees. The information collected may not benefit you directly, but what will be learned from this study should provide general benefits to employees, companies, and researchers.

This survey is anonymous. If you choose to participate, do not write your name on the questionnaire. No one will be able to identify you, nor will anyone be able to determine which company you work for. No one will know whether you participated in this study. Nothing you say on the questionnaire will in any way influence your present or future employment with your company.

Your participation in this study is voluntary. If you choose to participate, please email the survey to name.surname@itcarlow.ie, or alternatively post it to: Dr. Name Surname, Department of ______, IT Carlow, Kilkenny Road, Co. Carlow.

If you have any questions or concerns about completing the questionnaire or about being in this study, you may contact me, Name Surname at (059) 000000 or at name.surname@itcarlow.ie

IT Carlow’s Research Ethics Committee has reviewed and approved my request to conduct this project. If you have any concerns about your rights in this study, please contact the Chair of Research Ethics Committee at chairofethicscommitte@itcarlow.ie
APPENDIX V, ANNEX C:
EXAMPLE COVER LETTER FOR ANONYMOUS SURVEY

DATE

Dear Respondent,

I am a research supervisor at the Department of _________ at the Institute of Technology Carlow and I am conducting a study of employee turnover in over 20 large companies in Ireland. This research project is funded by the Department of Jobs, Enterprise and Innovation. The objective of this research project is to attempt to understand why people leave their jobs. Through your participation, it is expected to arrive at a better understanding of how best to satisfy the needs of organisations and the needs of employees.

Enclosed with this letter is a brief questionnaire that asks a variety of questions about your attitudes toward your current job. I am asking you to look over the questionnaire and, if you choose to do so, complete the questionnaire and send it back to me in the enclosed postage-paid envelope.

If you choose to participate, do not write your name on the questionnaire. I do not need to know who you are and no one will know whether you participated in this study. Your responses will not be identified with you personally, nor will anyone be able to determine which company you work for. Nothing you say on the questionnaire will in any way influence your present or future employment with your company.

I hope you will take a few minutes to complete this questionnaire. Without the help of people like you, research of this nature cannot be conducted. Your participation is voluntary and there is no penalty if you do not participate.

If you have any questions or concerns about completing the questionnaire or about being in this study, you may contact me, Name Surname at (059) 000000 or at name.surname@itcarlow.ie. If you have any concerns about your rights within this study, please contact the Chair of the Research Ethics Committee, Institute of Technology Carlow, Kilkenny Road, Carlow, by phone at (059) 000000, or by email at chairofethicscommittee@itcarlow.ie. This study was approved by the Research Ethics Committee on Date

Yours Faithfully

Name Surname
APPENDIX V ANNEX D:
INFORMED CONSENT TEMPLATE FOR RESEARCH INVOLVING GREATER THAN MINIMAL RISK OR WHERE SUBJECTS ARE NOT ANONYMOUS

CONSENT TO PARTICIPATE IN RESEARCH

Title or paraphrased title of the study

You are being invited to participate in a research study about explain the study’s purpose in a few words. This study is being conducted by insert name of Researcher and name of Principal Investigator / Research Supervisor (if Researcher is a learner), from the insert department affiliation at Institute of Technology Carlow (herein referred to as IT Carlow). If the Researcher is a learner, indicate that the study is being conducted as part of an undergraduate project, graduate learner project, thesis, or dissertation. If funded, identify the funding agency.

Your participation in this study is entirely voluntary. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

OPTIONAL: You have been asked to participate in this study because explain succinctly and simply why the prospective subject is eligible to participate. If appropriate, state the approximate number of subjects involved in the study. State whether there are inclusion or exclusion criteria for participation (e.g., medical conditions that would include or exclude a person).

• PURPOSE OF THE STUDY

Briefly state what the study is designed to examine, assess, or establish.

• PROCEDURES

If you volunteer to participate in this study, you will be asked to do the following things:

Describe the procedures chronologically using simple language, short sentences, and short paragraphs. If there are several procedures or if they are complex, the use of subheadings may help organise this section and increase readability.

Define and explain scientific or discipline-specific terms. Use language appropriate to the reader population.
If applicable, specify the subject’s assignment to study groups, length of time for participation in each procedure or study activity, the total length of time for participation, frequency of procedures and location of the procedures to be done.

If subjects will be recorded (audio, video, digitally), describe the procedures to be used.

If any study procedures are experimental, clearly identify which ones.

- **POTENTIAL RISKS AND DISCOMFORTS**

Describe any reasonable foreseeable risks or discomforts, including physical inconveniences and their likelihood, and explain how these will be managed. In addition to physiological risks/discomforts, describe any reasonably foreseeable psychological, social, legal, or financial risks or harms that might result from participating in the research.

If there are circumstances in which the researcher may terminate the study, describe them. (This refers to situations in which the study itself may be terminated. It is not the same thing as circumstances in which a specific subject may be withdrawn; this issue is to be discussed below, if relevant.)

In the event of physical and/or mental injury resulting from participation in this research project, IT Carlow does not provide any medical, hospitalisation or other insurance for participants in this research study, nor will IT Carlow provide any medical treatment or compensation for any injury sustained as a result of participation in this research study, except as required by law.

- **POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY**

Describe benefits to subjects expected from the research. If the subject will not benefit directly from participation, clearly state this fact.

State the potential benefits, if any, to science or society expected from the research.

**FOR BIOMEDICAL STUDIES ONLY – Include the following paragraph, if relevant**

Based on experience with this drug, procedure, device, etc. in animals, patients with similar disorders, researchers believe it may be of benefit to subjects with your condition or, it may be as good as standard therapy but with fewer side effects. Of course, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. The potential benefits may include: describe the anticipated benefits to subjects resulting from their participation in the research.

If there is no likelihood that participants will benefit directly from their participation in the research, state in clear terms. For example: “You should not expect your condition to improve as a result of participating in this research” or “This study is not being conducted to improve your condition or health. You have the right to refuse to participate in this study.”

- **CONFIDENTIALITY**

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc.
If information will be released to any other party for any reason, state the person or agency to whom the information will be furnished, the nature of the information, the purpose of the disclosure, and the conditions under which it will be released.

If activities are to be audio, video or digitally recorded, describe who will have access, if the tapes/files will be used for educational purposes, and when they will be erased or destroyed.

If a subject form is used, ADD “In case of an emergency, injury, or illness that occurs during this study, I hereby authorise the release of any and all health information to allow for medical care and treatment of my condition.”

- PARTICIPATION AND WITHDRAWAL

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or penalty.

*Include the following paragraph in this section only if relevant*

The investigator may withdraw you from this research if circumstances arise which warrant doing so. Describe the anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject's consent.

**FOR BIOMEDICAL STUDIES ONLY, ADD THE FOLLOWING SECTION HERE**

- ALTERNATIVES TO PARTICIPATION (if applicable)

Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether to participate in the study. If applicable, explain why these procedures are being withheld. If there are no efficacious alternatives, state that an alternative is not to participate in the study.

- IDENTIFICATION OF INVESTIGATORS

If you have any questions about the study, please contact Name, mailing address, phone number, and email address of the Researcher (and supervisor if Researcher is a learner).

*For some studies of greater than minimal risk, it may be necessary to include night/emergency phone numbers.*
• RIGHTS OF RESEARCH SUBJECTS

IT Carlow’s Research Ethics Committee has reviewed and approved my request to conduct this project. If you have any concerns about your rights in this study, please contact the Chair of the Research Ethics Committee.

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

________________________________________
Printed Name of Subject

________________________________________
Signature of Subject Date

________________________________________
Signature of Witness Date
APPENDIX V, ANNEX E:
EXAMPLE OF INFORMED CONSENT DOCUMENT FOR RESEARCH INVOLVING GREATER THAN MINIMAL RISK OR IN WHICH SUBJECTS ARE NOT ANONYMOUS

CONSENT TO PARTICIPATE IN RESEARCH

___________ Programme Study

You are invited to participate in a research study conducted by NAME SURNAME, who is a research learner attached to the Department of Name of Department at Institute of Technology Carlow. Name Surname is conducting this study for a Masters/ Doctoral dissertation. Dr. Supervisor Name is the Principal Investigator/ Supervisor for this project. This study is being funded by the Department of Jobs, Enterprise and Innovation.

Your participation in this study is entirely voluntary. You should read the information below and ask questions about anything you do not understand, before deciding whether or not to participate. You are being asked to participate in this study because you are (Provide rationale for selection)

● PURPOSE OF THE STUDY

The purpose of this study is to see how well the __________ Programme is working to help people with (e.g.) physical disabilities learn everyday skills. It is intended to use what we learn from the study to make changes and enhancements to the programme

● PROCEDURES

If you volunteer to participate in this study, we will ask you to do the following:

1. We will ask you to take part in 2 to 4 tasks over the course of a total of about a 3 week period of time.
2. These tasks may include: (1) keeping a diary (to be explained by the researcher), (2) answering questions about what you know, your attitudes toward things, and your behavior; (3) keeping a list of your daily activities; and (4) answering questions about things you have learned in the programme.
3. Sometimes the researchers will observe you while you take part in your activities at the centre.
4. Some activities may be videotaped. The video recorder will be placed in the corner of the day room and will be operated by one of the researchers.
5. We will ask your permission to obtain a list of medications (and dosages) you are currently taking while in the ______________ Programme.
• POTENTIAL RISKS AND DISCOMFORTS

We expect that any risks, discomforts, or inconveniences will be minor and we believe that they are not likely to happen. If discomforts become a problem you can discontinue your participation at any time.

• POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY

It is not likely that you will benefit directly from participation in this study, but the research should help us learn how to improve services for people with physical disabilities who have recently been discharged from hospital for physical or occupational therapy and other assistance before moving to their own home.

This study does not include procedures that will improve your physical disability or general health.

• COMPENSATION FOR PARTICIPATION

You will not receive any payment or other compensation for participation in this study. There is also no cost to you for participation.

• CONFIDENTIALITY

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of a code number for identification purposes for the researcher (NAME) and the supervisor (NAME). We will not use names or any other means of identification that may lead to an individual being identified in any of the information we get from this study or in any of the research reports.

Information that can identify you individually will not be released to anyone unconnected with the study. The researcher will, however, use the information collected in a dissertation and other publications. We also may use any information that we get from this study in any way we think is best for publication or education. Any information we use for publication will not identify you individually.

Any audio or video recording that we make will not be viewed by anyone unconnected with the study unless we obtain your written permission. The recordings will be retained/destroyed in line with IT Carlow’s Data Protection and Freedom of Information Policies & Procedures. These policies are publicly available on the IT Carlow website.

In case of an emergency, injury, or illness that occurs during this study, I hereby authorise the release of any and all health information to allow for medical care and treatment of my condition.

• PARTICIPATION AND WITHDRAWAL

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you do not want to answer. There is no penalty if you withdraw from the study and
you will not lose any benefits to which you are otherwise entitled. The investigator may withdraw you from this research if your medical advice is that continued participation may injure your health.

- **IDENTIFICATION OF INVESTIGATORS**

If you have any questions or concerns about the research, please feel free to contact

Name Surname          Dr. Name Surname
Researcher            Head of Department/ Supervisor
Department of         Department of
Institute of Technology Carlow Institute of Technology Carlow
name.surname@itcarlow.ie name.surname@itcarlow.ie
Tel: (059) 000000      Tel: (059) 000000

- **RIGHTS OF RESEARCH SUBJECTS**

IT Carlow’s Research Ethics Committee has reviewed my request to conduct this project and the research proposal was approved by the Research Ethics Committee on DATE

If you have any questions or concerns about being in this study, you may contact me, Name Surname at (059) 000000 or name.surname@itcarlow.ie. Alternatively, you can contact Dr. Name Surname at (059) 000000 or at name.surname@itcarlow.ie. If you have any concerns about your rights in this study, please contact the Chair of the Research Ethics Committee, Institute of Technology Carlow, Kilkenny Road, Carlow, by phone at (059) 000000, or by email at chairofethicscommittee@itcarlow.ie.

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

________________________________________
Printed Name of Subject

________________________________________
Signature of Subject

Date

________________________________________
Signature of Witness

Date
APPENDIX V, ANNEX F:
TEMPLATE FOR PARENTAL PERMISSION LETTER

Date

Dear Parent or Guardian:

I am a member of staff, research learner, learner, etc. in the enter department at Institute of Technology Carlow. I am conducting a research project on briefly, in a few words, describe study. I am writing to request permission for your child to participate in this study.

The study consists of describe what you will ask the child do to. If you will look at Faculty/Campus or other records, mention this here. The project will be explained in terms that your child can understand, and your child will participate only if he or she is willing to do so. Only I and members of the research staff, if any will have access to information from your child. At the conclusion of the study, children’s responses will be reported as group results only. If study results will be made available to parents, include a statement similar to the following: At the conclusion of the study a summary of group results will be made available to all interested parents.” Then explain what the parent needs to do to obtain a copy of the results.

Participation in this study is voluntary. Your decision whether or not to allow your child to participate will not affect the services normally provided to your child by the entity where research is being conducted (e.g., Faculty/Campus, hospital). Your child’s participation in this study will not lead to the loss of any benefits to which he or she is otherwise entitled. Even if you give your permission for your child to participate, your child is free to refuse to participate. If your child agrees to participate, he or she is free to end participation at any time, as are you on your child’s behalf. You and your child are not waiving any legal claims, rights, or remedies because of your child’s participation in this research study.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc.

If information will be released to any other party for any reason, state the person or agency to whom the information will be furnished, the nature of the information, the purpose of the disclosure, and the conditions under which it will be released.

If activities are to be audio, video or digitally recorded, describe who will have access to material, if it is intended that the tapes/ files will be used for educational purposes, and when they will be erased or destroyed.

If there is an expectation of a learner completing an assignment, mention it will not affect any grade received for completing the assignment by not participating in the study.

Should you have any questions or desire further information, please call me or email me at office phone and email address. If this is a learner project, also include the name and contact...
information of a supervising member of staff. Keep this letter after tearing off (if this is to be done) and completing the bottom portion (state how the parent is to return the signed consent form).

If you have any questions or concerns about being in this study, you may contact me, Name Surname at (059) 000000 or name.surname@itcarlow.ie. Alternatively, you can contact Dr. Name Surname at (059) 000000 or at name.surname@itcarlow.ie. If you have any concerns about your rights in this study, please contact the Chair of the Research Ethics Committee, Institute of Technology Carlow, Kilkenny Road, Carlow, by phone at (059) 000000, or by email chairofethicscommittee@itcarlow.ie.

Yours Faithfully,

Researcher signature,  
Name and affiliation

---------------------------------------------------------------------------------------------------------------------------

Please indicate whether or not you wish to allow your child to participate in this project by selecting one of the statements below, signing your name and (state how the parent is to return the letter). You should sign both copies and retain one for your own records.

_____ I grant permission for my child to participate in Name of Researcher’s study on brief description of study.

_____ I do not grant permission for my child to participate in Name of Researcher’s study on brief description of study.

____________________  __________  ______________________________  ______________________________
Signature of Parent/Guardian  Printed Parent/Guardian Name

____________________  __________  ______________________________  ______________________________
Printed Name of Child  Date
APPENDIX V, ANNEX G:
EXAMPLE PARENTAL PERMISSION LETTER

DATE

Dear Parent or Guardian:

My name is Name Surname, a research learner being supervised by Dr. Name Surname of the Department of ______ at the Institute of Technology, Carlow. I am writing to request permission for your child to participate in a research study to be used for my Masters/ Doctoral dissertation. I am conducting a research project on how well the ________ Programme helps children with physical disabilities learn everyday skills.

It is intended that what is learned from the study will contribute to changes and enhancements to the programme.

The study consists of the following activities:

1. We are asking your permission for your child to take part in 2 to 4 tasks over the course of a total of about 3 weeks. Each task will last about 30 minutes to 1 hour.
2. These tasks may include: (i) answering questions about what your child has learned while on the programme, how your child feels about being part of the programme, and your child’s behavior and (ii) answering short questionnaires on things your child has learned in the programme.
3. Sometimes the researcher will observe your child while he or she takes part in activities at the centre.
4. Some activities may be audio or video recorded. The recording device will be placed in the day room and will be operated by the researcher.
5. We will ask your permission to obtain a list of medications (and dosages) your child is currently taking while on the ________ Programme. We will not require, or have access to, your child’s medical records.

The project will be explained in terms that your child can understand, and your child will participate only if he or she is willing to do so.

Only Dr. Surname (the research supervisor) and I will have access to information from your child. At the conclusion of the study, children’s responses will be reported as group results only. At the conclusion of the study a summary of group results will be made available to all interested parents. Please indicate at the end of this consent form whether you wish to have these summary results. If so, please provide your mailing address. If you do not wish to provide your mailing address, you may obtain the results from the Internet at www.itcarlow.ie/researchresults/summary.

Participation in this study is voluntary. Your decision as to whether or not you allow your child to participate will not affect the services normally provided to your child by the ________ Programme and your child will lose no benefits to which he or she is otherwise entitled. Even if you give your permission for your child to participate, your child is free to refuse to participate. If your child agrees to participate, he or she is free to end participation at any time. You and/
or your child are not waiving any legal claims, rights, or remedies because of your child's participation in this research study.

Should you have any questions or require further information, please feel free to contact

Name Surname
Researcher
Department of
Institute of Technology Carlow
name.surname@itcarlow.ie
Tel: (059) 000000

Dr. Name Surname
Head of Department/ Supervisor
Department of
Institute of Technology Carlow
name.surname@itcarlow.ie
Tel: (059) 000000

Keep this letter after completing and returning the signature page to me.

If at any stage you have any questions or concerns about being in this study, you may contact me, Name Surname at (059) 000000 or name.surname@itcarlow.ie. Alternatively, you can contact Dr. Name Surname at (059) 000000 or at name.surname@itcarlow.ie. If you have any concerns about your rights in this study, please contact the Chair of the Research Ethics Committee, Institute of Technology Carlow, Kilkenny Road, Carlow, by phone at (059) 000000, or by email at chairofethicscommittee@itcarlow.ie.

SIGNATURE

Department of

________________________________________________________

Please indicate whether or not you wish to allow your child to participate in this project by selecting one of the statements below, signing your name and returning it to me. Sign both copies and keep one for your own records.

_____ I do grant permission for my child to participate in Name Surname's study of the Transitional Living Programme.

_____ I do not grant permission for my child to participate in Name Surname's study of the Transitional Living Programme.

________________________________________________________

Signature of Parent/Guardian

________________________________________________________

Printed Parent/Guardian Name

________________________________________________________

Printed Name of Child

________________________________________________________

Date

_____ Yes, I confirm that I would like a copy of the summary results of this study. My mailing address is below.
APPENDIX V, ANNEX H:
TEMPLATE FOR CHILD ASSENT FORM

ASSENT TO PARTICIPATE IN RESEARCH

Insert title of the study, using language understandable to the children in the study.

1. My name is identify yourself to the child by name/enter your name here. I am from the Institute of Technology Carlow.

2. We are asking you to take part in a research study because we are trying to learn more about - in a sentence or two, outline what the study is about in language that is both appropriate to the child’s maturity and age

3. If you agree to be in this study describe what you will ask the child to do, in language that is both appropriate to the child’s maturity and age

4. If you don’t want to be in this study, you don’t have to participate. Remember, being in this study is up to you and no one will be upset if you don’t want to participate or even if you change your mind later and want to stop. If there is an expectation of a learner completing an assignment, mention it will not affect any grade received for completing the assignment by not participating in the study.

5. At all times and at every point, we will keep your parents informed about the study.

6. You can ask any questions that you have about the study. If you have a question later that you didn’t think of now, you can call me insert your telephone number or ask me next time. You may call me at any time to ask questions about your condition or treatment. [Alternative wording may be more appropriate, depending on the study procedures]

7. Please talk this over with your parents before you decide whether or not to participate. (This statement may be omitted for anonymous surveys of older children.) Your parents have given their permission for you to take part in this study. Even though your parents said “yes,” you can still decide not to do this.

8. Signing your name at the bottom means that you agree to be in this study. If the study is related to treatment insert the following: Your doctors will continue to treat you whether or not you participate in this study. You and your parents will be given a copy of this form after you have signed it.
Include the following, if a signature is to be obtained.

________________________________________
Signature of Subject or
Signature of consent of Parent/ Guardian on behalf of Subject (if the subject is unable to sign themselves)

________________________________________
Printed Name of Subject
Date

________________________________________
Printed Name of Witness
Date

________________________________________
Signature of Witness
This signature confirms that the purpose of the study has been explained to the subject in an appropriate manner to ensure the subject understood what was expected of them.
APPENDIX V, ANNEX I:
EXAMPLE OF CHILD ASSENT FORM

ASSENT TO PARTICIPATE IN RESEARCH

Study of the _______ Programme

1. My name is Name Surname and I am a research learner at the Institute of Technology, Carlow.

2. My supervisor, Dr. Name Surname, and I are asking you to take part in a research study because we are trying to learn more about __________.

3. If you agree to take part in this study, I will be asking you to do a few things over the next few weeks.
   I will ask you questions about ________.
   I will ask you questions about ________.
   I will ask you questions about ________.
   I may make a video recording of you taking part in __________.
   After you go home, I may contact you later to ask you some more questions. If I do, you will have the chance then to decide whether you want to answer my questions.

4. If at any point you feel that you are unhappy with any part of this study, you can tell your parents or us and you can leave the study. Remember, being in this study is up to you and no one will be upset if you don’t want to participate or even if you change your mind later and want to stop. If you choose not to participate in the study you will not be expected to complete the assignment and it will not affect the grade you receive.

5. At all times and at every point, we will keep your parents informed about the study.

6. You can ask any questions that you have about the study. If you have a question later that you didn’t think of now, you can call me at (058) 00000 or ask me next time. You may call me at any time to ask questions about the study.

7. Please talk this over with your parents before you decide whether or not to participate. Your parent gave permission for you to take part in this study. Even though your parent has said “yes,” you can still decide not to do this.

8. Signing your name at the bottom means that you agree to be in this study. If you are not able to sign your name, you do not have to. Your doctor/therapists will continue to treat you whether or not you participate in this study. You will be given a copy of this form after you have signed it.

Include the following, if a signature is to be obtained.
Signature of Subject or
Signature of consent of Parent / Guardian on behalf of Subject (if the subject is unable to sign themselves)

__________

Printed Name of Subject                         Date

__________

Printed Name of Witness                          Date

__________

Signature of Witness

This signature confirms that the purpose of the study has been explained to the subject in an appropriate manner to ensure the subject understood what was expected of them.