Procedure Title: RESEARCH ETHICS PROCEDURE

Procedure Number: RES001 Revision No: 1

Quality Assurance Area Code: RES

Date Approved: 14/12/2018	Date Procedure to take effect: 14/12/2018	Procedure Number: RES001 Revision No: 1
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Approved by:	Name: Ethics Group	
Approving Authority:	Academic Council	
Head of Function responsible:		

1. Purpose

All research carried out by IT Sligo staff and students must conform to best international practice in relation to its ethical grounding The following procedure underpins how this grounding is assured and is intended to complement all other relevant statutory and regulatory requirements, and external ethical boards.

2. Scope

This procedure refers to research projects conducted by IT Sligo staff and students (including

undergraduate, taught postgraduate, and postgraduate).

All those who are taking part in research activity within IT Sligo must review this procedure and complete the process as outlined below prior to commencing the proposed research. There are different processes within this procedure based on whether the projects are taught Undergraduate and Postgraduate Research Projects, **or** Staff and Postgraduate research studies. The researcher will follow the guidance relevant to his/her research study.

3. Reference Documents

Data Protection Acts 1988 and 2003

4. Procedure Description

4.1 Introduction

Research can vary from small independent projects to projects within a large multidisciplinary programme, often involving collaboration with other Higher Education Institutes or industry, either nationally or internationally.

The overall process for evaluation of the ethics impact of any research at ITSligo is shown in the flow chart in Appendix 1. There are two levels of research ethics committees, at school level and at institute level. Within each school, there may be more than one committee due to the more specialized nature of some research projects, it may be appropriate to have an Ethics committee within a department or at a broader school level. For the purposes of this procedure they shall both be described as School Ethics Committee.

4.2 Undergraduate and Postgraduate (Taught) Research Projects

All Undergraduate and Postgraduate (Taught) Research Projects must complete an ethical Self-Declaration research form found in Appendix 2. This form must be co-signed by the student(s) and their supervisor(s). Additional information may be added to the form if deemed useful or required for clarification.

This form is submitted to the School Research Ethics Committee for review and consideration. This committee will ensure that the ethics strategies proposed is justified by weighing up the potential benefits and risks. In doing so theSchool Research Committee will consider:

Design and Conduct of the Study

- The thoroughness and completeness of the information submitted in the self-declaration form and its ability to respond to ethical questions arising within the context of the study;
- The suitability of the protocol and the data collection forms in relation to the objectives of the study (taking into account rules and regulations), the statistical methodology (including sample

size calculation), and the potential for reaching sound conclusions with the smallest possible exposure of subjects and number of research participants/ volunteers;

- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the participants/ volunteers and the concerned communities.

Recruitment of Research Participants/ Volunteers

- The characteristics of the population from which the Participants/ Volunteers will be drawn (including gender, age, literacy, culture, economic status and ethnicity) and the justification for any decisions made in this regard;
- The method by which the initial contact and recruitment of participants/ volunteers is to be conducted and its appropriateness to the study;
- The method by which full information is to be conveyed to potential participants/ volunteers or their representatives and by which means consent is to be obtained;
- Inclusion and exclusion criteria for participants/ volunteers.

Care and Protection of Research Participants/ Volunteers

- The safety of any intervention to be used in the proposed research;
- The suitability of the investigator for the proposed study in relation to his/ her qualifications and experience;
- If applicable, any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action;
- If applicable, the adequacy of health and social supervision and psychological support for participants/ volunteers during and after the course of the research;
- Steps to be followed if participants/ volunteers voluntarily withdraw during the course of the research;
- If appropriate, the arrangements for informing the participant's/ volunteer's GP, including the procedure for seeking consent to do so;
- A description of any financial costs to participants/ volunteers;
- The rewards and compensations, if any, for participants/ volunteers (including money, services and/ or gifts) and a justification for these;
- The provisions for compensation/ treatment in the case of injury/disability/ death of a participant/ volunteer attributable to participation in the research;
- The insurance and indemnity arrangements covering the liability of the investigator;
- A description of any grants, payments or other reward to be made to any researchers or research hosts, related to the conduct of the study.

Protection of Research Participant/Volunteer Confidentiality

- A description of the persons who will have access to personal data of the participants/ volunteers, including medical records and biological samples;
- The measures taken to ensure the confidentiality and security of personal information concerning research participants;
- The extent to which the information will be anonymised;
- How samples/ data will be obtained and the purposes for which they will be used;
- How long samples/ data will be kept;
- Both sub-committee members and investigators should be aware of the provisions of the General Data Protection Regulations and their obligations as set out in these Acts.

Informed Consent Process

- An outline of the process for obtaining informed consent;
- The adequacy, completeness, of written and oral information to be given to the participants/ volunteers and, when appropriate, their legally acceptable representative(s);
- The content and the wording of the Participant/ Volunteer information sheet;
- The content and the wording of the informed consent form and, where applicable, the provisions made for participants incapable of giving consent personally;
- Clear justification for the intention to include in the research any individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorisation for the participation of such individuals;
- Assurances that Participants/ Volunteers will receive information relevant to their participation (including their rights, safety and well-being).

If, after School Review, approval is awarded a record will be kept within a students submitted research thesis and in the school.

If at this time, approval is awarded subject to minor revisions, the researcher must make these revisions in a timely manner and resubmit to the same Ethics committee for their review and consideration.

If, at this time, approval is not awarded it will be forwarded to the Institute Ethics committee for their review and consideration.

IT Sligo School Research Ethics Committee decision will be communicated to the researcher and their supervisor.

Each Ethics committee within a school must submit a Research Ethics Committee Annual Report to the Institute Research Ethics Committee.

4.2 Postgraduate and Staff Research Projects

The researcher completes the relevant Research Ethics Self Declaration Checklist found in Appendix 3 (Postgraduate Self Declaration Form) or 4 (Staff Self Declaration Form). To ensure compliance with IT Sligo Research Ethics Procedure researchers are expected to add additional information to the Self-Declaration Checklist as they see fit.

If ethical issues are indicated within this checklist the researcher will forward their proposal to the Institute Research Ethics Committee for their review and consideration. This committee will ensure that the ethics strategies proposed is justified by weighing up the potential benefits and risks.

The committee will specifically consider:

Design and Conduct of the Study

- The thoroughness and completeness of the information submitted and its ability to respond to ethical questions arising within the context of the study;
- The suitability of the protocol and the data collection forms in relation to the objectives of the study (taking into account rules and regulations), the methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest possible exposure of subjects and number of research participants/ volunteers;
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the participants/ volunteers and the concerned communities;
- Criteria for prematurely withdrawing participants/ volunteers from the research;
- Criteria for suspending or terminating the entire research project;
- The adequacy of provisions made for monitoring and auditing the conduct of the research, including data safety;
- The adequacy of the site, including the supporting staff, available facilities, health and safety, and emergency procedures, where applicable;
- The manner in which the results of the research will be reported and published

Recruitment of Research Participants/ Volunteers

- The characteristics of the population from which the Participants/ Volunteers will be drawn (including gender, age, literacy, culture, economic status and ethnicity) and the justification for any decisions made in this regard;
- The method by which initial contact and recruitment of participants/ volunteers is to be conducted and its appropriateness to the study; The method by which full information is to be conveyed to potential participants/ volunteers or their representatives and by which means consent is to be obtained.
- Inclusion and exclusion criteria for participants/ volunteers

Care and Protection of Research Participants/ Volunteers

Where applicable:

- The safety of any intervention to be used in the proposed research;
- The suitability of the investigator for the proposed study in relation to his/ her qualifications and experience;
- The provisions made for receiving and responding to queries and complaints of participants/ volunteers throughout the course of the study;
- If applicable, any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action;
- If applicable, the adequacy of health and social supervision and psychological support for participants/ volunteers during and after the course of the research;
- Steps to be followed if participants/ volunteers voluntarily withdraw during the course of the research;
- If appropriate, the arrangements for informing the participant's/ volunteer's GP, including the procedure for seeking consent to do so;
- A description of any financial costs to participants/ volunteers;
- The rewards and compensations, if any, for participants/ volunteers (including money, services and/ or gifts) and a justification for these;
- The insurance and indemnity arrangements covering the liability of the investigator;
- A description of any grants, payments or other rewards to be made to any researchers or research hosts, related to the conduct of the study.

Protection of Research Participant/Volunteer Confidentiality

- A description of the persons who will have access to personal data of the participants/ volunteers, including medical records and biological samples;
- The measures taken to ensure the confidentiality and security of personal information concerning research participants, that comply with GDPR;
- The extent to which the information will be anonymised;
- How samples/ data will be obtained and the purposes for which they will be used;
- How long samples/ data will be kept.
- **Committee members and investigators should be aware of the provisions of the Data Protection Acts 1988 and 2003 and their obligations as set out in these acts.**

Informed Consent Process

- A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent and the time frame in which it will occur;
- The adequacy, completeness, of written and oral information to be given to the participants/ volunteers and, when appropriate, their legally acceptable representative(s);
- The content and the wording of the Participant/ Volunteer information sheet;
- The content and the wording of the informed consent form and, where applicable, the provisions made for participants incapable of giving consent personally;
- Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorisation for the participation of such individuals;
- Assurances that Participants/Volunteers will receive information relevant to their participation (including their rights, safety and well-being).

If, after the Institute Review, approval is awarded a record will be kept within the Institute Research Ethics Committee records.

If at this time, approval is awarded subject to minor revisions, the researcher must make these revisions in a timely manner and resubmit to the Institute Ethics committee for their review and consideration.

If, at this time, approval is rejected the researcher must reconsider the project in line with feedback before resubmission can be accepted

IT Sligo Institute Research Ethics Committee decision will be communicated to the researcher.

IT Sligo Institute Research Ethics Committee will produce a report annually on the work undertaken.

4.3 Reviewing Applicants

School Ethics Committee

The School Research Ethics Committee will convene in accordance with published meeting dates scheduled annually. There are specific times of the year where the volume of applications is such that more frequent meetings will need to occur. The established quorum requirements are to be met prior to the review of applications.

- Committee members will require all documentation to be submitted two weeks in advance to ensure opportunities to review before the meeting
    - Meetings should follow a standard meeting protocol i.e. Minutes, agenda items, actions
    - Applications for ethical review to be considered at the meeting
- The agenda may also include for discussion, where appropriate, general ethical issues (e.g. new guidelines), matters relating to the membership of the committee and matters relating to Committee procedures.

Quorum Requirements

A minimum of three members of the School Research Ethics Committee are required to be present at a meeting held to determine an opinion in relation to an application to the Committee. There must be a reasonable representation of member categories in any quorum, including at least the following:

a. The Head of Department or in their absence, their nominee
b. One academic from the discipline
c. One other to be decided based on needs of study.

The Committee will avoid potential conflicts of interest, and engage external personnel if required. Where a quorum is not present, the School Committee cannot consider or conclude on an application for research ethical review.

Other Attendees

4.4 Institute Research Ethics Committee

The Institute Research Ethics Committee (IREC) is a sitting committee and will convene in accordance with published meeting dates scheduled annually. There are specific times of the year where the volume of applications is such that more frequent meetings may need to occur. The established quorum requirements are to be met prior to the review of applications.

- Committee members will require all documentation to be submitted two weeks in advance to ensure opportunities to review before the meeting.
    - Meetings should follow a standard meeting protocol i.e. Minutes, agenda items, actions
    - Applications for ethical review to be considered at the meeting
- The agenda may also include for discussion, where appropriate, general ethical issues (e.g. new guidelines), matters relating to the membership of the committee and matters relating to Committee procedures.

Quorum Requirements

A minimum of four members out of the Institute Research Ethics Committee (IREC) are required to be present at a meeting held to determine an opinion in relation to a project application to the Committee. There must be a reasonable representation of member categories in any quorum, including at least the following:

- The Vice President of Research Innovation and Engagement, or their nominee.
- One academic from the discipline
- One to be decided based on needs of the study

- One from outside the applying school

The committee will avoid potential conflicts of interest, and engage external personnel where required.

Where a quorum is not present, the Committee cannot consider or conclude on an application for ethical review.

Other Attendees

5. Records Generated by this procedure

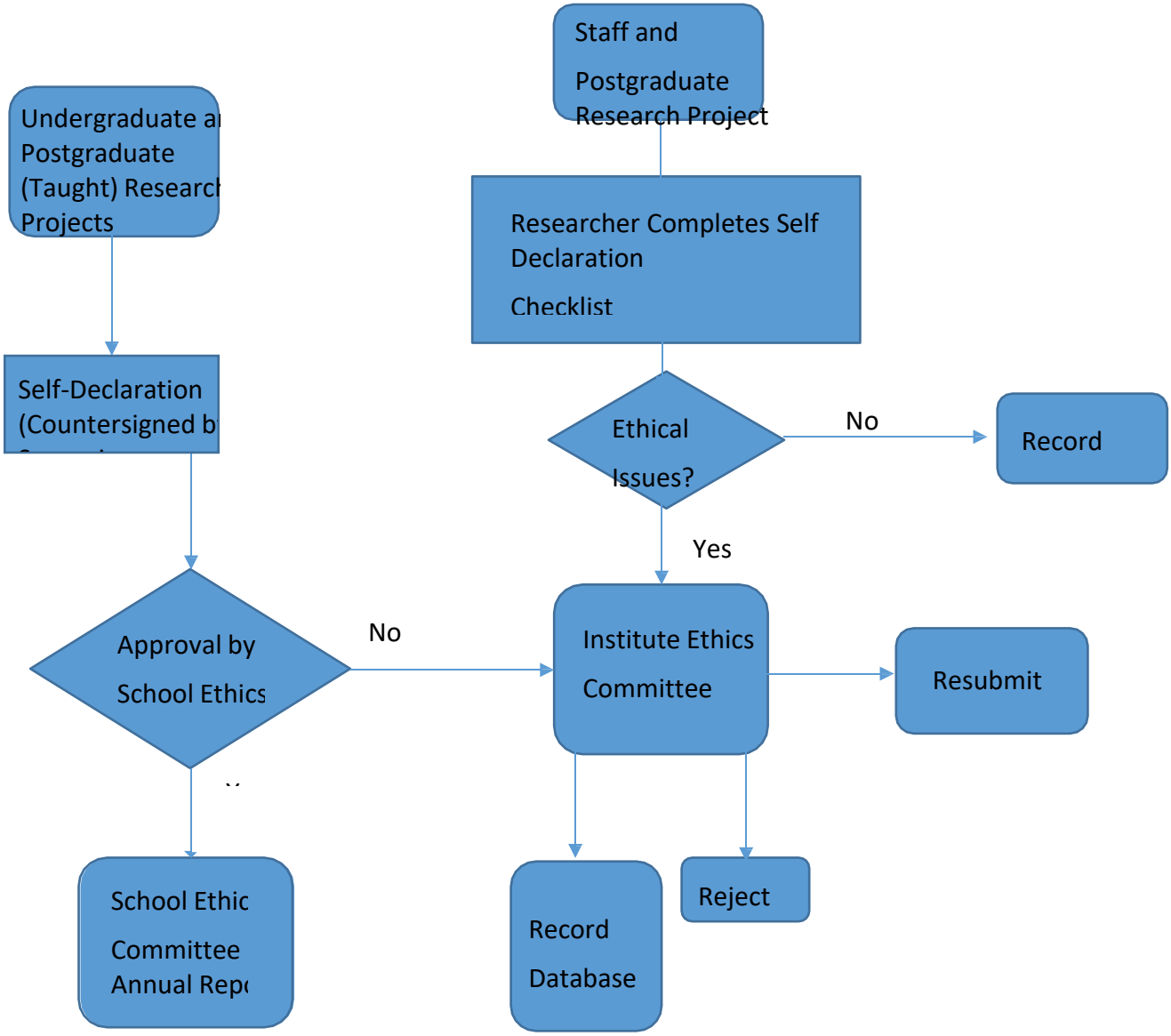
Records of Ethics committee meetings within schools are retained by the school administration.

Records of Institute ethics committee meetings are retained by the Research Department

6. Revision History

Revision No	Description of Change	Issue Date	Status
000	New Procedure	18/6/2018	Approved by Academic Council
001	Clarification on Dept committees within schools	14/12/2018	Approved by Academic Council

Appendix 1. IT Sligo Research Ethics Flowchart



Appendix 2: Undergraduate and Postgraduate (Taught) Research Project Ethics Review Self Declaration Form

Researcher Name: **Applicants (s) email address:** **Application Date:**

Research Project Title:

Briefly outline the project's aims, objectives, methodology, methods of data collection and analysis (500 words Max)

Please complete the questionnaire below by ticking a Yes/No or Not Applicable (N/A). This requires you to consider each question and where and how it may apply to your study.

	Yes	No	N/A	If you answer yes please provide additional information.
Does your research involve children or young people aged under 18 years?				
Will you have access to documents containing sensitive personal data about individuals? If yes, will consent be obtained?				
Does your research involve prisoners or others in custodial care (e.g. young offenders)?				
Does your research Involve individuals with learning or communication difficulties?				
Does your research involve those engaged in suspected illegal activities (e.g. drug taking; crime, illegal internet behaviour)?				
Does your research involve vulnerable service users (e.g.				

	Yes	No	N/A	If you answer yes please provide additional information.
patients, homeless)?				
Does your research involve animals?				
Does your research raise any issues of risk for you? (Especially if taking place outside working hours or off Institute premises)				
To the best of your knowledge Is there potential for physical and/or psychological harm/distress to participants?				
Will informed consent/assent be obtained from the participants?				
Will you advise participants what you will do with the results of the study and who will have access to this information?				
Will you advise participants that they may withdraw from				

	Yes	No	N/A	If you answer yes please provide additional information.
the research at any time and for any reasons?				
Will financial/in-kind payments (other than reasonable expenses and compensation for time) be offered to participants? (Indicate how much and on what basis this has been decided)				
Does your project engage with a vulnerable group, other than those listed above?				
Does your research involve biological fluids/tissue/biopsies?				

How will potential participants in your project be:

	Please provide a brief explanation
(i) Identified	
(ii) approached	

(iii) recruited	

What measures will be put in place to ensure the confidentiality of personal data?	

What measures will be put in place to ensure the safe storage of all collected data?	

If there are any other potential ethical issues that you think that the Committee should consider please explain them on a separate sheet. It is your responsibility to bring to the attention of the Committee any ethical issues not covered on this form.

Please attach a project proposal (where available), proposed participant information sheet and consent forms to this application.

Student(s) Signature _____

Where appointed, Supervisor Signature __ Date__

Appendix 3: Postgraduate Research Project Ethics Review Self Declaration Form

Researcher Name: Applicants (s) email address: **Application Date:**

Research Project Title:

Briefly outline the project's aims, objectives, methodology, methods of data collection and analysis (500 words Max)

Please complete the questionnaire below by ticking a Yes/No or Not Applicable (N/A). This requires you to consider each question and where and how it may apply to your study.

	Yes	No	N/A	If you answer yes please provide additional information.
Does your research involve children or young people aged under 18 years?				
Will you have access to documents containing sensitive personal data about individuals? If yes, will consent be obtained?				
Does your research involve prisoners or others in custodial care (e.g. young offenders)?				
Does your research Involve individuals with learning or communication difficulties?				
Does your research involve those engaged in suspected illegal activities (e.g. drug taking; crime, illegal internet behaviour)?				

	Yes	No	N/A	If you answer yes please provide additional information.
Does your research involve vulnerable service users (e.g. patients, homeless)?				
Does your research involve animals?				
Does your research raise any issues of risk for you? (Especially if taking place outside working hours or off Institute premises)				
To the best of your knowledge Is there potential for physical and/or psychological harm/distress to participants?				
Will informed consent/assent be obtained from the participants?				
Will you advise participants that they may withdraw from the research at any time and for any reasons?				
Will you advise participants				

	Yes	No	N/A	If you answer yes please provide additional information.
what you will do with the results of the study and who will have access to this information?				
Will financial/in-kind payments (other than reasonable expenses and compensation for time) be offered to participants? (Indicate how much and on what basis this has been decided)				
Does your project engage with a vulnerable group, other than those listed above?				
Does your research involve biological fluids/tissue/biopsies?				

How will potential participants in your project be:

	Please provide a brief explanation
(i) Identified	

(ii) approached	
(iii) recruited	

What measures will be put in place to ensure the confidentiality of personal data?	

What measures will be put in place to ensure the safe storage of all collected data?	

If there are any other potential ethical issues that you think that the Committee should consider please explain them on a separate sheet. It is your responsibility to bring to the attention of the Committee any ethical issues not covered on this form.

Please attach a project proposal (where available), proposed participant information sheet and consent forms to this application. Student(s) Signature _____

Where appointed, Supervisor Signature _____ **Date**_____

Appendix 4 : Staff Research Project Ethics Review Self Declaration Form

Research Project Title:

Researcher Name: Applicants (s) email address: Application Date:

Briefly outline the project's aims, objectives, methodology, methods of data collection and analysis (500 words Max)

Please complete the questionnaire below by ticking a Yes/No or Not Applicable (N/A). This requires you to consider each question and where and how it may apply to your study.

	Yes	No	N/A	If you answer yes please provide additional information.
Does your research involve children or young people aged under 18 years?				
Will you have access to documents containing sensitive personal data about individuals? If yes, will consent be obtained?				
Does your research involve prisoners or others in custodial care (e.g. young offenders)?				
Does your research Involve individuals with learning or communication difficulties?				
Does your research involve those engaged in suspected illegal activities (e.g. drug taking; crime, illegal internet				

	Yes	No	N/A	If you answer yes please provide additional information.
behaviour)?				
Does your research involve vulnerable service users (e.g. patients, homeless)?				
Does your research involve animals?				
Does your research raise any issue of risk for you? (Especially if taking place outside working hours or off Institute premises)				
To the best of your knowledge Is there potential for physical and/or psychological harm/distress to participants?				
Will informed consent/assent be obtained from the participants?				
Will you advise participants that t may withdraw from the research a any time and for any reasons?				
Will you advise participants what will do with the results of the stud and who will have access to this				

	Yes	No	N/A	If you answer yes please provide additional information.
information?				
Will financial/in-kind payments (other than reasonable expenses a compensation for time) be offere participants? (Indicate how much and on what basis this has been decided)				
Does your project engage with a vulnerable group, other than those listed above?				
Does your research involve biological fluids/tissue/biopsies?				

How will potential participants in your project be:

	Please provide a brief explanation
(iv) Identified	
(v) approached	
(vi) recruited	

What measures will be put in place to ensure the confidentiality of personal data?	

What measures will be put in place to ensure the safe storage of all collected data?	

If there are any other potential ethical issues that you think that the Committee should consider please explain them on a separate sheet. It is your responsibility to bring to the attention of the Committee any ethical issues not covered on this form.

Please attach a project proposal (where available), proposed participant information sheet and consent forms to this application.

Staff Signature(s)_____ Date_____