Galway-Mayo Institute of Technology

Research Ethics Policy

Approved by Academic Council on: May 7th, 2010

and by the Governing Body on 27 May 2010

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1. Introduction

Ethical issues occur in all types of research. Good ethical practice comes from being aware of regulatory guidelines, statutory prohibitions and Institute policies & best practice. The Galway-Mayo Institute of Technology is committed to promoting and supporting ethical practice across all of its educational activities, including research.

The Institute's research ethics policy covers everyone carrying out research for the Institute, whether their place of research is within or outside the Institute premises. The Institute's research ethics policy seeks to develop best practice in research in accordance with appropriate ethical practice from a variety of professional bodies and statutory instruments as well as best practice in the Irish third level educational sector at large.[1]

The policy forms the basis for dealing with all research ethical issues as referred in the Institute's Research Code (*Academic Code of Practice – No. 5*). This includes issues arising from staff research, undergraduate and postgraduate research degree programmes. In all cases, researchers must comply with this policy. This policy will be revised every two years, whereas standard operating procedures (see Appendix 2) and guidance to researchers will be issued and revised periodically as the Institute's Research Ethics Committee decides.

2. Guiding Principles and the Need for Ethics Review

A number of well documented guiding principles govern the ethical review of research proposals, particularly the *Declaration of Helsinki.* These principles aim to protect the well-being and rights of research participants / volunteers and animals used in research. The policy and procedures conform to the following general principles:

1. The promotion of honesty, openness and fairness in the conduct of research for the benefit of all stakeholders and in the dissemination of research outcomes.
2. The promotion of professionalism, transparency and accountability of researchers.
3. Respect for confidentiality of data on human subjects.

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[1] **http://pubs1.tso.parliament.uk/pa/cm199697/cmselect/cmstand/688/code1.htm, http://www.public-standards.gov.uk/ http://www.archive.official-documents.co.uk/document/parlment/nolan/nolan.htm http://www.wellcome.ac.uk/doc_WTD002753.html:**
- Wellcome Trust Guidelines on Good Research Practice, January 2002" The Irish Council for Bioethics, Operational Procedures for Research Ethics Committees: Guidance 2004, Declaration of Helsinki, Policies of IOTI and Irish Universities.

4. Respect for the appropriate confidentiality of commercial information supplied to researchers.
5. Identification of possible conflicts of interest whether financial, legal or personal between the researchers, the Institute and any external person or bodies.
6. Promotion of best practice in research.
7. Proper acknowledgement of the role of all involved in the research,
8. Respect and consideration of the broader social and cultural implications of research.
9. Recognition that questions of equity and morality arise in who should receive the benefits of research and who should accept its burdens.
10. Acceptance of the principle that the benefits of research should be maximised and the possible harms should be minimised.

2.1 Respect for Persons

Respect for persons means regard for the welfare, rights, beliefs, perceptions, and customs, both individual and collective, of individuals involved in research. Respect for persons is most commonly manifested through the exercise of informed consent, which requires that people's beliefs and opinions be respected, and that they be allowed to choose for themselves whether or not they wish to participate in research. In order to choose they must be informed of their options, including the possible risks and benefits of those options, and their rights to withdraw from the research to which they have given their informed consent.

2.2 Privacy and Confidentiality

Privacy and confidentiality are an integral part of the protection and promotion of human dignity and help to protect and maintain a person's mental or psychological well-being. The need for research should be weighed against infringements of privacy and steps must be taken to ensure that individuals are protected from any harm that might be caused as the result of access to their personal information.

2.3 Validity of Research Proposals

The scientific merit of a study is itself an ethical issue. The essential features of ethically justified research involving human participants as objects are that: the research offers a means of developing information, not otherwise obtainable; the design of the research is scientifically sound, that the investigators and other research personnel are qualified and capable, and that the methods to be used should be appropriate to the objectives of the research and the field of study.

2.4 Risks

As research involves advancing the frontiers of knowledge, its undertaking usually involves a degree of uncertainty about the precise magnitude of and kind of benefits and harms that attend proposed research. If there are any risks resulting from participation in the research, then there must be benefits, either to the subject, or to humanity or society in general.

2.5 Justice

Justice imposes duties to neither neglect nor discriminate against individuals or groups who may benefit from advances in research, to avoid imposing on a particular group an unfair burden of participation in research and to design research so that the selection and recruitment of research participants/volunteers is fair. Justice requires also that the research be responsive to the health conditions or needs of vulnerable participants. In such cases there must be clear and unambiguous justification for the research and for its application to such participants, and normally there should be potential for direct health-related benefit to the subject, or the absence of any significant risk or discomfort.

2.6. Principles for research involving animal participants

In dealing with research involving animal[2] subjects, the following additional principles will apply: Researchers will receive permission from the appropriate licensing authority prior to submission to Institute procedures. Research will be carried out on animals only when there is no alternative procedure available. Research will be carried out in a way to minimise the discomfort to the animals involved. Research proposals will adhere to the principles of reduction, refinement and replacement.

[2] For the purpose of this report animals are: *any live non-human vertebrate including free-living larval and/or reproducing larval forms, but excluding foetal or embryonic forms*; (EU Council Directive 86/609/EEC).

3. Scope of Procedures

It is the purpose of this document to outline the procedures to be followed when preparing an application for research funding and/or for a place on a supervised research degree programme undertaken at GMIT, to ensure any ethical considerations have been highlighted. It also describes the process by which project proposals will be reviewed where an ethical issue has been identified. The procedures apply to all staff, postgraduates, undergraduates, contract or guest researchers in the Institute.

All Research involving or impacting upon human and animal participants requires ethics review by the Institute's **Research Ethics Committee (REC)**, before the research project is started and before research funding can be drawn down.

4. When is Ethics Clearance Required?

Experimentation which involves one or more of the following may need to obtain ethical clearance.

- Human experimentation – including surveys, behavioural observation etc.
- Animal experimentation
- Clinical trials involving human participants
- Research involving human remains, cadavers, tissues, discarded tissue (e.g. placenta), and biological fluids
- Genetic manipulation or GMOs
- Use of known teratogens, carcinogens and any cytotoxic substances in clinical trials
- Use of harmful substances in human or animal participants
- Use of ionising radiation with human participants
- The possibility of a conflict of interest due to financial incentives / benefits from a sponsor
- The collection, storage and use of data of a sensitive or confidential nature
- The potential for conflict over authorship; fair recognition of all the participants an the research
- If ethical clearance is a stated requirement of the funding agency
- Emerging areas of research not yet listed or any research where the researcher is uncertain of the requirement.

The onus is on the researcher (or in the case of undergraduates and postgraduates, the research supervisor) to be aware of this. Failure to comply may be regarded as misconduct and actions will follow as detailed in the Institute's *Academic Code of Practice – No. 5.* Review is not normally required for:

- Research utilising existing publicly available documents or data
- Observational studies in public places in which the identity of the participants remains anonymous
- Quality assurance studies
- Audits.

The remit of the REC is to look at proposals purely from the research ethics perspective in terms of the research methodology, protection of participants, etc. The containment of harmful, teratogenic, carcinogenic or toxic substances and/or radiation when not being administered to humans or animal participants, are deemed to be Health and Safety issues. The opinion of the REC should be sought whenever there is any doubt about the applicability of this guidance to a particular research project.

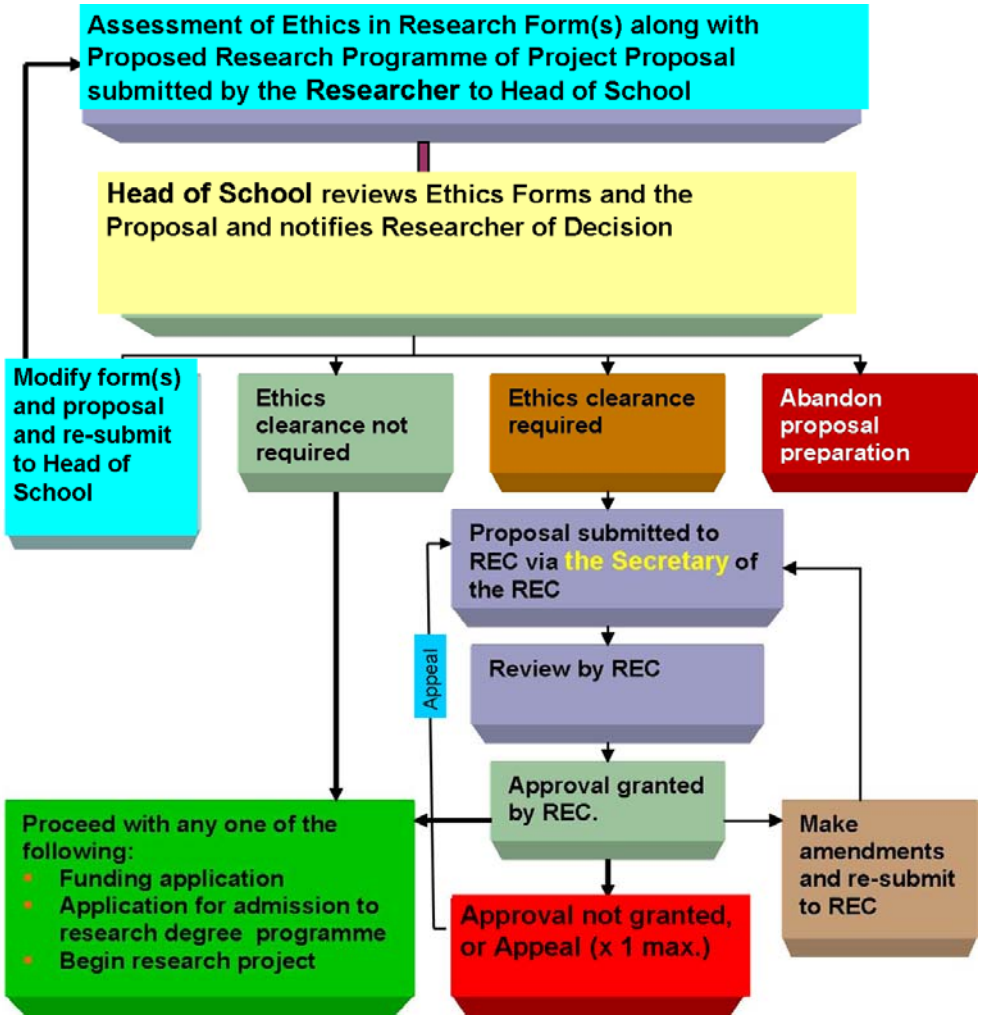
5. Preliminary Assessment of Ethical Issues

The onus is on the researcher (or in the case of postgraduates, the research supervisor) to highlight any potential ethical issues to the sponsoring Head of School prior to preparing and submitting research funding and postgraduate registration applications.

Where an ethical issue has been highlighted for a research project, the proposed researcher(s) must obtain clearance from the REC before the project starts. This may also be a requirement of the funding agency, and in that instance REC review needs to be conducted prior to the submission of the funding application.

All researchers are required to submit an *Assessment of Ethics in Research Form* to the sponsoring Head of School. Where the research is to be conducted by the staff member themselves, the form should be submitted when permission is being sought to conduct the proposed research. The proposed sponsoring Head of School. will review the ethics/risk form(s) submitted and will notify the researcher where ethics review by the REC is required within 5 working days of submission of the Assessment of Ethics in Research Form.

Where ethics review is not required, the completed *Assessment of Ethics in Research Form* should be held in the sponsoring School Office in the postgraduate student file. The full procedure for submitting an application for ethics review by the REC is outlined in Section 6. A flowchart outlining the steps involved is shown below.



Note:

1 Where a funding agency requires an ethical review prior to a research funding application then the procedures in Section 6 below also apply.

2 Where an ethical consideration has been highlighted, research funds will not be released and the registration of postgraduate research students will not normally be processed until the proposal has been approved by the Research Ethics Committee.

3 Where an ethical consideration has been highlighted, no research work can commence before the proposal has been approved by the Research Ethics Committee.

4	A re-assessment of ethical and risk factors must be undertaken by researchers in any research project where any significant change in the direction or focus of an ongoing research project is intended.
5	The process for dealing with applications that have been reviewed by the REC or Board of a collaborating institution or hospital is covered in Section 6.1.– Multi-centre Studies.

6. Procedure for Submitting an Application for Ethics Review

An application for ethics clearance in respect of proposed research must be made in writing on the appropriate form and signed by the qualified researcher responsible for the conduct of the study. This will usually be the group leader: lead academic investigator or principal academic supervisor for a proposed research degree programme or research project organising an application using the forms provided by the REC (Appendix 2).

One signed, original of the completed form(s) and electronic copy should be submitted to the Secretary of the REC, at least 10 working days in advance of the scheduled meeting [to be held every two months] in question to allow adequate time for distribution to and reading by the REC, along with the following when not included on the form(s) above:

(a) the protocol of the proposed research (clearly identified and dated), together with supporting documents and appendices

(b) a summary, synopsis or diagram ('flowchart') in non-technical language

(c) a description of the ethical considerations involved in the research

(d) case report forms, diary cards, and other questionnaires intended for research participants/volunteers

(f) when the research involves the study of a product (such as a pharmaceutical or device under investigation) an adequate summary of all pharmacological and toxicological data available on the product, together with a summary of clinical experience with the product to date (e.g. recent investigator's brochure, a summary of the product's characteristics) should be included

(g) current curriculum vitae of the applicant(s) – to determine expertise in the area proposed

(h) material used (including advertisements) for participant/volunteer recruitment

(i) patient/volunteer information

(j) a full description of the process to obtain and document consent

(k) suitable arrangements for indemnifying participants/volunteers and investigators

(l) all significant previous decisions[3]

Meetings will be scheduled every two months, typically adjacent to Academic Council meetings. The REC will only meet where applications have been received 10 working days in advance of the meeting in question. The Secretary will notify REC members where meetings will not be held in that regard. An annual schedule of REC meeting dates and times will be posted on the Institute's website at the start of each academic year. All documentation necessary for submitting an application to the REC will be made available on the Institute website including dates for submission of applications and meeting dates, Application form(s), Appendices, Answers to Frequently Asked Questions.

The applicant will be emailed with a decision within 6 working days of the meeting held. The decision will also be notified to the sponsoring Head of School. The Ethics Committee and the Executive Board will receive a report on decisions taken by the REC from the Secretary after each meeting held. If amendments are requested then they should be sent via email to the REC Secretary ensuring that amendments are highlighted either by underlining the appropriate sections or using the tracked changes facility in MS Word. If these amendments are satisfactory a formal letter of approval will be issued.

In the case of a full resubmission the revised application will be subject to approval by at least five of the original assessors, as dictated by the Chairperson in conjunction with the vice-Chair and Secretary, but does not need to come back to a subsequent full Committee meeting. One appeal is permitted and the REC decision is binding.

6.1 Multi-centre studies

Researchers involved in multi-centre projects/studies in the role of direct supervisor or collaborator which falls into the categories listed previously in Section 4 must submit an application for ethical review of the proposed project/studies to the REC. However, where the research proposal has already been reviewed by an external REC (for example, collaborating educational institutions or hospitals) then the following procedure applies:

[3] e.g. those leading to a negative decision or modified proposal) by other Research Ethics Boards / Committees (e.g. a hospital) or regulatory authorities for the proposed research (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for previous negative decisions should be provided.

1. An *Assessment of Ethics in Research Form* should be submitted to the sponsoring Head of School., along with a completed *Ethical Approval from Other Committees Form;* a letter of approval from the collaborating establishment and a copy of their official REC outcome, where available.
2. The Head of School, will consult with the Chairperson of the REC. Where they are satisfied that the appropriate procedures have been followed for the external ethics review then approval will be granted without the proposal going before the Institute REC. Where they are not satisfied then the proposal will be sent for full review to the REC.

Where samples from the off-campus study are to be brought back to the Institute for further investigation or study, then a full ethical review of the research proposal must be conducted at this stage. In addition, a complete Hazard Assessment is required for submission to the H&S Officer and recommendation received.

6.2 Fast-tracking

With applications for projects that only involve audit procedures or anonymous questionnaires for research to practitioners or to students of the Institute, these can be forwarded for fast-track processing to the REC Secretary. This requires a signed hard copy of the appropriate application form(s) and supporting documentation to be lodged with the Secretary 5 working days before the date of the scheduled REC meeting, together with a checklist indicating the reason for fast-tracking signed by the Head of School. or Head of Department. These checklists will be reviewed by the Chairperson of the REC, in conjunction with the vice-Chair and Secretary.

In all other cases, an electronic copy of the application and a stapled hard signed copy must be lodged with the REC Secretary by the latest date for receipt of application, i.e. 10 working days prior to the board meeting at which approval is sought (schedule will be available on the website).

6.3 Deferred Applications

Applications will be deferred to the following meeting if;

- the application does not reach the Secretary of the REC by 5.00pm by the published deadline
- the form used is not the current version as posted on the website
- the cover sheet checklist is not completed
- participant information sheets and/or consent forms are not submitted

- appropriate documentation referred to in the application is not submitted
- the Lead Researcher declaration is not completed in full
- in the case of student applicants, the research supervisor has not completed the requisite section
- the application is without the following signatures: applicant signature, research supervisor signature (applicable in student applications) and Head of School/Department Signature.

7. Management and Governance

7.1. Ethics Committee

The purpose of this Committee is to:

- Establish an appropriate code of ethics for the Institute;
- Identify protocols to be followed
- Identify protocols to be followed by persons using college data and communications technology.

It has the following terms of reference:

- To develop, codes and standards of ethics for staff, students, employees, partners and contractors of the Institute.
- To make recommendations to the Executive Board and Academic Council on issues related to the development and maintenance of codes and standards of ethics.
- To support the Executive Board and Academic Council in the development of a Code of Ethics for the Institute and its implementation.
- To engage with external academic bodies, supervisory or accrediting agencies as requested by the Executive Board, Academic Council or the Registrar.

7.2. Research Ethics Committee

7.2.1. Aims

The Research Ethics Committee (REC) is an Executive Committee convened by the Executive Board and has been established with the following aims:

1. To protect the rights and welfare of human and animal participants in research studies or trials conducted by or involving GMIT researchers through a review process.

2. To facilitate the conduct of ethically sound, legally compliant research at the Institute in accordance with national and EU legislation.
3. To engage with external academic bodies, supervisory or accrediting agencies as required by Academic Council or the Registrar.
4. To advise the Ethics Committee and thereby Academic Council on the development of ethical policies and procedures at the Institute.

7.2.2. Terms of Reference of the Research Ethics Committee

These are:

1. To ensure that research activities in the Institute conform to the principles outlined above and to oversee the implementation the Research Ethics Policy within the Institute

2. To inform itself of best practice in the promotion and management of ethical issues.

3. To develop ethical policy and procedures for research activities in the Institute.

4. To validate procedures and protocols developed by Schools and research groups in the Institute.

5. To adjudicate on the ethical aspects of research proposals from staff and postgraduate students which are brought to its attention by individuals and groups within the Institute.

6. To promote best ethical practice on research and to encourage dissemination of good ethical practices among staff and students

7. To ensure that all research carried out in the Institute conforms to the requirements of external ethics bodies which have statutory or professional responsibility for research activity in that area.

8. In dealing with researchers, the Committee will be mindful of the need to protect the academic freedom of the researcher, and respect the autonomy and professional competence of the researcher.

9. To evaluate the ethical procedures of the Institute and to report on these to the Academic Council

10. To report to the Executive Board, Academic Council and the Governing Body on its activities.

In terms of external support, oversight and evaluation, the REC:

1. May engage external experts where necessary to assist it in deciding on particular proposals or on the adequacy or appropriateness of procedures.
2. Shall engage external expertise to assist it in the evaluation of Procedures and Processes and structure.
3. Members of the committee from a particular discipline area shall not participate in the evaluation of proposals from that particular area.

7.2.3. Composition of the Research Ethics Committee

The guiding principle for appointing members to a REC is to ensure that the committee has the appropriate expertise, skills, knowledge and perspectives to ensure an adequate and thorough ethics review. The REC should be multidisciplinary and multi-sectoral in composition. Attention should be paid to age and gender balance. One third of the total membership should be lay members. The membership of the **REC** is as follows:

1. The Chairman shall be a member of the Institute appointed by the Academic Council.
2. Two active researchers shall be nominated by each School and appointed by the Academic Council as members of the Committee.
3. A member of staff of the Institute who has legal expertise appointed by the Academic Council
4. A member of the public nominated by the committee at its first meeting and appointed by the Academic Council.
5. The REC may from time to time co-opt either external or internal members where they perceive their expertise is required.
6. The REC shall report to the Governing Body, Executive Board and Academic Council on an annual basis. The report shall indicate the adequacy or otherwise of the arrangements within Schools for ethical oversight of research activity and on other appropriate matters.
7. The REC shall inform itself of issues relevant to its activities and shall endeavour to disseminate such new information and best practice to the Institute community.
8. Members of the Committee will be appointed for four years. One member from each School shall resign every two years. Members are eligible for re-nomination.
9. A secretary shall record minutes of the meeting and administer communications.

A minimum of five members of the REC is required to be present at a meeting held to determine an opinion in relation to an application to the REC. There should be a reasonable representation of members, which must include the chairperson, or in his/her absence a vice-Chairperson. The Chairperson may appoint a person to act as an alternate for each member of the REC, where the alternate satisfies the same membership criteria as the member. When alternates substitute for a primary member, the alternate member should have received and reviewed the same material that the primary member received or would have received. An alternate can only vote if the member for whom he/she acts as an alternate is absent.

Where a Chairperson or members of the REC believe there is insufficient expertise on the committee to assess an application or an issue, the Board should seek additional expert advice. Experts may have specialist knowledge in particular fields of science or medicine or they may be representatives of communities or special interest groups. Co-opted expert members are not entitled to vote. More detail on who is allowed to vote is given in Section 8.2 – Decision Making Process. When an REC member believes they have a conflict of interest on a subject which will compromise their ability to make an impartial decision, they should declare that conflict of interest and withdraw themselves from the discussion and/or activity.

8. Review Procedure

8.1. Preparation

The REC will review projects involving human or animal participants in the categories outlined in Section 4 above. Project proposals may include:

- Student research projects
- Staff research projects
- Questionnaires for use in research.

All eligible applications for review will be listed on a spreadsheet distributed to the Board members by the secretary at least 5 days before the next meeting. Each application will be read by members of the Research Ethics Board in advance of the meeting. Any concerns identified should be notified to the Secretary at least 3 working days prior to the scheduled meeting. REC members should provide comments on applications to the REC through the Secretary where they cannot attend a scheduled meeting.

The Chairperson and the REC Secretary will consult in sufficient time in advance of the

scheduled REC meeting to highlight potential issues and set an agenda for the formal meeting. The committee should:

- Meet in accordance with publicised scheduled dates every two months.
- Members should be given sufficient time to review relevant documentation
- Meetings should be minuted. There should be an approval procedure for the minutes
- When appropriate, the sponsor and/or investigator may be invited to present the proposal to the members and answer any questions a member may have
- When appropriate, the principal researcher may be called in to inform the discussions.
- Ensure that all properly submitted and valid applications shall be reviewed in a timely fashion

8.2. Elements of a Review

When reviewing research proposals the Committee may wish to consider the following aspects of the proposed work:

- Scientific design and conduct of the study
- Recruitment of research participants/volunteers
- Care and protection of research participants/volunteers
- Protection of confidentiality of participants/volunteers
- Informed consent process from the Human Participant
- Community considerations

Both REC members and investigators should be aware of the provisions of the Data Protection Acts 1988 and 2003 and their obligations as set out in those Acts. http://www.dataprotection.ie

8.3 Decision Making Process

The REC should ensure that all supporting documentation for an application is complete before coming to a decision on a research proposal. The Committee should comply with a pre-defined method for arriving at a decision. It is recommended that the Committee use the consensus model where the process of discussion and debate will lead to a decision, rather

than a formal vote-casting process. Under the consensus model, the proposal will be approved when all members present are willing to allow the proposal to proceed. In cases in which consensus seems unlikely, the chairperson may call for a vote with a simple majority required for approval. Dissenting members should be afforded the opportunity to append an opinion to the REC decision. The comments of members who cannot be in attendance will be used to inform discussions, but they cannot vote in abstentia.

The REC may request the principal researcher to participate in discussions about their proposal, but may not be present when the REC is making its decision. It is desirable to adopt a consistent approach to granting or declining approval of a proposal. It is recommended that the following terminology be used in communicating the decision of the REC to an applicant:

i. Approved, the applicant may conduct the research as outlined in the research proposal submitted to the REC

ii. Provisionally approved, subject to recommended revisions to the proposal or answers to questions posed to the applicant. The revisions and/or answers must be resubmitted to the Secretary, for review as dictated by the REC as follows, before final approval will be granted by the Secretary, vice-Chair and Chairperson *or* at least five REC members over the email

iii. Approval declined, detailed reasons for declining approval should be forwarded to the applicant, with or without an invitation to resubmit a substantially altered proposal for reconsideration.

No research may be conducted prior to receiving final approval. The REC decision should be communicated, by the Secretary, to the applicant in writing within 6 working days of the meeting at which the decision was taken. The chairperson should sign and date all such communications. The decision should include, but is not limited to the following:

(a) project identification number and/or date of the proposal that the decision is based on

(b) exact title of proposal reviewed

(c) name and title of applicant

(d) name of the REC taking the decision

(e) date and place of the decision

(f) chairperson and list of members present when decision was taken

(g) clear statement of the decision taken

(h) terms and conditions, if any, of approval of proposal, with clearly defined reasons for such terms and conditions

(i) clearly stated reasons if approval has been declined

(j) whether approval was by expedited review.

8.4 Amendments to Research Methods over the Lifetime of a Project

Any significant alteration to an existing or ongoing research project that had been previously approved by the REC must receive prior approval again from the REC before implementation. Significant alterations include changes to:

(a) personnel [4]

(b) method

(c) design of the study

(d) duration of the study

(e) informed consent procedures

(f) patient information leaflets

(g) method of recruitment.

This requires a new submission of the appropriate forms outlining the reasons for the proposed alteration(s).

9. Documentation & Archiving

Particular attention must be given to any research: involving potential risk to the researcher(s) and/or subject(s); raising ethical issues or involving pharmaceutical preparations; and/or research on pregnant women, persons under the age of 18, persons with physical or mental disabilities, other vulnerable categories or members of ethnic or minority groups, or work involving animals.

[4] including where work has been subcontracted to another investigator) any changes to named Researchers responsible for the conduct of the research; any change to the personnel involved in obtaining informed consent or having access to personal information about research participants/volunteers, identifiable human material or identifiable data.

The *World Medical Association* has developed the *Declaration of Helsinki* as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human research includes research on

9.1 Guidelines for Storage of Information by the Researcher(s)

Documents that will bear personal information such as participant's name, address and telephone number require close scrutiny. Often only one document e.g., the consent form, will need to bear such information.

An identity number should be generated for each participant, in this way data/information will be anonymous. With the exception of the one document that contains participant's personal information all other information will be distinguished via this identity number.

Data should be handled in the following way:

1. Each researcher will store the document bearing personal information in a locked cabinet with access strictly restricted to personnel working on the study.
2. All computerised data/information will be stored in a locked cabinet, again with restricted access and pass worded.
3. The researcher responsible for the project will be the person with access to the data/information generated by the study.
4. All computerised data/information collected should be anonymous by using identity numbers for the participants.
5. The data/information will be stored for the duration of the study, i.e. until the work is fully reported and disseminated. It will then be kept in a locked cabinet for five years, unless the REC dictates the data be stored for a longer time period.

9.2 Guidelines for Storage of Information for the Research Ethics Committee

All documentation and communications of the REC will be held in the Office of the Registrar. They should be dated, filed and archived according to provisions set out in the Institute's data retention procedures. Documents must be stored in a secure place where there is adequate protection against fire. A statement is required in the Data Retention Schedule of GMIT defining the access and retrieval procedures for documents, including

details of who is authorised to access and/or retrieve REC documents. Documents that should be filed and archived include, but are not limited to:

(a) a written standard operating procedure for data retention related to research
(b) annual reports of the REC
(c) curriculum vitae of each REC member
(d) record of all income and expenses of the REC, including expenses paid to REC members and co-optees
(e) guidelines on application procedures
(f) agendas of REC meetings
(g) minutes of REC meetings
(h) copies of all materials submitted by applicants
(i) correspondence by the REC concerning applicants, decisions and follow-up
(j) copies of decisions and any advice and/or requirements issued to applicants
(k) all written documentation received during follow-up
(l) notification of completion or premature suspension/termination of studies
(m) final study reports

Documents should be kept for a minimum of three years following notification of completion or premature suspension/termination of a study.

9.3 Annual Report

The REC should produce an annual report to be sent to the Governing Body, Executive Board and Academic Council containing the following, but not limited to:

(a) membership/membership changes
(b) number and dates of meetings held
(c) changes to the standard operating procedures
(d) a list of proposals considered, the decision reached on each

Copies should also be sent to the Ethics Committee. Annual reports are public documents and should be available upon request.

Appendix 1: Code of Conduct for Researchers

This Code is part of the Research Ethics Policy governing all of GMIT's research activities. It draws on a variety of resources including those listed below.[5]

Standard Operating Procedures for the implementation of this code of conduct are available: *Procedures for the Examination and Resolution of Allegations of Research Misconduct*

1. Standards of Professional Behaviour in Research

1.1 All researchers within the Institute (including all students of the Institute) have a duty to society, to their profession, to the Institute and to those funding their research, to conduct their research in as conscientious and responsible a manner as possible. The Nolan Committee on Standards in Public Life in the U.K identified seven principles which have relevance to best practice in the conduct of research: *selflessness, integrity, objectivity, accountability, openness, honesty and leadership*. These standards also form the basis of the Wellcome Trust Guidelines on Good Research Practice, January 2002. Together, these principles provide a foundation for the personal integrity that should be reflected in the professional conduct of research by every individual who contributes to research at the Institute. Institute staff members in leadership or supervisory positions have an obligation to foster personal integrity in the conduct of any individual carrying out research for the Institute under their direction. They are also responsible for the ethical basis of the research and its funding, and for the safety of all involved in the research process. Many professional associations have ethical codes and guidelines for the conduct of research and all individuals carrying out research for the Institute are also expected to comply with such standards when collaborating with such associations for research purposes or as members of such associations.

1.2 Research misconduct is least likely to arise in an environment where good open research practice (e.g. documentation of results, peer review of research, regular discussion and seminars) is encouraged and where there is adequate supervision at all relevant levels. It is a responsibility of Heads of School and Department to convey clearly to research group leaders or principal investigators/supervisors in their area the standards, protocols and ethics for research in their departments and relevant areas, and to ensure that adherence to those standards is a matter of course. Principal investigators/supervisors and research group leaders must in turn

[5] Taken from
http://pubs1.tso.parliament.uk/pa/cm199697/cmselect/cmstand/688/code1.htm,
http://www.public-standards.gov.uk/
http://www.archive.official-documents.co.uk/document/parlment/nolan/nolan.htm
http://www.wellcome.ac.uk/doc_WTD002753.html

convey clearly to all researchers under their care the standards and protocols for research in their relevant areas, and to ensure that adherence to those standards is a matter of course.

1.3 All individuals (including students) carrying out research for the Institute should be made familiar with, and be expected to comply with, the Institute's Research Code (*Academic Code of Practice – No. 5)*. The Heads of Department or Function should also bring to the attention of any individual, including visiting researchers carrying out research for the relevant Department or Function any specific standards and ethics which may be applicable in that Department or Function. Every individual carrying out research for the Institute is expected to follow these principles. The following principles are of particular relevance to research:

1.3.1. Honesty

A. At the heart of all research endeavour, regardless of discipline or institution, is the need for researchers to be honest, transparent, and amenable to reasonable enquiries in respect of their own actions in research, the outputs and outcomes of their research and in their responses to the actions of other researchers. This applies to the whole range of research, including experimental design, generating and analysing data, publishing results, patenting and acknowledging the direct and indirect contributions of colleagues, collaborators and others.

B. All individuals in the Institute's employment must refrain from plagiarism, piracy or the fabrication of results and committing any of these actions is regarded as a serious disciplinary offence.

1.3.2. Openness

A. While recognising the need for researchers to protect their own research interests in the process of planning their research and obtaining their results, the Institute encourages researchers to be as open as possible in discussing their work with other researchers and with the public. Once results have been published, where appropriate, the Institute expects researchers to make available relevant data and materials to others, on request.

B. In addition, where available and relevant to the research or individual researcher in question, the Institute expects researchers to observe the standards of practice set out in guidelines published by funding bodies, scientific societies and other relevant professional bodies.

C. Intellectual property: Researchers should be aware of the fact that pre-mature disclosure of information in the public domain by what ever means can render the subsequent patenting of this knowledge impossible.

1.3.3. Leadership and Co-operation in Research Groups

A. The culture and tone of procedures within any organisation must be facilitated

and resourced by individuals in authority. Within the Institute, it is the responsibility of the President, Registrar, Head of Research, Heads of School, Heads of Departments and Senior Staff to ensure that a climate is created which allows research to be conducted in accordance with good research practice.

B. Within a research group, responsibility lies with the group leader: centre manager, or principal investigator or research student supervisor. Group Leaders should create a research environment of mutual co-operation, in which all members of a research team are encouraged to develop their skills and in which the open exchange of research ideas is fostered. They must also ensure that appropriate direction of research and supervision of researchers and research students is provided.

C. Good research practice should be encouraged and there must be adequate supervision at all relevant levels (e.g. documentation of results, peer review of research, regular discussion and seminars).

D. It is the responsibility of Heads of School and Heads of Department to convey clearly to principal investigators or research group leaders the standards and protocols for research in their departments and relevant areas, and to ensure that adherence to those standards is a matter of course.

E. Group leaders must in turn clearly convey to all researchers under their care the standards and protocols for research in their relevant areas, and to ensure that adherence to those standards is a matter of course.

1.3.4. Documenting Results and Storing Primary Data

A. Throughout their work, researchers are required to keep clear and accurate records of the research methods followed and of the results obtained, including interim results. This is necessary not only as a means of demonstrating proper research practice, but also in case questions are subsequently asked about either the conduct of the research or the results obtained. Guidelines and procedures exist at GMIT for capture and protection of research work undertaken for industry and research likely to generate commercially valuable know-how, in particular in the form of patents.

B. For similar reasons, data generated in the course of research must be kept securely in paper or electronic form, as appropriate. The Institute expects such data to be securely held for a period of ten years after the completion of a research project, as required by several Research Councils. The storage of such Data must also be kept in accordance with the Institute's Data Retention Schedule available from the FOI Officer.

1.3.5. Publishing Results

A. It is usually a condition of research funding that the results are published in an appropriate form, usually papers in refereed journals. This has long been widely

accepted as the best system for research results to be reviewed and made available to the research community for verification or replication.

B. The issue of authorship is important in the context of good research practice. The Institute expects anyone listed as an author on a paper to accept personal responsibility for ensuring that they are familiar with the contents of the paper, and that they can identify their contributions to it. The practice of honorary authorship is unacceptable. Further information is available in the *Academic Code of Practice – No. 5.*

1.3.6. Acknowledging the Role of Collaborators and Other Participants

In all aspects of research, the contributions of formal collaborators and all others who directly assist or indirectly support the research must be properly acknowledged. This applies to any circumstances in which statements about the research are made, including provision of information about the nature and process of the research, and in publishing the outcome. Failure to acknowledge the contributions of others is regarded as unprofessional conduct. Conversely, collaborators and other contributors must carry their share of the responsibility for the research and its outcome.

1.3.7. The Needs of New Researchers

Researchers who are new to the Institute's research community may face particular difficulties in compliance with good research practice. Responsibility for ensuring that students and other new researchers understand good research practice lies with all members of the Institute, but particularly with Heads of Department and Research Group Leaders.

1.3.8. Integrity in Submitting Research Proposals

Group Leaders should take all reasonable measures to ensure the accuracy and completeness of information which is contained in applications for funding and in managing research projects, to ensure compliance with all sponsor, institutional, legal, ethical and moral obligations.

1.3.9. Integrity in Managing Research Projects

Group Leaders should take all reasonable measures to ensure compliance with sponsor, institutional, legal, ethical and moral obligations.

1.3.10. Conflict of Interest

It is the responsibility of all individuals who carry out research for the Institute to identify and declare to the Institute any conflicts of interest, whether legal, ethical, moral, financial, personal or other nature, so that it does not become a complicating or actionable issue.

1.3.11. Ethical Practice

A. Research Involving Human Participants and Biological Samples. Ethical approval is required prior to conducting research involving human or animal

participants or using biological samples from the Research Ethics Committee (REC). In addition approval is also required from collaborating Hospital RECs and from other regulatory bodies as relevant, and as required by individual research sponsors (e.g. Health Research Board). Researchers should also ensure the informed consent and confidentiality of personal information relating to the participants in research and that the research fulfils any legal requirements such as those of the Data Protection Act and the Freedom of Information Act.

B. Research Involving Animals Ethical approval is required prior to conducting research involving animals from the REC and the research must comply with all statutory licensing requirements. Researchers should consider, at an early stage in the design of any research involving animals, the opportunities for *reduction*, *replacement* and *refinement* of animal involvement.

C. Research Involving Genetically Modified Organisms (GMO's) Ethical approval is required from the REC and the research must comply with all statutory licensing requirements with regard to the generation of GMO's, their modification, their containment, and their release to the environment.

1.3.12. Research Misconduct

The Institute takes seriously any allegation of research misconduct and has written procedures for investigating and resolving such allegations. Any member of the Institute who believes that an act of research misconduct has occurred or is occurring should notify the relevant Head of School. If, for any reason, this is not possible or appropriate, the individual should contact the Registrar. A procedure for the *Examination and Resolution of Allegations of Research Misconduct* exists to deal with these issues.

Appendix 2: Documentation List

The following are the current Standard Operating Procedures (SOPS) of the REC. Any changes to the list or written content can only be decided by the REC.

SOP ET – 1: Examination and Resolution of Allegations of Research Misconduct
SOP ET – 2: Guideline regarding Participant Information Leaflets and Informed Consent Forms
SOP ET – 3: Guideline on Research involving Genetically-Modified Organisms
SOP ET – 4: Guideline to Assist Management in the Determination of Ethical Issues
SOP ET – 5: Declaration of Helsinki
SOP ET – 6: Assessment of Ethics in Research Form
SOP ET – 7: Application for Ethical Clearance for a Research Project Involving Human Participants
SOP ET – 8: Ethical Approval from Other Committees Form
SOP ET – 9: Application for Ethical Clearance for a Research Project Involving Animal Participants
SOP ET – 10: Hazard Assessment Form
SOP ET – 11: Use of drug / medical device additional information form
SOP ET – 12: Use of GMO Form
SOP ET – 13: Use of ionizing radiation additional information form