

**Institiúid Teicneolaíochta Tamhlacht
Institute of Technology Tallaght, Dublin**

**Process and Procedures for the
Management of Ethics:
Research Projects**

Approved Nov. 2007

Table of Contents

1.	Introduction	3
2.	Guiding Principles and the Need for Ethics Review	3
3.	Scope of Procedures	4
4.	When is Ethics Clearance Required?	4
5.	Preliminary Assessment of Ethical & Risk Factors within a Department	5
6.	Procedure for Submitting an Application for Ethics Clearance	7
	6.1 Multi-centre Studies	8
	6.2 Fast-tracking	8
	6.3 Deferred Applications	9
7.	The Research Ethics Committee	9
	7.1 Terms of Reference of the Research Ethics Committee	10
	7.2 Composition of the Research Ethics Committee	10
	7.3 Functions and Responsibilities	11
	7.4 Standard Operating Procedures	11
	7.5 Annual Report	12
8.	Review Procedure	12
	8.1 Elements of a Review	12
	8.2 Decision Making Process	12
	8.3 Amendments to Research methods over the Lifetime of a Project	13
9	Documentation & Archiving	14
	9.1 Guidelines for Storage of Information by the Researcher(s)	14
	9.2 Guidelines for Storage of Information for the Research Ethics Committee	15
	Appendices	16

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 Institute of Technology Tallaght is committed to promoting and supporting ethical practice across all of its educational activities, including research. In all cases researchers must comply with the Institute's Ethics Policy while conducting their research.

The policy forms the basis of the Institute Code of Conduct for Researchers [**Appendix 1**] and is an integral part of the Code of Practice for Research Degree Programmes. It forms the basis of the Institute's Ethics Policy for all its research activities, including postgraduate research degree programmes. It draws on a variety of resources as referenced in the footnote below.¹

The Ethics Policy is composed of two distinct sections:

1. Code of Good Practice in Research;
2. ITT Dublin Policy and Procedures on the Examination and Resolution of Allegations of Research Misconduct.

2. Guiding Principles and the Need for Ethics Review

A number of well documented guiding principles govern the ethical review of research proposals.² These principles aim to protect the well-being and rights of research participants/volunteers and include:

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.

¹ 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: Wellcome Trust Guidelines on Good Research Practice' January 2002

² - The Irish Council for Bioethics, Operational Procedures for Research Ethics Committees: Guidance 2004.
- Declaration of Helsinki.

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.

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 ITT Dublin, 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 and contract researchers in the Institute.

All Research involving or impacting upon human and animal participants requires ethics review by the Institute's Research Ethics Committee, 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. 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 Part 2 of the Institute's Code of Conduct for Researchers.

1. Human experimentation – including surveys, behavioural observation etc.
2. Animal experimentation

3. Clinical trials involving human participants
4. Research involving human remains, cadavers, tissues, discarded tissue (e.g. placenta), and biological fluids
5. Genetic manipulation
6. Use of known teratogens, carcinogens and any cytotoxic substances in clinical trials
7. Use of harmful substances in human or animal participants
8. Use of ionising radiation with human participants
9. The possibility of a conflict of interest due to financial incentives / benefits from a sponsor
10. The collection, storage and use of data of a sensitive or confidential nature
11. The potential for conflict over authorship; fair recognition of all the participants in the research
12. If ethical clearance is a stated requirement of the funding agency
13. Emerging areas of research not yet listed or any research where the researcher is uncertain of the requirement.

Review is not normally required for:

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

The remit of the Research Ethics Committee (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 Ethics within a Department

The onus is on the researcher (or in the case postgraduates, the research supervisor) highlight any potential ethical issues to the sponsoring Head of Department 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 [Form ITT DUBLIN RE_1]* to the sponsoring Head of Department,³ irrespective of whether ethical clearance is required or not. Where a postgraduate/postdoctoral researcher or other research person is to be recruited for the proposed project then this form should be submitted when a request for permission is being sought to recruit the

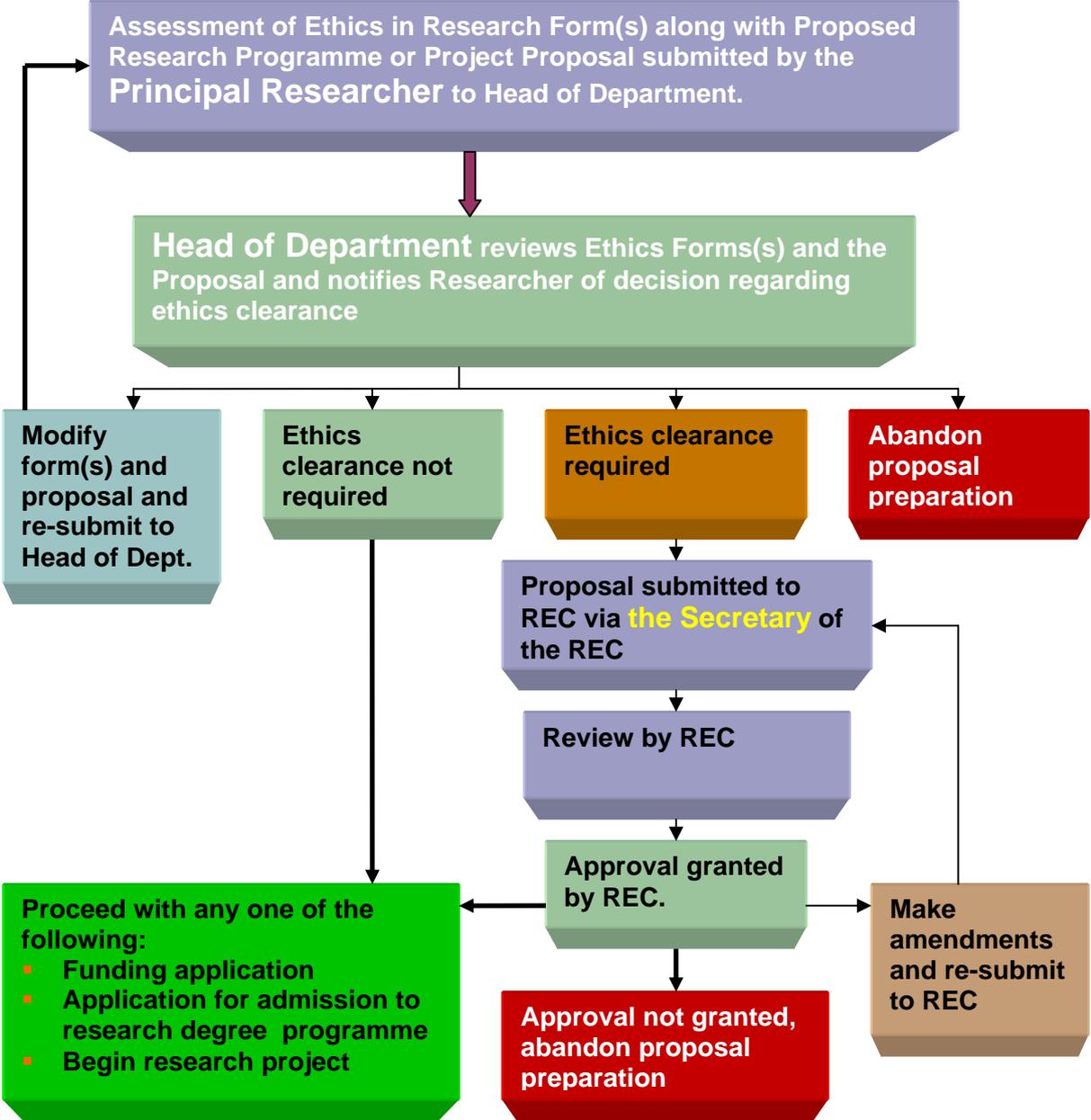
³ Where the Head of Department is the proposed academic researcher, then the form should be submitted to the Head of School.

forementioned researcher. 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 Department will review the ethics/risk form(s) submitted and notifies 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 completed *Assessment of Ethics in Research Form [Form 1]* 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 Research Ethics Committee 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 *Application for Ethical Clearance for a Research Project Involving Human Participants Form [Form ITT DUBLIN RE_2]* and signed by a qualified researcher responsible for the conduct of the study. This will usually be the lead academic investigator or principal academic supervisor for a proposed research degree programme.

An *Ethical Approval from Other Committees Form [Form ITT DUBLIN RE_3]* is also required for Multi-centre Studies as per Section 6.1 below.

Where the studies involve animal experimentation then a separate form must be completed - *Application for Approval of a Research Project Involving Animals Form [Form ITT DUBLIN RE_4]*.

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 REB, along with the following where 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 (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.

Meetings will be scheduled every two months, typically on the last Thursday of the month in question. 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 Research Ethics Committee 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 Research Ethics Committee will be made available on the Institute website. The dates for submission of applications and meeting dates, Application form(s), Appendices, Answers to Frequently Asked Questions, will also be posted on this website.

The Research Ethics Committee decision will be binding.

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 Department. The Ethics Committee and Senior Management 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 Word.** If these amendments are satisfactory a formal letter of approval will issue.

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.**

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 Research Ethics Committee (for example, collaborating educational institutions or hospitals) then the following procedure applies:

1. An *Assessment of Ethics in Research Form* should be submitted to the sponsoring Head of Department, 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 Department, will consult with the Head of School and 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 Research Ethics Committee. Where they are not satisfied then the proposal will be sent for full review to the Research Ethics Committee.

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 would be required for submission to the Departmental H&S Committee and their recommendation.

6.2 Fast-tracking

With applications for projects that involve **only 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 bimonthly Research Ethics Committee meeting, together with a **checklist** indicating the reason for fast-tracking **signed by the Head of Department or Head of School**. 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. The Research Ethics Committee

Academic Council recommended the establishment of an Ethics sub-Committee in June 2005. The remit of this sub-Committee is to

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

Terms of Reference

1. To develop, codes and standards of ethics for staff, students, employees, partners and contractors of the Institute.
2. To make recommendations to Academic Council on issues related to the development and maintenance of codes and standards of ethics.
3. To assist Academic Council in the making, maintenance, review and updating of a Code of Ethics for the Institute.
4. To engage with external academic bodies, supervisory or accrediting agencies as required by Academic Council or the Registrar.

The **Research Ethics Committee (REC)** on the other hand is an **Executive Committee convened by the Senior Management Team** and has been established by them to:

- Review project proposals of those researchers wishing to conduct research involving human and/or participants and make recommendations to SMT on whether the proposed research of that nature can be conducted at the Institute or not.

The REC should take a human subject-centred approach when reviewing project proposals to review and to approve, propose modifications to, reject or terminate any proposed or research.

The **Research Ethics Committee** has a number of primary aims:

1. To protect the rights and welfare of human and animal participants in research studies or trials conducted by or involving ITT Dublin researchers.
2. To facilitate the conduct of ethically sound, legally compliant research at the Institute in accordance with national and EU legislation.
3. To advise the Ethics sub-Committee and thereby Academic Council on the development of ethical policies and procedures at the Institute where required.

7.1 Terms of Reference of the Research Ethics Committee

1. To review and approve research proposals where human and/or animal participants are to be involved.
2. To engage with external academic bodies, supervisory or accrediting agencies as required by Academic Council or the Registrar.

7.2 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 **Research Ethics Committee** may comprise the following:

- (a) Chairperson
- (b) Vice-chairperson
- (c) Secretary
- (d) Member(s) with knowledge of and current experience in the areas of research which are regularly considered by the R.E.C. (e.g. scientists).
- (e) Member(s) with knowledge of and current experience in the professional care, counselling or treatment of people (e.g. nurse, medical practitioner, psychologist, as appropriate)
- (f) Member(s) with training in ethics
- (g) Member(s) with a qualification in law
- (h) Member(s) with training in statistics
- (i) Lay member(s) [must not be connected with the Institute]
- (j) A Head of Department
- (k) A Head of School
- (l) An expert in animal studies (e.g. a vet or suitably experienced scientist) as required.

An administrative officer should also be present to record minutes.

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 the 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.

7.3 Functions and Responsibilities

1. The REC should meet every two months as required to:
 - Review proposals for research to be carried out in Institute or by Institute staff.
 - Provide an annual report to the Ethics Committee and Academic Council on its activities in the intervening period.
2. REC members have a commitment to review the structures and processes for protecting and safeguarding the rights and interests of participants participating in research, while promoting and facilitating research excellence.
3. A member should be prepared to have his/her name, profession and affiliation published.
4. Members are expected to treat as confidential all applications, meeting deliberations, information on research participants/volunteers and related matters.
5. 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.
6. REC members should provide comments on applications to the REC through the Secretary where they cannot attend a scheduled meeting.

7.4 Standard Operating Procedures

The Research Ethics Committee 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.

The Chairperson, vice-Chair and the REC Secretary will consult a few days in advance of the scheduled REB meeting to highlight potential issues and set an agenda for the formal meeting.

The Committee should meet in accordance with publicised scheduled dates. Meeting requirements should include the following:

- (a) meetings should follow a previously scheduled agenda
- (b) members should be given sufficient time to review relevant documentation
- (c) meetings should be minuted. There should be an approval procedure for the minutes
- (d) 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

- (e) when appropriate, independent experts (e.g. researchers with specific competence, ethicists, statisticians) may be invited to attend to inform the discussions
- (f) when appropriate, the principal researcher may be called in to inform the discussions.

7.5 Annual Report

The REC should produce an annual report to be sent to SMT 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 sub-Committee and Academic Council. Annual reports are public documents and should be available upon request.

8. Review Procedure

All properly submitted and valid applications shall be reviewed in a timely fashion by the Research Ethics Committee.

8.1 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

Members are encouraged to refer to the following for additional information on each of the topics listed above:

- The Irish Council for Bioethics “[Operational Procedures for Research Ethics Committees: Guidance 2004](http://www.bioethics.ie/pdfs/guide.pdf)” available at <http://www.bioethics.ie/pdfs/guide.pdf>
- Data protection guidance material available at <http://www.dataprotection.ie/viewdoc.asp?DocID=219>

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>

8.2 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 Research Ethics Committee 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.

8.3 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 (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
- (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. The following guidelines have been provided in the Appendices:

- Appendix 2** Guidelines regarding participant information and consent (includes sample forms for completion by participants/researchers etc.)
- Appendix 3** Guidelines for projects involving performance/abilities of school children
- Appendix 4** Guidelines on research involving genetically modified organisms

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 identifiable human material or identifiable data. The full text of this Declaration is presented in **Appendix 5**.

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

Taken from the current Institute's Data Protection Policy document

Consider carefully the documents that will bear personal information such as participant's name, address and telephone number. 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 anonymised. 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 anonymised 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 Research Ethics Committee 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 procedures defining the access and retrieval procedures for documents, including details of who is authorised to access and/or retrieve REB 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.

APPENDICES

Table of Contents

<u>Appendix 1</u>	Code of Conduct for Researchers	17
<u>Appendix 2</u>	Guidelines Regarding Participant Information and Consent	25
<u>Appendix 3</u>	Guidelines for projects involving performance/abilities of school children	32
<u>Appendix 4</u>	Guidelines on Research involving Genetically Modified Organisms	33
<u>Appendix 5</u>	Declaration of Helsinki	35

Appendix 1

Code of Conduct for Researchers

PART 1 Code of Good Practice in Research

This Code has been developed by the Ethics Sub-Committee of Academic Council and forms the basis of the Institute's Ethics Policy for all its research activities, including postgraduate research degree programmes. It draws on a variety of resources as referenced in the footnote.⁵

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 a conscientious and responsible manner possible. The Nolan Committee on Standards in Public Life in the U.K.¹¹ 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 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.

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/parliament/nolan/nolan.htm>
- http://www.wellcome.ac.uk/doc_WTD002753.html: Wellcome Trust Guidelines on Good Research Practice January 2002

- 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 Code of Good Practice in Research. The Heads of Department or Function should also bring to the attention of any individual 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 are of particular relevance to research:

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 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, 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.

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.

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 Director, 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. 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. Principal investigators and research group leaders must in turn convey 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.

Documenting Results and Storing Primary Data

- A. Throughout their work, researchers are required to keep clear and accurate records of the research procedures 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.
- 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 policy available from the Information Officer.

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 - through the refereeing process - 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.

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.

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.

Integrity in Submitting Research Proposals

Principal Investigators/Supervisors 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.

Integrity in Managing Research Projects

Principal Investigators/Supervisors should take all reasonable measures to ensure compliance with sponsor, institutional, legal, ethical and moral obligations in managing projects.

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.

Ethical Practice

A. Research Involving Human Participants and Biological Samples.

Ethical approval is required prior to conducting research involving human participants and using biological samples from the **Institute Research Board**. In addition approval is also required from collaborating Hospital Research Ethics Committees 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 **Institute Research Ethics Board** 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 **Institute Research Ethics Board** 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.

Research Misconduct

The Institute takes seriously any allegation of research misconduct and has written procedures for investigating and resolving such allegations, as outlined in Part 3 of this Code of Practice below. Any member of the Institute who believes that an act of research misconduct has occurred or is occurring should notify the relevant Head of Department. If, for any reason, this is not possible or appropriate, the individual should contact the relevant Head of School or the Registrar.

PART 2 Procedures for the Examination and Resolution of Allegations of Research Misconduct

Definition of Misconduct in Research⁶

All individuals carrying out research for the Institute are expected to observe high standards of professional behaviour both in the practice and in the publication of research.

Any practice or conduct by an individual that deviates significantly and unacceptably from the professional academic standards applicable to the relevant Department or Function for proposing, conducting and publishing research constitutes research misconduct. Violation of Institute policy is likely to render any individual researcher liable to the Institute's disciplinary procedures.

⁶ Note: research misconduct in relation to the examination process is dealt with in the Research Regulations following the procedures outlined in Appendix N.

Research misconduct includes, but is not limited to:

- (i) falsification or fabrication of data, including intentionally misleading or deliberately false reporting of research information;
- ii) unacknowledged appropriation of the work of others, including plagiarism, the abuse of confidentiality with respect to unpublished materials, or misappropriation of results, physical materials or other resources;
- (iii) conduct which seriously deviates from accepted ethical standards in research;
- (iv) falsification of credentials.

The setting of standards of professional behaviour in research is not intended to compromise the freedom, within the law, of Academic Staff to question and test received wisdom and to put forward new ideas and controversial or unpopular opinions.

The procedures below apply to all individuals carrying out research in the Institute including, without limitation,

- all Institute employees, irrespective of whether their current place of work is within or outside Institute premises
- all visiting researchers to the Institute irrespective of whether they are employed by the Institute, including persons with honorary positions, conducting research within, or on behalf of, the Institute,
- all postgraduate students of the Institute; and,
- all visiting postgraduate students.

After investigation into alleged misconduct by any individual who is not an employee of the Institute, the Director or representative or duly convened investigating group will determine the nature of any further action to be taken in relation to the misconduct.

Any disciplinary proceedings against a registered postgraduate student or researcher in respect of alleged research misconduct shall be dealt with in accordance with the provisions of the Institute Code. However, the application of this research misconduct procedure through the Institute's Disciplinary Procedures for academic and other staff shall take precedence over the Code where an individual is both a student and an employee of the Institute.

It is intended that any action carried out in terms of this procedure will be sufficient to comply with the preliminary and investigation stages required by the Institute's Disciplinary Procedures for academic and other staff.

Procedures

The Institute is committed to ensuring that all allegations of research misconduct are examined thoroughly, fairly and expeditiously.

Initial Allegation of Research Misconduct

Any member of the Institute (employee, student, or visiting researcher) or external examiner of student work who believes that an act of research misconduct has occurred or is occurring should, in the first instance, attempt to address the issue informally with either the individual concerned or the appropriate Head of Department or Function. In the event that the person who believes research misconduct is or has occurred is not satisfied with the outcome of any such informal approach or if such an approach is believed to be inappropriate, a formal complaint should be made in the first instance to the Head of the relevant Department or Function, who shall notify the Registrar and the Human Resource Manager (for academic staff) of the complaint as soon as is practicable.

If for any reason the complainant believes that it is inappropriate for the complaint to be made to the relevant Head of Department or Function, a formal complaint should be made directly to the Registrar. Where such a complaint is reported directly to the Registrar, the relevant Head of Department or Function and the Human Resources Manager (for an academic

staff member) will usually be informed about the receipt of the complaint. However, all practicable steps will be taken to protect the anonymity of any individual reporting suspected misconduct until such time as it is decided that a formal investigation is warranted.

Any person or organisation external to the Institute wishing to report suspected research misconduct should contact the Registrar.

Every complaint of research misconduct will be taken seriously. In the event that such complaint is found to be both without basis and is deemed to be malicious, vexatious or frivolous, the Institute may consider disciplinary proceedings against the instigator of the complaint.

Preliminary Action to determine whether a formal examination is warranted

The Registrar shall, assisted by the Head of the relevant Department or Function where appropriate, identify any external funding sources for the research which is the subject of the complaint, and any external collaborators. The Registrar shall also ask the person making the allegation to submit in writing a detailed statement in support of the allegation indicating what informal steps, if any, have already been taken with a view to resolving the issue. The Registrar may also, at his or her discretion, choose to evaluate anonymous allegations, depending on the seriousness of the issues, the credibility, and the feasibility of confirming the allegation with credible sources. At this stage the individual concerned shall be notified in writing by the Registrar of the allegation and informed that it is to proceed under this procedure. At the same time, he or she should be given a copy of this Code which includes Procedures for Investigating and Resolving Allegations of Misconduct in Research.

The Registrar shall, normally within a maximum of 5 working days of the allegation being reported to him or her, appoint an Investigation Team consisting of 2 individuals who, in the opinion of the Registrar have no conflicts of interest in the case, are unbiased, and have expertise to evaluate the appropriate research issues.

Where feasible the Investigation Team shall consist of one staff member from the School (or, in the absence of a related School, the relevant administrative centre) in which the research activity in question has been conducted and one staff member from elsewhere within the Institute. The Investigation Team shall specifically limit its role to that of evaluating only the facts to determine whether there is sufficient evidence of research misconduct to proceed with a formal investigation. The Investigation Team shall keep proper records of their proceedings. The individual against whom the complaint has been made shall be notified by the Registrar of the members of the Investigation Team.

The initial investigation will normally involve the Investigation Team examining relevant research records and materials. The Investigation Team shall complete its initial investigation and submit its report in writing to the Registrar, normally within a maximum of 5 working days from the date the Team is appointed. The report shall state what evidence was reviewed and conclude whether the investigation should end or continue to further formal investigation.

Care must be taken to maintain the anonymity of the initiator of the complaint where possible at this stage.

The Registrar shall, normally within 2 working days of receipt of the report, notify the individual concerned and his or her Head of Department or Function in writing of the outcome of the initial investigation. The Registrar shall also inform the instigator of the complaint whether a formal investigation is to proceed and that this information is to remain confidential.

Formal Investigation

The purpose of the Formal Investigation is to examine and evaluate all relevant facts in relation to the allegation of research misconduct. In addition its purpose is to determine whether there are sufficient grounds for proceeding with the complaint in respect of a postgraduate student, under the General Student Discipline Policy & Procedures (**Appendix O of the Code of Practice for Research Degree Programmes**) or in respect of Institute employees, under the Institute Procedures for the Resolution of Grievances/Disputes which includes Disciplinary Procedures for Academic Staff (**Appendix P of the Code of Practice for Research Degree Programmes**). Where the alleged misconduct is in respect of research carried out for the Institute by an individual not employed by the Institute, the purpose of the Formal Investigation is to allow the Director to determine whether any further action should be taken.

The Head of Development following notification by the Registrar shall, only where necessary in terms of the funding conditions, notify the any bodies which provide funding related to the research of the individual concerned of the ongoing investigation. The Registrar shall also notify any other body related to the research concerned in the event that the Institute is contractually obliged to notify that body about the ongoing investigation. At the initial stages of the investigation such bodies shall be informed that the allegations have not yet been fully investigated and that the Institute does not expect any funding body to suspend the grant or contract as adequate steps are being taken to proceed with the investigation.

In the case of alleged misconduct by any individual not employed by the Institute, the relevant individual's employer should only be informed that an investigation is taking place where the misconduct relates to the research that the individual concerned is carrying out for the Institute and the individual is carrying out that research by virtue of his or her employment with that other employer. The Institute shall also ensure that, by carrying out an investigation into the alleged misconduct, it complies with any contractual arrangements in place between the Institute and the employer of any individual carrying out research for the Institute.

However, it is essential to keep circulation of details of the allegations and investigation as limited as possible. Any such information must be disclosed subject only to an undertaking of confidentiality from the recipient.

An Investigation Panel, which may include the members of the existing investigation team, shall be appointed by the Human Resources Manager in conjunction with the Registrar, normally within a maximum of 2 days. The Registrar shall not serve on the Investigation Panel. The Panel shall keep written records of the proceedings and will be provided with secretarial assistance by the Institute if required. The Panel shall inform the individual concerned in writing of the confirmed membership of the Panel and of the scope of the intended investigation, and of their right to legal or appropriate representation, should they see fit.

The Panel shall:

- (a) Interview the individual concerned and any other parties it chooses, including the initiator of the complaint and other members of the research group;
- (b) Widen the scope of its investigation if it considers that necessary, subject to keeping the individual concerned informed, in writing, of the increased scope of the investigation;
- (c) Require the individual concerned - and if it judges it necessary, other members of the Institute - to produce files, notebooks and other records;
- (d) Seek evidence from other parties;
- (e) In the event of the defendant not cooperating with the investigation panel, the panel will be empowered to draw conclusions and make decisions about the allegations;

- (f) The panel will make decisions on the balance of probability;
- (g) It shall be the panel's position to prove the allegations and not the individual's duty to disprove them; the presumption of innocence applies.

The individual concerned shall be given a full opportunity to comment on all the evidence gathered by the Investigation Panel before the report is finalised. Where he or she is interviewed by the Panel he or she should be informed that he or she may be accompanied by a member of staff or a representative of a Trade Union, or a legal representative, or a representative of their choosing.

The Investigation Panel shall submit a report in writing, normally within a maximum of 20 working days of the confirmation of the members of the Investigation Panel, to the Director and the Registrar. The report shall generally describe the investigative process, indicating whether or not it finds there are sufficient grounds for proceeding with the complaint under the appropriate Disciplinary Procedures (Appendix G or H). The Panel shall make a recommendation to the Director about whether it has found that there are such grounds. In addition, the Panel may make recommendations on the future operation of these procedures.

The Director will determine the nature of any further action to be taken regarding investigated misconduct in relation to any research carried out for the Institute by any individual not employed by the Institute. This may include advising the employer of the individual concerned of the findings of the investigation. The Director may also consider the suspension or withdrawal of any honorary contract. Where no action is to be taken in relation to individuals not employed by the Institute, the Registrar shall take all appropriate steps to inform all parties previously notified of the alleged misconduct, of this outcome.

After the completion of the appropriate Disciplinary Procedures, the Director may, in addition to or instead of any sanction to be imposed under those procedures:

- (a) convey the outcome of the Disciplinary Proceedings to the professional body or bodies it deems appropriate (e.g. the Irish Medical Council), any relevant grant-awarding bodies or any other public body with any interest, the editors of any journals which have published articles by the person against whom the allegation has been upheld or any other body which, in the opinion of the Institute, is likely to be affected by the research misconduct in question. All such disclosure must be limited to misconduct upheld in relation to research relevant to such bodies or published by such journals;
- (b) recommend to HETAC and Governing Body, where misconduct has been established and the research concerned contributes to or contributed to a degree or other academic award of the Institute, the revoking or withholding of that award;

If the allegation has not been upheld after completion of the Disciplinary Procedures, the Registrar shall take all appropriate steps to inform all parties previously notified of the alleged misconduct, of the outcome of the Disciplinary Procedure. In the event that the Institute becomes aware that the allegations which have been investigated have become public, the Institute may consider taking reasonable steps to confirm the outcome of the Disciplinary Proceedings to the parties concerned.

The time scales set out in this procedure are not binding upon the Institute and can be extended where reasonably required. The individual under investigation will be notified in writing of any such extension and the reason for it. Where any of the Institute personnel named as having responsibilities under this procedure are absent or unavailable, the Director may appoint alternates.

Appendix 2

Guidelines Regarding Participant Information and Consent

A Participant Information Leaflet and Consent Form must be submitted to the Research Ethics Board. If there is an external sponsor, submit the sponsor's information leaflet and their consent form. For non-sponsored projects the investigator may draw up a participant information leaflet based on the following outline. The leaflet should be written in clear non-technical English and aimed at the potential participants in the project, and not at members of the Research Ethics Committee. All the headings in the following outline should be included. For several of the headings, the recommended wording is provided in *italics* and should be used if appropriate for the particular study.

A sample consent form is also provided below.

1. Title of study: xxx

2. Introduction: Provide a brief description of the research project, stating the purpose of the study, the procedures involved, and the extent of the participant's involvement, e.g. time span of participation, expected number of visits to the laboratory or clinic.

3. Procedures: List the criteria for selection for participation in the study, e.g. that the participant has a particular complaint, is between certain ages, is not covered by the criteria for exclusion, and, if a woman, is not pregnant or likely to become pregnant. Then detail the nature of the participant's involvement, e.g. that the participant will undergo initial tests, will then take a course of medication, will have return visits to the doctor and subsequent examinations, etc. Note that the participant must be informed about the manner in which a drug is to be administered and whether an inactive substance (a placebo) may be administered.

4. Benefits: List any potential benefits of the study. These may include direct benefits or be related to future more general benefits as a result of knowledge gained.

5. Risks: List the material risks, discomforts and side effects involved in participating in the study. Material risks are those that a prudent person in the participant's position would regard as significant in considering whether or not to undergo the procedures in question. If the risks attaching to a treatment are unknown this should be stated.

6. Exclusion from participation: *You cannot participate in this study if any of the following are true:* (list the criteria excluding an individual from participating in the study).

7. Confidentiality:

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study group.

8. Compensation:

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

9. Voluntary Participation: *You have volunteered to participate in this study. You may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study.*

10. Stopping the study: *You understand that the investigators may withdraw your participation in the study at any time without your consent.*

11. Permission: State that the trial has Research Ethics Committee approval from all institutions involved.

12. Further information: *You can get more information or answers to your questions about the study, your participation in the study, and your rights, fromwho can be telephoned at If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.*

INFORMED CONSENT FORM - SAMPLE 1

Research Involving Human Participants

(Adapt as relevant to your study)

The researcher should retain the original of the signed form in a secure file, give one copy to the participant, and send one copy to the sponsor (if appropriate).

Project title:		
Principal Investigators:		
BACKGROUND: (provide short summary of what project involves for participants, including the procedures to be carried out and the assurance of confidentiality)		
Participant Declaration: (This should be written in the first person and include agreement that I (i.e. the participant): <i>Tick yes or no as appropriate</i>		
Have read or have had the information sheet read to me and that I understand the contents.	Yes	No
Have been given an opportunity to ask questions and am satisfied with answers.	Yes	No
Consent to take part in the study.	Yes	No
Understand that participation is voluntary and that I can withdraw at any time.	Yes	No
Understand that withdrawal will not affect my access to services or legal rights.	Yes	No
Consent to possible publication of results.	Yes	No
I (the participant) give my permission to: Use the data obtained from you in other future studies without the need for additional consent.	Yes	No
Researcher Declaration: (This should be written in the first person and include agreement that I (i.e. the researcher): <i>Tick yes or no as appropriate</i>		
Have explained the study to the participant	Yes	No
Have answered questions put to me by the participant about the research	Yes	No
Believe that the participant understands and is freely giving consent	Yes	No
Participant's Statement: I have read, or had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand I may withdraw from the study at any time. I have received a copy of this consent form.		
Participant's Name:		
Contact Details:		
Participant Signature: (where participant is over the age of 18)		

Date:

The form needs to be signed by the consentor (or a parent or guardian in the case of the participant being unable to understand the scope, nature or significance of the study or in the case of the participant being under 18 years) and dated.

NAME OF CONSENTER, PARENT or GUARDIAN:

SIGNATURE RELATION TO PARTICIPANT:

Date:

Researcher's Statement:

I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Signature:

Date:

INFORMED CONSENT FORM ⁷ SAMPLE 2 FOR RESEARCH PARTICIPANTS IN INTERVIEWS

The aim of this form is to facilitate informed consent by communicating with participants in language that they can understand. The material below is a sample – it does not have to be reproduced verbatim. Adapt it to fit the circumstances of your own study. Some of the sample text below assumes a study involving qualitative interview data. If that's not your methodology, adapt the text to the approach you are using.

Information Sheet

Purpose of the Study: As part of the requirements for [degree] in ITT Dublin, I have to carry out a research study. The study is concerned with [keep it brief and simple – 1-2 sentences. There is no need to go into the theoretical complexities of the topic.]

What will the study involve? The study will involve [Indicate the procedure and time commitment, giving the simplest possible explanation and avoiding jargon and unnecessary detail.]

Why have you been asked to take part? You have been asked because [Because they are specifically or generally suitable to provide data for your study].

Do you have to take part? [The answer is no! – participation is voluntary. Explain about signing a consent form. Ideally they get to keep the information sheet and a copy of the consent form. They should be told that they have the option of withdrawing before the study commences (even if they have agreed to participate) or discontinuing after data collection has started. Where data are identifiable (e.g. from interviews yielding qualitative data), it's useful to allow for afterthoughts by letting them withdraw within two weeks of participation and ask to have their data destroyed. Explain all this in writing.]

Will your participation in the study be kept confidential? [Yes! - but remember, there's no such thing as absolute confidentiality – don't ever make promises you may not be able to keep. Usually the relevant term is anonymity rather than confidentiality. For example:] Yes. I will ensure that no clues to your identity appear in the thesis. Any extracts from what you say that are quoted in the thesis will be entirely anonymous.

What will happen to the information which you give? [Kept confidential from third parties (including workers' superiors, if relevant); will it be destroyed after a period? For example:] The data will be kept confidential for the duration of the study. On completion of the thesis, they will be retained for a further five years in a secure environment and then destroyed.

What will happen to the results? [For example:] The results will be presented in the thesis. They will be seen by my supervisor, a second marker and the external examiner. The thesis may be read by future students on the course. The study may be published in an academic journal.

What are the possible disadvantages of taking part? [If you think there are none, say so, but not in a black-and-white way. Before approaching this and other persons you should have

⁷ The following draws extensively on a document produced by Dr R. Swain of UCC, and is used with permission. Copyright is vested in same and all rights therein remain with Dr Swain.

discussed with your supervisor the implications of asking for the participation of this person and other like them. Upon asking them you may realise that a research question may raise issues that you are not qualified to deal with, even if you should then refer them on to other agencies. If they may feel distressed, mention the possibility and refer to the next section. For example:] I don't envisage any negative consequences for you in taking part. It is possible that talking about your experience in this way may cause some distress.

What if there is a problem? *[Tell them what they can do, for example:] At the end of the interview [/procedure], I will discuss with you how you found the experience and how you are feeling. If you subsequently feel distressed, you should contact...[e.g. the investigator, The Samaritans – give contact details - or their GP].*

Who has reviewed this study? *[Institute Research Ethics Committee? Local Hospital's Ethics Committee? Both? For example:] Approval must be given by the Institute before studies like this can take place.*

Any further queries? *If you need any further information, you can contact me: [Name, mobile number, email address. Specify times and dates you will be available, be available then and reply promptly should you be unable to take the call, or reply to the e-mail, at that time. To protect your own privacy, you should delete this information from the finished thesis].*

If you agree to take part in the study, please sign the consent form overleaf. [Note the formatting – it's best not to have text dribbling on to the next page – but don't make the font size too small, either – say, not less than size 12. Remember you can adjust the size of the margins.]

ADDITIONAL GUIDELINES FOR A PARTICIPANT INFORMATION LETTER

Include the following points:

- 1. Names of researchers**
- 2. Working title of study**
- 3. Description of study**
 - Aims and objectives of study (what the study is about, why this population)
 - Contribution required from participant (what the study involves, what the participant will be asked to do)
 - Possible benefits of the study
 - Possible risks to participants and after effects
 - Location of research
 - What will happen to the results of the study
- 4. Confidentiality of information**
 - How information will be stored
 - How confidentiality will be ensured
- 5. Compensation**
- 6. Voluntary participation**
 - Not obliged to take part
 - May withdraw at any time
- 7. Permission**
 - Ethical approval from X institutions
- 8. Further information and how to take part**
 - Instructions on completion of consent form
 - Contact details of researcher

Appendix 3

Guidelines for projects involving performance/abilities of school children

- Except with very young children, individual assent should be obtained from each child as well as formal consent from a parent/guardian
- Children in second level education should give written assent except for “children” age 16 or over who may give their consent
- If study data are passed to the school they should be anonymised
- If it is seen as appropriate for remedial purposes that data on a particular identifiable child are passed to the school, this must be approved in advance by the parent/guardian
- If the investigator is a student, the decision to pass information on an identifiable child to parent/guardian or school must be made by the investigator’s supervisor.

Appendix 4

Guidelines on Research involving Genetically Modified Organisms

Information Sources: Table 1 EU legislation

Directive/Regulation	Purpose	Competent Authority	Aspects regulated
Directive 90/219/EEC	Regulates the contained use of GMM s	EPA	Contained use of genetically Modified Micro-organisms (GMM's), also GM animals & GM plants.
Directive 90/220/EEC Directive	Regulates the deliberate release of GMO's into the environment for: i. R&D purposes-Field Trials ii. Placing GMO products on the market	EPA Department of Environment & Local Government are responsible for certain functions, e.g. decisions to place GMO's on the market under Article 21 of this Directive.	Environmental assessment for the cultivation and importation of GMO's in the EU; Animal feed aspects - feeding of 'live' GMO's to animals; Human health aspects (including toxicity and allergenicity), related to the cultivation of GM crops in the EU.
Directive 90/679/EEC	Regulates biological agents in the workplace	Health and Safety Authority (HSA)	Workplace contact
Directive 94/55/EC	Regulates the transportation of certain GMO's	Department of Enterprise Trade & Employment	Transportation
Regulation 258/97/EC	Regulates Novel Foods & Novel Food Ingredients-including GMO's	Department of Health & Children	Foods and food ingredients containing or consisting of GMO's; Foods and food ingredients produced from, but not containing GMO's, for example, oil from GM soybeans.
Regulation 1139/98/EC	Regulates the labelling of certain foodstuffs produced from GMO's	Department of Health & Children	Labelling of foods derived from GM soybean and GM maize (Ciba maize).
2309/93/EEC	Regulates GMO's for medicinal and veterinary use	Irish Medicines Board (IMB)	Regulates medicinal & veterinary products including those products which contain or consist of GMO's.
Directive 91/414/EEC	Regulates the use of plant protection products	Pesticide Control Service of the Department of Agriculture & Food	Regulates the use of herbicides, insecticides & fungicides etc. on crops including GM crops.

Section 1.01 Table 2 EU Legislation in preparation

Directive	Purpose	Competent Authority	Aspects regulated
Seed for cultivation	The proposed Directive will amend current Directives relating to seed	Department of Agriculture & Food will be responsible	Regulates GM seed to be placed on catalogues for use in agriculture.
Animal feed	The proposed Directive will amend current Directives relating to animal feed	Department of Agriculture & Food will be responsible	Regulates animal feeding stuffs containing or consisting of GMO's and feed derived from GMO's.

ALSO CONSULT:

- Environmental Protection Agency: <http://www.epa.ie/>
- Department of the Environment & Local Government <http://www.environ.ie/>
- Department of Health & Children - <http://www.doh.ie>
- Department of Agriculture and Food- <http://www.irlgov.ie>
- Pesticide Control Service-DAF- <http://www.irlgov.ie/daff/>
- Department of Enterprise, Trade and Employment- <http://www.entemp.ie>
- Irish Medicines Board <http://www.imb.ie>
- Health and Safety Authority <http://www.hsa.ie>
- Food Safety Authority of Ireland <http://www.fsai.ie/>
- The Department of Arts, Culture, Gaeltacht and the Islands - <http://www.irlgov.ie/ealga/>
- EU Commission Sites: <http://europa.eu.int/comm/dg11/abc.htm>
- <http://europa.eu.int/comm/dg24/>

Appendix 5

Declaration of Helsinki

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 identifiable human material or identifiable data

Recommendations Guiding Physicians in Biomedical Research Involving Human Participants.

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964 and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983 and the 41st World Medical Assembly, Hong Kong, September 1989.

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration" and the International Code of Medical Ethics declares that "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient".

The purpose of biomedical research involving human participants must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human participants.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may effect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human participants. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the law of their own countries.

Basic Principles

1. Biomedical research involving human participants must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
2. The design and performance of each experimental procedure involving human participants should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in

conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human participants should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human participant must always rest with a medically qualified person and never rest on the subject of the research, even though the participant has given his or her consent.
4. Biomedical research involving human participants cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the participant.
5. Every biomedical research project involving human participants should be preceded by careful assessment of the predictable risks in comparison with foreseeable benefits to the participant or to others. Concern for the interests of the participant must always prevail over the interests of science and society.
6. The right of the research participant to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the participant and to minimize the impact of the study on the participant's physical and mental integrity and on the personality of the participant.
7. Physicians should abstain from engaging in research projects involving human participants unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential participant must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the participant's freely-given informed consent, preferably in writing.
10. When obtaining informed consent for the research project the physician should be particularly cautious if the participant is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.
11. In the case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the participant is a minor, permission from the responsible relative replaces that of the participant in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.
12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

Medical Research Combined with Professional Care (Clinical Research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-

establishing health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighted against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient - including those of a control group, if any - should be assured of the best-proven diagnostic and therapeutic method.
4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons for the proposal should be stated in the experimental protocol for transmission to the independent committee.
6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

Non-Therapeutic Biomedical Research involving Human Research Participants (Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
2. The participants should be volunteers - either healthy persons or patients for whom the experimental design is not related to the patient's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the participant.