

Trinity College Dublin

**Policy on
Good Research Practice**

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1. Introduction

Scholarly research has been conducted at Trinity College, Dublin for over four centuries. In that time, there has been no indication other than this research has been carried out to the highest international standards. However, in many areas, research has become very competitive and more complex in its collaborative links. In 2002, to bring Trinity into line with best international practice the Board adopted a policy on Good Research Practice. This 2009 revision re-appraises and where appropriate has updated or amended the 2002 guidelines and provides for a new superintending structure of ethical matters for College in the form of an over-arching Ethics Policy Group.

The guidelines laid down in this policy apply to all staff and students, including all staff categories, all research students and all in the research community, including visitors, throughout the college, including its affiliated teaching hospitals and other institutions. This policy has been adapted and developed from others in common use internationally. Good research practice cannot be policed. Rather it must be inculcated in the research ethos of the college at the level of the individual executor of research, and through wide dissemination of this policy both publicly online and in the induction of new staff and students, we undertake to inform all concerned about their rights and duties as laid out in this document.

Good research practice will in certain cases place some limits on the nature of research being carried out. However, the principle of academic freedom must at all times be defended. It is recognised that, given the novel nature of this policy and its complexity, additional future revision will be likely required. The research Committee should provide a progress report to Council on the implementation of this policy every five years.

2. Ethics

Preamble

The following guidelines apply to *all* research conducted in or under the auspices of Trinity College Dublin with particular emphasis on research involving human subjects and participants; animals; human biological material or genetically modified organisms. To protect the welfare and rights of research subjects: participants involved in research, it is essential that research is conducted in an ethical manner. All individuals involved with research have a role to play in facilitating and making sure that research is conducted ethically. The ethical conduct of research is a shared responsibility.

General Guidelines

In all research, in addition to the Law of the Land, the over-arching ethical principles for Trinity College can be summarised as:

- **respect** for the individual subject or population
- **beneficence & the absence of maleficence** (research should have the maximum benefit with minimal harm)
- **justice** (all research subjects and populations should be treated fairly and equally)

For human participants involved in research, TCD stipulates that the autonomy of the potential research participant should be respected by providing, in clear and accessible format, the maximum information on the implications of participation in a project and allowing independent and informed decision-making on whether to participate. The information should include written details of risks and benefits in participating, and a guarantee of confidentiality, preferentially through implementation of a controlled scheme for participant anonymisation. In the main, participants should sign a consent form to agree to take part in the research. Negative consent - for example, absence of signed statement declining participation - is not generally permissible and may only be employed in cases such as in anonymous surveys conducted in behavioural research, or in questionnaires employed in epidemiological studies. In all cases, participants should be made aware of their right to withdraw from the research without penalty at any time, including the withdrawal of their data after participation. All participants should also be formally notified that they are also free to access their own data at any time under the Freedom of Information Act.

When research involves those with literacy difficulties, children or other potentially vulnerable groups of participants, rigorous adherence to the appropriate professional codes of ethical practice is required and particular attention must be paid to issues such as access, informed consent by both participants and carers (negative consent is not permissible in these cases), and the duty of care and conduct adopted in College shall conform to that detailed in the guidelines published by the TCD Children's Research Centre, which have been developed in consultation with the UK National Children's Bureau. Additional formal authorization for the research or clearance of research staff by An Garda Síochána may be required in certain cases.

For research using pharmaceuticals TCD subscribes to those guidelines set down by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

To assure the protection of human subjects of research in both biomedical and behavioural research involving human participants TCD adopts the guidelines detailed in the NIH Belmont Report.

Research involving animals in TCD is governed by EC directive 86/609. Researchers must have completed a comprehensive training programme and must additionally be licensed by the Department of Health and Children. All research involving animals is regulated by the College's bioresource committee. Animal studies are permitted by the College only when it is clear that such work will positively contribute to the advancement of knowledge intended improve the health and welfare of patients – both animals and humans. Studies using animals are not to be undertaken lightly, studies can only be conducted on the basis of well-defined scientific objectives, with specific consideration to the welfare of the animals and must always minimise the number of animals used. Wherever possible, viable alternates to using live animals must be employed – including simulations, cellular systems and sourced tissue samples. It is a stipulated requirement for researchers to demonstrate that there are no alternatives available before permitting research work using animals.

For guidelines on research involving genetically modified organisms (GMOs) and genetically modified (GM) products, TCD will be wholly compliant with Irish legislation, noting that The Environmental Protection Agency (EPA) is the authority in Ireland which implements GMO Regulations, including research consents, on:

- The contained use of Genetically Modified Organisms
- The deliberate release of Genetically Modified Organisms into the environment
- The transboundary movement of Genetically Modified Organisms

TCD formally adopts the guidelines of the EPA in this regard. Our researchers are legally obliged to submit a notification to the Environmental Protection Agency in accordance with the requirements of the Contained Use legislation, seeking the Agency's consent before commencing work with GMOs.

In the area of *utility* of stem cells derived from human embryos in research, in the absence of a national framework or legislation on this matter, TCD subscribes to an ethical code of practice on the *use of established human embryonic stem cell lines* (hES cells) in research compliant with that detailed in the published opinion of the Irish Council for Bioethics, and to the guidelines of the Irish Medical Council. Any transfer of established human embryonic derived cell lines to TCD for use in research must be accompanied by a full materials transfer agreement, including details of the ethical compliance of the transferring institution for the derivation of the line in accordance with ISSCR guidelines. Researchers wishing to employ stem cells derived from human embryos in their research in Trinity College Dublin are required to have their proposed use of such materials reviewed by a College ethics subcommittee in the context of compliance with international ISSCR ethical guidelines. TCD

formally limits the permitted range of experimentation involving on hES cells, to those defined as category 1 and category 2 section (10.2e) in Section 10 of the ISSCR Guidelines (see Appendix).

For clarity, this policy serves to :

- restrict hES research in TCD to the use of pre-existing hES cell lines, with such research being “confined to cell culture or involve(s) routine and standard research practice”. (ISSCR Category 1);
- facilitate under ISSCR Category 2 (10.2e) the use of hES cell lines to generate chimaeric models in animals such as mice and rats;
- exclude the generation or study of chimaeric non-human primates;
- prevent any research in areas classified as ISSCR Category 3 (including therefore the use of hESC in humans or non-human primates);
- prevent any research in which chimaeric animals containing hES cells are bred.
- prevent any research on human embryos so precluding the generation of any new hES cell lines at TCD;

This policy position is deemed pragmatic insofar as it underpins TCD’s enshrined principles of academic research freedom through facilitating qualified and responsible researchers who wish to import and study established hES cell lines within an ethical framework of use. Such researchers, with requisite internal ethical approval, will be able to carry out a wide range of studies on these cells *in vitro* and in routine animal models. This policy makes a clear distinction between the study of non-human primates and common laboratory animals such as mice and rats. TCD researchers will not be able to create new hES cell lines under this policy.

In all cases where research is carried out under the Auspices of Trinity College Dublin, within or without the defined campus properties, the College expects compliance with the policies as set out in this document and additional compliance with the policies of the relevant body of the organization wherein any external research is conducted.

Appended to this document are selected supporting external published resources offering guidelines on good ethical research practice.

Trinity College Ethics Structures

College Research Ethics Policy Group

This group, (the REPG) functioning as a standing subcommittee of the College Research Committee will serve as the over-arching institutional research ethics body mandated to ensure appropriate policy is in place governing all research conducted under the auspices of Trinity College Dublin. This group will function independently of but in co-ordination with other Faculty, School or Unit sub-committees on ethics, and will serve as the final authority in matters of ethical conflict or dispute.

Roles & responsibilities

- To recommend ethical policy to the College Research Committee for adoption and implementation;
- To assume ownership and responsibility for the contents of the College's Policy Document on Good Research Practice, so maintaining a central set of broad guidelines governing the wide array of research in College, with the provision for the development of expedited guidelines as and when required;
- To serve as an arbitrator on matters pertaining to research ethics at the University;
 - Routine review of ethical policy compliance is devolved to Faculty, School or Unit subcommittees. In cases where conflict arises between the promoters of research and the reviewing committee, the promoter has the right to appeal decision to the REPG for review at one of its bi-annual meetings. Any ruling of the REPG on such appeals is final.
- To be responsible, where appropriate, for liaison with external organisations;
- To superintend the provision of relevant ethical policy information for staff and students engaged in research.
- To advance proposals for streamlining the *process* of ethical review in College, while safeguarding maximal compliance with the policy on good research practice
- To convene on an annual basis to review the notifications from extant subcommittees and to consider any submissions made in relation to review of ethical policy in TCD, or more frequently as required, furnishing an annual report to the Research Committee on ethical matters.
- Requisite Notifications from approved College ethics sub-committees shall include:
 - standard operation procedure with details including:
 - membership
 - frequency of meetings
 - definition of studies requiring ethics clearance
 - application form
 - lines of reporting
 - autonomy
 - indemnity
 - utility of necessary legal support & advice
 - appeals
 - identification of unmet policy needs

Extant Ethics Sub-committees based in or affiliated with Trinity College, Dublin

- Trinity College Bio-Resources Use of Animals in Scientific Research
- Faculty of Health Sciences Research Committee
- School of Psychology Research Ethics Committee
- School of Social Work and Social Policy Ethics Approval Committee
- School of Nursing and Midwifery Research Ethics Committee
- School of Linguistic, Speech and Communications Sciences Research Ethics Committee
- The Joint Research Ethics Committee (St James's Hospital, Adelaide and Meath Hospital and Dublin Dental Hospital)
- St Patrick's Hospital Research Ethics Committee
- Rotunda Hospital Research Ethics Committee

The REPG is charged with maintenance of this list and designation of approved status to such ethics sub-committees affiliated or of College.

Units without ethical review subcommittees

It is the recommendation that in all cases where a School or Unit does not have a standing subcommittee facilitating research ethics review and approval that any application to conduct research which requires ethical approval would be referred in the first instance through the School Director of Research to the Faculty Dean of the researcher in question. The Director of Research should indicate their view on compliance or otherwise of the proposed research with the ethical guidelines detailed in this document. On receipt of such referral, the Faculty Dean can direct the applicant to the utility of an alternate established committee for review, or convene a specific review committee for the purposes of conducting the requested ethical review of compliance with the guidelines detailed in this policy. Faculty Dean(s) will submit records of any such referrals or specific reviews to the Research Ethics Policy Group. In cases where more than ten (10) cases requiring review arise within any academic year from any given Faculty structure for which no review group is extant, the Faculty in question will convene a standing ethics review committee for that unit.

Processes of review

While recognizing that the extant review bodies of College has specific and established processes and terms of reference, it is recommended that all ethical review committees would examine their processes of review and adopt all appropriate enabling methodologies with a view to ensuring the timely approval of research applications shown to be compliant with the guidelines of this document.

It is additionally recommended that all research ethics reviews would contain the following specific checkpoint question : 'Has this research application or any application of a similar nature been refused ethical approval by a review committee of College?' Review committees are requested to specifically document the details of any affirmative such instances in their bi-annual submissions of review / approval statistics to the Research Ethics Policy Group.

TCD position on reciprocity of ethical approvals from third party collaborating institutions

Trinity College Dublin recognizes that our collaborating institutions worldwide conduct research under established ethical procedures and policies. To facilitate collaboration Faculty, School or Unit sub-committees are granted the discretion to recognize reciprocity of recognition of ethical approvals granted in collaborating institutions. i.e. – such ethical approval will be duly considered in any internal review of TCD based research activities, and will form a starting point for such review. In such instances, applicants seeking ethical reciprocity consideration will be expected to furnish details on the ethical approval granted in the collaborating institution and an explanatory text on how that approval is in keeping with the College's ethical policy and guidelines as detailed in this document.

3. Integrity

Preamble

Research Integrity covers many issues including research misconduct, conflict of interest and policies for inquiring into allegations of research misconduct.

General Guidelines

This section starts by addressing the definition of research misconduct whilst making provision for honest error or differences of opinion. A subsection on potential conflict of interest and its definition follows. Disclosure of any potential conflict of interest is essential for the responsible conduct of research and reference is made to the Appendix at the end of this document showing the form to be used in making a declaration of interest. The next subsection outlines the stages that should take place when dealing with an allegation of research misconduct. These guidelines additionally recognize the existing relevant mechanisms are in place in College such as in the case of Policies and Procedures for Dealing with Complaints of Harassment including Sexual Harassment, Bullying or Fraud.

Research Misconduct

Research Misconduct is defined as but is not limited to fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Research misconduct includes misquotation or misrepresentation of other authors or inappropriate attribution of authorship. Research misconduct does not include honest error or honest differences of opinion in interpretations or judgements of data. In particular, the analysis of either old or new material and subsequent drawing of new conclusions, is not considered to be Research misconduct.

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment, or processes, or changing, distorting, dishonestly misinterpreting or omitting data or results such that the research is not accurately represented in the research record. The omission of data is considered falsification when it misleads the reader about the results of the research. Publication of data known or believed to be false or misleading is regarded as falsification. The *research record* is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, or dishonest use of unacknowledged sources. Plagiarism is also dealt with as part of the wider General Regulations of the University of Dublin, as detailed in the Annual Calendar

Maliciously making false accusations of research misconduct against someone is considered a serious matter that may be dealt with using College's established disciplinary measures. However, drawing new conclusions from material previously interpreted in a different way,

which may result in previous conclusions being contested, is not regarded as maliciously making false accusations of research misconduct.

Research misconduct includes failure to obtain appropriate permission where required to conduct research, whether deliberate, reckless or negligent and also includes misuse of research funds or research equipment. Fraud or misuse of research funds or research equipment may also be dealt with under separate Financial Regulations and Fraud Policy in the College.

Research Misconduct also includes collaborating with others to become involved in research misconduct or encouraging others to be involved or concealing research misconduct by others when there is clear evidence to that effect.

Deception in relation to research Proposals. Principal Investigators should take all reasonable measures to ensure that accuracy and completeness of information is contained in applications for funding. Misrepresentation of a researcher's qualifications or ability to perform the research in grant applications or similar submissions may constitute falsifications or fabrication in proposing research.

Integrity in Managing Research Projects. Principal Investigators should take all reasonable measures to ensure compliance with sponsor, institutional, legal, ethical and moral obligations in managing projects.

Behaviour in the Conduct of Research. The University acknowledges that it must play a proactive role in helping researchers achieve Good Practice in Research. Researchers must strive continually to improve their scholarship and to ensure that their knowledge is current. Above all, they must bring due care and diligence to bear upon the discharge of their academic duties in relation to research. This is so for staff involved in research on animals, as well as humans (section 2 – Ethics) who must not engage in unethical behaviour. In particular staff involved in research must ensure that deviation from good research practice does not occur where this results in unreasonable risk of harm to humans, particularly children and vulnerable adults, animals or the environment. Researchers must refrain from participating in or initiating work that they are not competent to perform. They should be willing, when in doubt, to obtain such advice and assistance as will enable them to execute their research competently. In human or animal experimentation, departing from approved protocols (see section 2, Ethics) accepted by a specific discipline would constitute serious misconduct.

General Principles of Sound Research Design. In seeking new knowledge, it is imperative that a good methodology (i.e. sound research design) be employed that ensures trust in the accuracy of the data collected and facilitates correct interpretation of the data.

In keeping with the wider General Regulations of the University of Dublin, researchers must refrain from any conduct or action in their role as a researcher employed by or working in the University which would unfairly detract from the good name of the institution and any relevant professional body to which they may belong.

Conflict of Interest

The text below sets out the definition of conflict of interest and refers to a Declaration of Interest document that is to be signed at contract signature stage.

The primary purpose of seeking declarations of interest is one of transparency.

The College and society as a whole has the right to know that a recognised expert in a given area has an interest, material or otherwise which could be seen to pose a conflict. Declaring such interests is one way of indicating that the declared interest is perfectly ethical and need not interfere in the researcher's capacity to conduct independent research.

Definition of Conflict of Interest

For the purposes of this policy, the definition of Conflict of Interest shall include, but not be limited to, the following:

- When a person's judgement concerning a primary interest could be unduly influenced by a secondary interest.
- Apart from financial interests (including benefit in kind), conflicts might, for example, be personal, academic or political.
- Conflicts of interest can occur at any stage of the research endeavour. For example, submitting the same proposal to different grant bodies may be acceptable, whereas accepting more than one source of funding for exactly the same proposal may not be acceptable.
- There is nothing inherently unethical in finding oneself in a position of conflict of interest; what is required is to recognise the fact and deal with it accordingly.

Disclosure of potential conflict of interest

Disclosure of any potential conflict of interest is essential for the responsible conduct of research. This should cover disclosure of such interests to the persons responsible for institutional research management, to the editors of journals to which papers are submitted and to bodies from which funds are sought.

An obligation is placed on the recipients of all research grants to declare any interest that would interfere with or compromise the performance of research supported by the grantor. This is to ensure the technical integrity and impartiality of the researcher's work.

The absence of, or an official declaration of interest for all participants or proposed participants in research, must be disclosed at the point of contract acceptance (or earlier if required by research sponsors).

Every researcher should exercise responsibility when applying to and/or accepting money from a sponsor. Intentionally failing to reveal a known interest may be regarded as research misconduct and may be subject to disciplinary action.

When circumstances may exist (at contract acceptance stage or during the course of any research project) which could lead to a conflict of interest or be seen to do so, the investigator is required to divulge sufficient such information in writing to the University.

If a researcher working with an organisation is approached by a competing entity, the onus is on the researcher to inform the latter entity that he/she is already conducting some work for the former entity provided there is a substantial overlap in the research endeavour. Similarly, the researcher should only accept a contract with the latter entity if he/she has informed the former entity of this new contract (if there is a substantial overlap in the research endeavour).

Given that documents relating to the Declaration of Interest will be accessible to any who may request it under the Freedom of Information Act, the onus is on a researcher to think carefully about their position before filling in the declaration of interest form.

Declaration of Interest Documents should be kept for a minimum period of five years.

Determination of Research Misconduct. The College will investigate all allegations of Research Misconduct using the procedures outlined in accordance with its established disciplinary procedures (detailed in the College Calendar). These College policies provide a framework for dealing with elements of allegations of Research Misconduct. The Offices of the Senior and Junior Deans have responsibility for this aspect of Good Research Practice.

The University takes seriously any allegation of research misconduct and will respond to any such allegation through a process of assessment and investigation, with a view to resolution.

Any member of the University who believes that an act of research misconduct has occurred or is occurring should report in writing to the Office of the Dean of Research, for onward referral to the Senior and/or Junior Dean(s).

A finding of research misconduct requires that there be a significant departure from accepted practices of the relevant research community; and the misconduct be committed intentionally, or knowingly, or recklessly; and the allegation be proven by a preponderance of evidence

Raising a false or malicious allegation is a serious breach of this policy. Allegations which are found to be malicious will be treated as serious misconduct under College disciplinary procedures. This provision should not deter the reporting of genuine complaints. Research misconduct includes retaliation of any kind against a person, who acting in good faith, reported or provided information about suspected or alleged misconduct.

4. Good Publication Practice

General Guidelines

- Researchers have a fundamental right to publish their findings. This right must be taken into consideration when contractual agreements are made with funding partners. An individual researcher's right in this context must be within the framework of any collaboration with other participants, having respect for agreements made and for other participants' rights.
- Researchers should publish their findings in good time and should not unnecessarily withhold data that may be of interest to the public or to the advancement of knowledge.
- Research findings should be disseminated in such a way that the researcher's peers and/or the public can make objective assessments of the results. Suitable vectors include peer-reviewed or similarly reputable publications in journals, books, software, policy statements, specialist conferences or expert reports.
- The quality of the results of a project must provide the sole reason for the decision to publish. Therefore, finished research results should be presented for publication even when results differ from previous expectations. Deviations from this principle result in biased reporting.
- Supervisors of postgraduate students should firmly protect the students' rights in terms of publication and authorship. All authors of review articles should have read and critically assessed the literature quoted in the review. These rules must uphold the student's basic rights as a colleague who has contributed substantially to the creative process.
- Duplicate publication of data from the same study is not acceptable.
- Before dissemination, authors should familiarise themselves with published ethical guidelines. Examples of such guidelines in the scientific area are the COPE guidelines or the Vancouver Requirements. In all research, the College expects that authors do not publish libellous or defamatory material and that standard codes of political, ethnic or moral ethics are not breached.
- Authors must ensure that they are not guilty of plagiarism in their publication. Thus, they should provide a complete reference list of all sources of information used in the preparation of their article or talk; they should fully cite the sources of tables, diagrams, quotations, paraphrases, etc. that are included in the article, and they should obtain permission from holders of copyright where necessary.

- Material published on the college Website is supervised and edited by a College Web Steering Committee. The code of conduct for users of the computer facilities in College precludes the use of College facilities to publish material that is “obscene, libellous, defamatory or in violation of any right of any third party”.

Authorship Rights and Responsibilities in group research

In many disciplines, research may be carried out in collaboration with other colleagues, either contractually or informally. In particular, where national and international funding agencies are involved in sponsoring the research, a principal investigator within college is identified. This investigator assumes the overall responsibility for the project within College. Authorship rights and responsibilities of researchers working as part of a research group within College are summarised in the guidelines below.

- The principal investigator of a research team should authorise all aspects of a proposed publication. This includes the content of the paper, early discussion of publication and authorship practice for the work, the appropriate authorship, the place of publication, the protection of intellectual property rights, the agreed rights of sponsors and any release of results on the Internet.
- To obtain the right to authorship a researcher should:
 - Contribute substantially to the creative process within any of the following areas; generation of hypotheses, design of experiments, experimental work, collection, analysis or interpretation of data.
 - Contribute substantially to the preparation of the article to be published either through preparation of drafts or through critical revision.
 - Accept in writing the final draft and be prepared to take public responsibility for the content. It follows that all authors must be given the opportunity to review and approve the final version of an article to be submitted for publication.
 - Within reasonable limits accept responsibility for the contents of the report being based on honest research.
- It is important that the list of authors on a publication accurately reflects the originators of the work, therefore authors have a responsibility to accept the right of authorship. By extension, individuals have a duty not to accept gift authorship or to relinquish their rightful authorship to co-workers who do not satisfy the criteria for authorship.
- A right to authorship must not be tied to an individual’s function, position or seniority. In this respect, the role of a supervisor may vary considerably and the right of a supervisor to authorship should be subject to the four criteria stated above.
- Supportive and isolated assistance or guidance in a research programme that does not justify authorship should be acknowledged in a separate section of the paper.

- All involved parties (authors, sponsors and editors of journals) have a duty to publish information of any sponsorship or other major material help obtained for a project.
- Researchers participating in a collaborative research project should not prepare separate publications or deliver an oral dissemination without prior consent of the collaborators.
- Individuals who use results from a research project for a special publication such as an academic dissertation must formally request permission from the research group and must fully acknowledge the source of the data in the dissertation.
- The principal researcher in a publication must assume the responsibility of correcting errors and if necessary retracting published findings if errors are found that substantially degrade the worth of the work.

5. Supervision of Research

Preamble

The supervision of Research is an essential function of the University and the following guidelines are included as proposed Good Practice in this area.

The document is divided into a section regarding the responsibilities of the School in terms of research supervision, a section dealing with the suitability of the supervisor, a section covering the responsibilities of the supervisor.

The guidelines issued by the TCD Graduate Studies Office with regards to the process of supervision of research remain in the same form as published by the Graduate Studies office and all supervisors are referred to them as an essential resource in research supervision.

6. Data

6.1 Preamble

Primary data are those that have been collected by, or on behalf of, the researcher. The retention of primary data is of particular importance for research which is dependent on the collection of observations relating to the data subject, for example in social, medical, scientific and experimental research. A well-implemented policy on the retention of primary data enhances the quality, reputation and value of the research undertaken and provides the possibility of auditing and verifying the results of research which is based on primary data. This policy has been adapted and developed from others in common use; in particular, from those of the Biotechnology and Biological Sciences Research Council, the University of Glasgow and the Medical Research Council.

6.2 General policy

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. For similar reasons, data generated in the course of research must be kept where this is possible and should be retained securely in paper, electronic or other form, as appropriate to the task and the type of research undertaken. In general the College requires such data to be securely held for a period of ten years after the completion of a research project; see section 6.3.5 below.

6.3 Guidelines

- Data should be stored in a way that permits a complete retrospective audit where necessary.
- Data records should be stored safely, with appropriate contingency plans.
- Data records should be monitored regularly to ensure their completeness and accuracy.
- Original data or images should be recorded and retained. This is especially important where data or images are subsequently enhanced. If possible, both original and enhanced data/images should be stored.
- Primary research data (and where possible, relevant specimens, samples, questionnaires, audiotapes, etc.) must be retained in their original form within the College for a minimum of ten years from completion of the project where this is practical. Where this is not possible the nearest practical alternative to retaining the original evidence must be employed (e.g. an image or data set from the original). It is the responsibility of each School to specify arrangements appropriate to their area.
- Work of significant public importance should be archived in a suitable location.

- Research records relating to clinical or public health studies should be retained for a sufficiently extended period to provide scope for longer follow-up if necessary.
- Researchers who are leaving the College and who wish to retain data, or copies of data, must get permission from their head of School to do so. Where personal data are involved, the request should be refused unless it is clear that future use will be consistent with the terms of the original consent given. Source data must continue to be held by the College following the departure of the researcher in order to fulfil the commitment to good research practice.
- Publication of the data (including in theses) does not negate the need to retain source data.

School codes of practice

- Where the nature of a School's research involves primary data, the head of School is required to adopt a code of practice for the retention of this data in their School. The code shall take into account the nature of the discipline concerned and any special factors affecting the environment for research in their School. This code must be publicly available and published on the School's website.
- The retention of different types of primary data raises different issues and may require different procedures. Factors affecting the precise codes adopted by Schools include the nature of the primary material, which may be problematic, such as degradable specimens, toxic specimens, voluminous source material, awkward material, records needing special readers or in electronic formats no longer current, etc. Limitations on storage arising from costs of storage, staff resources required, physical problems of storage, accessibility in the context of changing technology, etc. may require a School to adopt the nearest practical alternative to retaining original source material.
- Researchers are required to adhere to the School code on the retention of research data.
- Heads of School, or those appointed to act on behalf of the head, will ensure that the code adopted for their School is implemented by those concerned.
- Researchers or others in a School wishing to remove or dispose of research data may only do so with the approval of the head of School, or deputy.

For electronically generated data:

- Data should be backed-up regularly; duplicate copies should be held on disc in a secure but readily accessible archive.
- Where feasible, a hard copy should be made of particularly important data.
- Where primary data is retained in electronic form appropriate software must be available to process it.
- Special attention should be paid to guaranteeing the security of electronic data.

As regards electronic data in the (bio)medical area the following additional basic policies apply:

- All raw data should be recorded and retained in indexed laboratory notebooks with permanent binding and numbered pages or in an electronic notebook dedicated to that purpose.
- Machine printouts, questionnaires, chart recordings, autoradiographs, etc. which cannot be attached to the main record should be retained in a separate ring-binder/folder that is cross-indexed with the main record.
- Records in notebooks should be entered as soon as possible after the data are collected. Recorded data should be identified by date of the record and date of collection if the two do not coincide. Subsequent modifications or additions to records should also be clearly identified and dated.
- Special attention should be paid to recording accurately the use of potentially hazardous substances (e.g. radioactive materials) in both laboratory notebooks and any central logbooks.
- In clinical studies, consent forms should be kept securely with the raw data, and normally for the same period of time.
- Supervisors should regularly (monthly or as appropriate to the nature of the work) review and “sign off” notebooks of researchers to signify that records are complete and accurate. Queries should be discussed immediately with the individual who recorded the data and any resultant changes to the records should be signed by both. Authentication of data collected and recorded electronically requires special consideration.

Appendix 1- Trinity College Dublin: Declaration of Interest Form

(Information provided on this Form may be accessed under the Freedom of Information Act)

As part of the College's good research policy an obligation is placed on the recipients of research grants to declare any interest that would interfere with or compromise the performance of research supported by the grantor. Declarations of interest of all participants or proposed participants in research must be disclosed at the time of contract acceptance. Declaration of interest extends to the researcher or his/her partner or members of his/her family or the research grouping with which the researcher has an employment relationship has an interest. An apparent conflict of interest exists when an interest would not necessarily influence the researcher but could result in the researcher's objectivity being questioned by others. Intentionally failing to reveal a known interest will be regarded as research misconduct and may be subject to disciplinary action

Please note that this Declaration of Interest may be accessed under the Freedom of Information Act.

Where a conflict of interest appears to have been revealed the University may need to consult with the grantor to ensure that the conflict of interest does not compromise the research funded by the grantor. It should be stressed that the existence of a conflict of interest does not automatically disqualify a researcher from participating in an award.

There are different types of conflict of interest. For example the following list, which is not exhaustive, is provided for your guidance.

1. A current proprietary interest in a substance, technology or process (e.g. ownership of a patent), considered in or otherwise related to the subject matter of the research
2. A current financial interest, e.g. shares or bonds, in a commercial entity with an interest in the subject of the research (shares > 10,000 Euro except share holdings through general mutual funds or similar arrangements where the expert has no control over the selection of shares)
3. Positions such as employment, consultancy, directorship with current or expected financial remuneration with any commercial entity which has an interest in the subject matter related to the research contract. Consultancy is defined as professional activity related to the person's field or discipline, where a fee-for-service or equivalent relationship with a third party exists
4. Performance of any paid work or research during the past 4 years commissioned by an organisation with interests in the subject-matter of the research endeavour. Also included is any other non funded interest in such an organisation with interests in the subject-matter of the research endeavour during the past 4 years.
5. With respect to the above, an interest in a competing substance, technology or process, or an interest in or association with, work for or support by a commercial entity or organisation having a direct competitive interest should similarly be disclosed.

Title of Research Project:

Sponsor's Name:

Declaration:

Have you or your partner/family and/or research group any financial or other interest in the subject-matter of the research in which you will be involved, which may be considered as constituting a real, potential or apparent conflict of interest? If **yes** give details in the space below.

Type of Interest: e.g. patent, shares etc and to whom they belong.

I, We the undersigned investigators, do hereby declare that we are familiar with the College's Code of Good Research Practice and in particular with the section on conflict of interest. I/We believe that, to the best of my/our knowledge, accepting the grant/conducting this research mentioned above through the University of Dublin, Trinity College does not involve me/us in any conflict of interest. We/I are also aware that if during the course of this research project any conflict of interest arises we/I will undertake to inform the University as expeditiously as possible and understand that the University may choose to inform the grantor. I/We hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me/us.

Name(s):

Signature(s):

Date:

Witness to the Signatures:

Appendix 2 - DATA PROTECTION ACTS - ADVICE IN RELATION TO ACADEMIC RESEARCH

Introduction

The Data Protection Acts 1988 and 2003 govern the processing of *personal data*. These Acts safeguard the privacy rights of living individuals regarding the processing of their personal data by those who control such data. The Acts place a duty of care on the College in favour of those individuals about whom we process data.

This advice note is designed to provide staff with an overview of the legal obligations of the College with regard to issues of the use of personal data in academic research and how we can achieve best practice in relation to our compliance. The use of personal data for research is especially likely in the health sciences, certain natural sciences, the social sciences and psychology but can occur in any area that involves the study of living people. Researchers often place considerable attention on obtaining the relevant ethical approval for their research but it is also essential to meet the initial and on-going Data Protection requirements. This advice is not a definitive statement of Data Protection law. If you have any specific questions or concerns in relation to any matters pertaining to personal data, please contact the College's Information Compliance Officer; see page 7 for contact details.

This advice note should be read in conjunction with the College's data protection policy and with the other data protection advice notes which are available at the College's Data Protection website http://www.tcd.ie/info_compliance/dp/.

Definitions

In order properly to understand the College's obligations, there are some key terms which should be understood by all relevant College staff.

- **Data controller** means a person who, either alone or with others, controls the contents and use of personal data.
- **Data processor** means a person who processes personal data on behalf of a data controller but does not include an employee of a data controller who processes such data in the course of his employment.
- **Personal data** means data relating to a living individual who is or can be identified either from the data or from the data in conjunction with other information that is in, or is likely to come into, the possession of the College.
- **Sensitive personal data** refers to personal data regarding the individual's
 - racial or ethnic origin, political opinions or religious or philosophical beliefs;
 - membership of a trade union;
 - physical or mental health or condition, or sexual life;
 - commission or alleged commission of any offence or any related proceedings.
- **Processing** is extremely broadly defined and includes practically all imaginable acts of collection, access, uses, storage, deletion and the disclosure of personal data to others.

Data Protection principles applied to academic research

Principle 1: Obtain and process information fairly

Where information is being gathered directly from the data subjects the data subject must be made aware, when the data are being collected, at least of:

- the identity of the data controller (e.g. Trinity College Dublin);
- the identity of a representative, where appropriate;
- the purpose(s) for which the data are intended to be processed;
- the persons or categories of persons to whom the data may be disclosed; and
- any other information which is necessary so that the processing of the data may be fair, such as informing users which information sought is mandatory and which optional and any particular implications for them in providing the information being sought and their right to access and rectify the data.

Where the data have been obtained in any other way, the general rule is that, in addition to the above information, the data subject must be made aware, on or before the time the data are first processed, of the categories of data concerned and the name of the original data controller. This does not apply in certain very specific and limited circumstances specified in the legislation (See Section 5, below: 'Special provisions for research').

Please see Data Protection advice note No. 2 on this principle, which describes the permissible conditions for the legitimate processing of personal information and the more stringent conditions that apply to the processing of sensitive personal information. Broadly, this requires the consent of the data subjects concerned and in the case of sensitive data the consent must be explicitly given, i.e. where the data subject has been informed, as above, including of the purpose(s) in processing the data and has given his/her data on that basis.

Principle 2: Keep it only for one or more specified, explicit and lawful purposes

In addition to this requirement, it should be noted that the data subject should have been informed of the purpose when the data were being collected and also that the data subject has the right to be informed on request in regard to the purpose of holding his or her personal data.

Principle 3: Use and disclose it only in ways compatible with those purposes

Use of data must be necessary for the purpose and data may not be further processed in a way that is incompatible with the purpose for which the data are kept. The Data Protection Commissioner has advised¹ that:

Any use or disclosure must be necessary for the purpose(s) or compatible with the purpose(s) for which you collect and keep the data. You should ask whether the data subject would be surprised to learn that a particular use of or disclosure of their data is taking place.

A key test of compatibility is:

¹ Data Protection Commissioner, 'Data Protection Acts 1988 and 2003 - A Guide for Data Controllers'

- *do you use the data only in ways consistent with the purpose(s) for which they are kept?*
- *do you disclose the data only in ways consistent with that purpose(s)?*

Principle 4: Keep it safe and secure

Maintaining the security of personal data is an onerous responsibility and requires security measures that relate to the relevant physical material, computer facilities, computer networking, rules for access, training of relevant staff and this security must be maintained for the duration for which the data are kept, even after the active phase of the research project has been completed. Security measures must be appropriate to the nature and format of the data and the risk of harm from unauthorised disclosure. Appropriate procedures and security protocols will need to be developed for the researchers and physical and other security measures adopted to protect the data. Special care needs to be taken in any use of laptop computers, memory sticks, back-up disks, or other portable computer devices which increase the risk of losing data. In this regard, the Data Protection Commissioner advocates the use of encryption technology to protect data stored on remote devices because they are more prone to loss or theft and normal username/password access may not be sufficient to protect against unlawful access to the information stored on the device.

Principle 5: Keep it accurate and complete and, where relevant, up-to-date

From a Data Protection viewpoint this is important where there is a duty of care owed to the data subject which would be the case, for example, if there were actions which may be based on inaccurate data. This principle does not apply to back-up data.

Principle 6: Ensure that it is adequate, relevant and not excessive

Only the minimum personal data should be held to fulfil the specified purpose of the research project.

Principle 7: Retain it for no longer than is necessary for the purpose or purposes

The Data Protection legislation does not specify particular periods beyond which data may not be held. It is the responsibility of the research organisers to determine the retention period for their research data. Periods can vary depending on the research discipline and its purpose and the type of data concerned. Retention periods should be determined on a case by case basis having regard to legal obligations, conditions imposed by research sponsors, commercial or ethical sensitivity and good practice elsewhere. In some situations it may be sufficient for the research purpose to retain only de-identified data. For as long as personal data are held the obligations of Data Protection remain. Once the retention period has expired the personal data must be destroyed with care in a manner appropriate to the format of the medium.

Principle 8: Give a copy of his/her personal data to an individual, on request

Data subjects are entitled to make an access request under the legislation for a copy of their personal data and for information relating to that data. This must be complied with within a specified deadline. In designing a research project that involves the processing of personal data, it is advisable from the

beginning to devise an efficient means of answering such requests and the safest course of action is to assume that individuals will enjoy a general right of access in respect of their own personal data. However, if a data access request is received, the recipient should consult with the College's Information Compliance Officer who will be able to advise on the scope of the right of access and the narrow exceptions set out in the legislation. For example, the Data Protection Acts dis-apply the right of access if the data are kept *only* for the purpose of preparing statistics or carrying out research provided that the data are not used or disclosed for any other purpose and the resulting statistics or the results of the research are not made available in a form that identifies any of the data subjects. The right of access is also dis-applied in the case of back-up data.

Transfer of personal data abroad

The legislation restricts the transfer of personal data outside of the European Economic Area (i.e. the EU and Iceland, Liechtenstein and Norway). Special conditions must be met where the country importing the data does not have an EU-approved level of Data Protection law.

Anonymising personal data

The Data Protection Acts only apply to *personal data*. Where data are anonymised, such that no living individual is identifiable, or likely to be able to be identified, the Data Protection Acts no longer apply to those data and therefore the restrictions imposed by the legislation need no longer be of concern. True anonymisation of data involves the irreversible de-identification of the data. Where codes or reference numbers are used that permit the re-identification of the data (often called 'pseudonymisation') then the data are not truly anonymous and are still covered by the requirements of the Data Protection legislation. Even when data are apparently anonymous, care must be taken to ensure that the identity of individuals cannot be inferred from circumstances such as a unique, or near unique, combination of data which would reveal an individual's identity. In issuing statistics, for example, if there are only one or two individuals that fall into a certain category it may be necessary to combine categories to ensure anonymity. Wherever possible anonymisation of personal data is the preferred way of protecting individuals' privacy.

Special exemptions relevant to research

The Data Protection Acts have certain provisions that are particularly relevant to those planning academic research projects.

Access right of the data subject: The right of access does not apply to data kept *only* for statistical and research purposes and the resulting statistics or research are not made available in a form that identifies any of the data subjects. See Data Protection principle 8, above.

Historical research: The Data Protection principles 1 to 7 do not apply to data kept *solely* for the purpose of historical research or archival data and the keeping of which complies with the prescribed regulations.

Medical research: See below: 'Processing sensitive personal data for health research'.

Processing of personal data for research purposes: The normal approach to legitimising the use of personal data is to obtain the consent of the data subjects. However, the Data Protection Acts provide for limited exceptions in certain cases where data are being processed *only* for research purposes.

- **Data Protection principle 1 (fair obtaining and processing)**

Normally, the Data Protection Acts require that, so far as practicable, the uses of personal data be transparently set out to the data subjects at the time their data is captured. However, there are some exceptions to this general transparency requirement in the case of research data. In particular:

(a) Data kept for statistical or research or other scientific purposes are not considered as having been obtained unfairly by reason only that their use for the particular scientific purpose was not disclosed when they were obtained if the data are not used in such a way that damage or distress is, or is likely to be, caused to any data subject.

(b) Where data subjects do not provide the data directly to the College, these transparency requirements do not apply if the data processing occurs only for statistical purposes or for the purposes of historical or scientific research and where the transparency requirements prove impracticable, impossible or would involve disproportionate effort.

- **Data Protection principles 3 (further processing) and 7 (limited retention)**

These principles do not apply to personal data kept for statistical or research or other scientific purposes. These provisions permit data to be used for further purposes, to be held for longer than needed for the original purpose and to be further processed but only for statistical, research or scientific purposes.

It is important to bear in mind that the exceptions to obtaining informed consent to the processing of personal data are narrow and can be difficult to apply to practical situations. Therefore any research activity which involves the processing of personal data without data subject consent should be checked first with the Information Compliance Office.

Research conducted by students

As the College is a *data controller* of personal data processed in the course of College activities, in many cases the College will be bound by the Data Protection rules even in cases where the research is undertaken by students. It is therefore safest to assume that this Advice Note applies to all research undertaken within the College whether by staff or students.

Planning research

Each step of the intended research should be planned in advance and scrutinised from a Data Protection perspective so as to avoid as many difficulties as possible and to incorporate adequate protection for the personal data which it is unavoidably necessary to process. If the pre-research planning is inadequate, *post hoc* solutions may need to be put in place to meet Data Protection obligations. The data protection management of large and complex projects involving the processing of personal data can be very demanding and require resources specifically for that purpose, e.g. by

providing a data manager. Where data are to be held and used over a long period of time there are on-going maintenance requirements which need to be estimated and planned in advance.

Consent of data subjects

In accordance with the first Data Protection principle (Obtain and process information fairly), the normal requirement to legitimise the use of personal data for research purposes is the consent of the data subjects concerned, though there are certain limited situations where consent may not be needed; examples would be research permitted under the terms of other legislation or the matters referred to in section 5 of this document. As mentioned, this consent must be explicitly given in the case of processing sensitive personal data. Explicit consent requires a deliberate 'opt-in' and it is not permissible to presume consent and offer the data subject the opportunity to 'opt-out'. A useful way of obtaining consent is to prepare, for the attention of data subjects, a description of the research project that provides all the information required by the first Data Protection principle and explains how their data will be collected, used and safeguarded and the duration for which it will be retained. This can be accompanied by a consent form for recording the individuals' consent to the proposed processing of their data. The completed consent forms should be retained as proof of the consent given. Alternatively, it may be possible to integrate the consent form with, for example, a survey questionnaire soliciting personal data. In general, the consent thus obtained sets the limits on how the subjects' data may be handled. It is important that the consent obtained covers everything that is required. If this is not done properly it may be necessary, at a later stage, to obtain further consent and this would involve delay and additional expense.

Using personal data within the College

Personal data gathered during a research project must be safeguarded and used within the terms provided by the consent of the data subjects. Disclosure to others within the College should only be made on a need-to-know basis. Unintended disclosures should be guarded against.

Employing agents in processing personal data

There are times when, rather than discharge a service itself, researchers may wish to 'outsource' the supply of a service to an external supplier. If the service involves the processing of personal data on behalf of the College then there must be a written contract between the College, known in this context as a 'Data Controller', and the supplier of the service. As a general rule it is wise to provide for Data Protection obligations when contracting with suppliers of services even where the handling of personal data is not immediately the subject of the service. If there is no provision for Data Protection compliance an additional agreement will have to be entered into wherever necessary. Data Protection is relevant anytime where service providers would have access to the personal data of individuals, such as students or data subjects in the research activity. Please see Data Protection advice note No. 1 for further information. Data legitimately sent by the College to its service supplier in this way is not being sent to a third party but to an agent of the College.

College departments undertaking research acting as agents for external bodies

On occasions, College departments may undertake to carry out research for external organisations using their data, or acting as their agents in gathering and analysing data on their behalf. For example, a College department may provide specialist expertise in analysing personal data held by an outside body, or may collect data and analyse them on behalf of such a body. In a situation of this kind the commissioning organisation is the *Data Controller* and the College department carrying out the agreed functions on behalf of the organisation is a *Data Processor* (See definitions in section 2, above). The Data Protection legislation requires the Data Controller to enter into a formal written contract with the Data Processor which specifically guarantees that the Data Processor will ensure the secure processing of the data in line with the Principle 4 (the Security Principle). Frequently the commissioning Data Controllers will include Data Protection provisions in their contracts with the relevant College department and the College should not accept an appointment requiring it to process personal data for a Data Controller in the absence of such a contract being in place. As part of the fair obtaining and processing requirements of the legislation, if the contract provides for the College department to collect personal data the Data Controller is required to inform the data subjects of their identity and the identity of their agent (i.e. the College department undertaking the work). The College department is bound by all aspects of the legislation in carrying out the contracted research work.

Transferring personal data, to other bodies or jurisdictions

Normally, disclosing data outside the College can only be undertaken with the consent of the data subjects and any such planned disclosures should be included in the initial process to obtain the data subjects' consent. There are restrictions on the transfer of data outside the European Economic Area where the country importing the data does not have an EU-approved level of Data Protection law. This is a complex area where advice should be sought on a case-by-case basis. Data may however be exported in such cases if the data subjects concerned consent to the transfer.

Processing sensitive personal data for health research

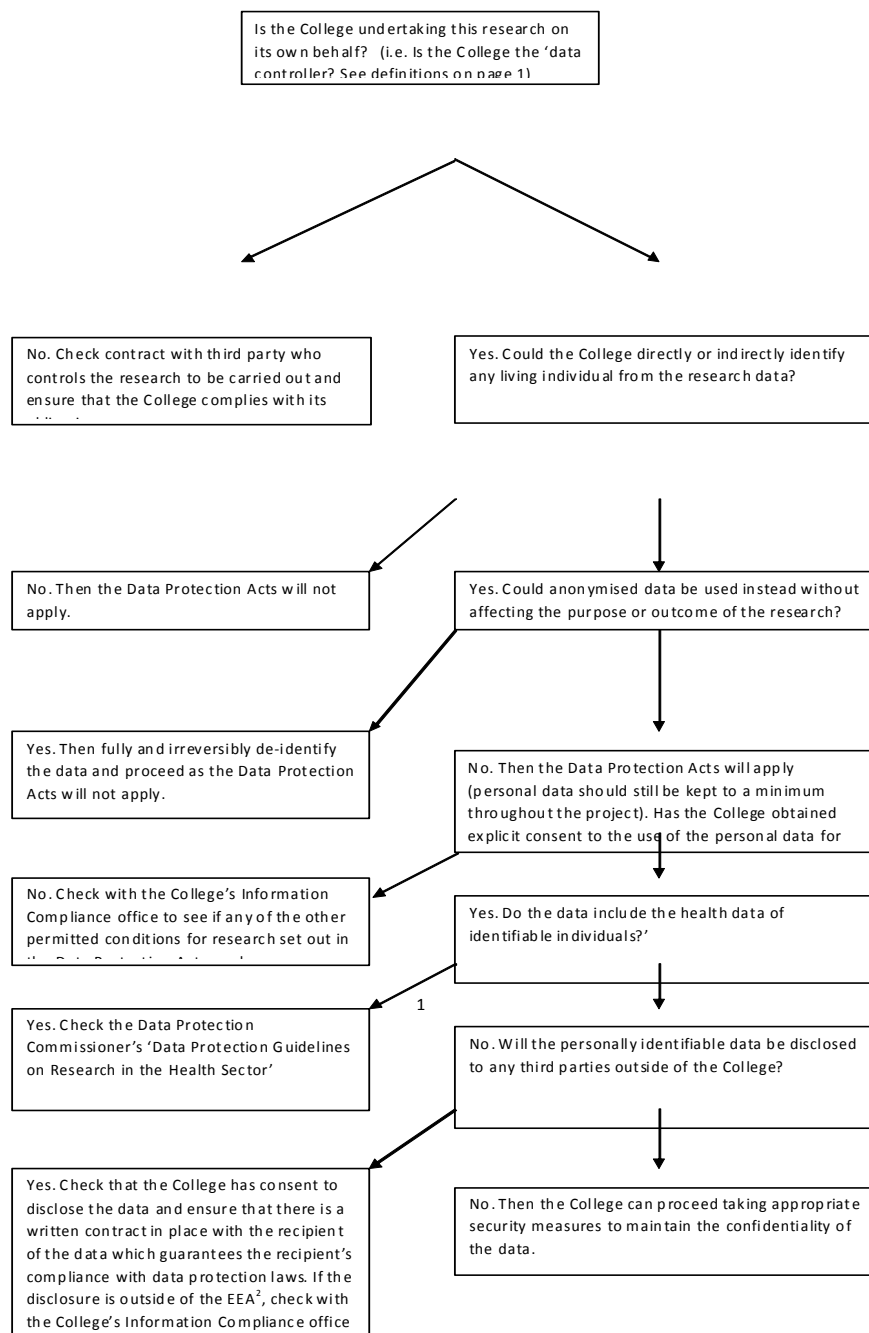
The Data Protection Commissioner has issued 'Data Protection Guidelines on Research in the Health Sector', dated November, 2007, which is available on the Commissioner's website. This document provides extended guidance on what is permissible and sets out a best practice approach to undertaking research projects using personal data. All College personnel who have access to identifiable patient or other health data should familiarise themselves with these Guidelines before undertaking any health research.

Privacy considerations other than those of Data Protection

Data Protection is not the only consideration in relation to privacy. There may also be other considerations or undertakings as to confidentiality, or medical, ethical, or professional codes of practice that apply to the handling of relevant personal data. Data Protection legislation only applies in the context of living data subjects and these other approaches may well require the maintenance of privacy in regard to deceased data subjects.

15. Flow chart of data protection advice

Flowchart summarising the approach which should be adopted to academic research which involves the processing of personal data.



Appendix 3- Selected relevant websites

For guidelines on biomedical research see the Declaration of Helsinki (2008) :
<http://www.wma.net/>

For guidelines on research involving pharmaceuticals see ICH :
<http://www.ich.org/>

Human subjects – The Belmont Report

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

For guidelines using human participants in behavioural research see
US Department of Health and Human Services: Office for Human Research
Protections: <http://ohrp.osophs.dhhs.gov/>

The American Anthropological Association's code of Ethics:
<http://www.aaanet.org/committees/ethics/ethcode.htm>

The British Sociological Association: <http://www.britsoc.org.uk/about/ethic/ht>

Detailed guidelines for such research are available:

The (UK) National Children's Bureau <http://www.ncb.org.uk/resguide.htm>

EC legislation on Biomedical Ethics

<http://www.cordis.lu/rtd2002/science-society/ethics.htm>

The use of medications and medical devices in research may require the permission of the
Irish Medicines Board under the Control of Clinical Trials Acts 1987 and 1990
<http://www.imb.ie/pubs/pubs.htm>

The use of radiation is covered by permission from the Radiological Protection Institute of
Ireland
<http://www.rpii.ie>

Additional details are available on the Trinity College Radiation website

<http://www.tcd.ie/Buildings/Radiation/index.html>

(Note: There is no regulatory requirement for non-ionising radiation techniques such
as ultrasound and magnetic resonance imaging (MRI))

Irish Legislation on genetically modified organisms

<http://www.environ.ie/environ/envindex.html>

Oireachtas Registers of Interests – http://www.irlgov.ie/poc/2376_246.htm

Trinity College, Dublin – Policy and Procedures for Dealing with Complaints of Harassment including Sexual Harassment – <http://www.tcd.ie/Secretary/Policies/harass.html>

Trinity College Dublin – Fraud Policy – <http://www.tcd.ie/Secretary/Policies/fraud.html>

Committee on Publication Ethics. -
The COPE Report 1998 <http://bmj.com/misc/cope/tex1.shtml>

MRC Ethics Series. Good Research Practice, 2000. <http://www.mrc.ac.uk>

Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication *Updated October 2008. accessed at* <http://www.icmje.org/index.html> 04.05.09

The Danish Committee on Scientific Dishonesty Guidelines for Good Scientific Practice ISSN 1395-098. Copenhagen, 1998. <http://www.forsk.dk/eng/uvvu/index.htm>.

Biotechnology and Biological Sciences Research Council
Statement on Safeguarding Good Scientific Practice
http://www.bbsrc.ac.uk/funding/overview/good_practice.pdf

Medical Research Council
Ethics Series - Good Research Practice
http://www.mrc.ac.uk/pdf-good_research_practice.pdf

Research with Children

<http://www.tcd.ie/childrensresearchcentre/Docs/GoodResearchPracticewithChildren.pdf>