Trinity College Dublin

Policy on Good Research Practice

V3.0

Approved as Policy by Council on 11th June 2014 (CL/13-14/193 (i)) and Board on 25th June 2014

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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 was updated in 2009 and led to the introduction of a new superintending structure of ethical matters for College in the form of an over-arching Research Ethics Policy Group. In 2013 a review of research ethics policies in College resulted in the formation of the Research Ethics Policy Committee that has responsibility for the oversight of all policies relating to research ethics and research integrity, in addition to this document. This 2014 revision incorporates recent changes to research ethics and research integrity policies.

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. 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 may 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 required. The Research Committee should provide a progress report to Council on the implementation of this policy every five years.

In all cases where research is carried out under the auspices of Trinity College Dublin, within or without the defined campus properties, the College requires 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. Failure to comply with the policies may result in disciplinary action under the College's disciplinary procedures.

2. Ethics

2.1 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 and 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.

2.2 General Guidelines

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 National Institues of Health Belmont Report (1978) and the Helsinki Declaration (revised 2013). 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 or not to participate. The information provided to the participant should include written details of risks and benefits in participating, and an undertaking to protect confidentiality, preferentially through implementation of a controlled scheme for participant anonymisation, except in situations including where a participant gives consent to the disclosure of information to third parties, if disclosure is required by a judge in a court of law, or to protect the interests of the participant, another individual or the welfare of society. Participants should sign a consent form to agree to take part in the research. Negative consent - for example, absence of a 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.

2.2.1 Research on vulnerable participants

Research policy within TCD gives special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, terminally ill, mentally disabled persons, or economically or educationally disadvantaged persons. Research with a vulnerable group is only justified if the research is responsive to the needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research. Potential harm to such cohorts must be mitigated and valid justification for inclusion must be provided such as the unsuitability of less vulnerable populations. Considerations related to the well-being of the participant should always take precedence over the interests of science and society. TCD approved Level 2 research ethics committees (see section 2.3) have the authority to approve research on vulnerable participants that is of minimal risk or that will benefit the subjects directly or which with minimal risk may advance knowledge in a defined area.

While respect for basic pillars such as autonomy and confidentiality are implicit in all research involving human subjects, they are especially pertinent in situations where the people concerned are vulnerable or already marginalised or stigmatized. In the latter situations there can be danger of exacerbating or further entrenching negative social stereotypes thereby further marginalizing the individual or group. Types of potential harm that must be recognized and addressed include but are not limited to: psychological harm (e.g. recalling a traumatic event), social stigma (e.g. loss of reputation), cultural effects (e.g. going against existing cultural norms), political effects (e.g. disturbing existing power relationships) and economic repercussions (e.g. loss of employment).

It should be noted that additional formal authorization or clearance of research staff by An Garda Síochána may be required in certain cases. Garda vetting is conducted in respect of personnel working in a full-time, part-time, voluntary or student placement capacity in a position within a registered organisation, through which they have unsupervised access to children and/or vulnerable adults.

2.2.2 Research using pharmaceuticals

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, http://www.ich.org/).

2.2.3 Research using animals

Research involving animals in TCD is governed by Directive 2010/63/EU on the protection of animals used for scientific purposes in accordance with the requirements of the S.I No 543 of 2012 and externally regulated by the Irish Medicines Board (IMB). The authorisation system by IMB is based on a three strand system of control: (1) Establishment authorisations: Institutions where procedures are carried out on animals must be vetted by the IMB and hold an establishment

authorisation, (2) Project authorisations: Scientific procedures can be performed on an animal only following a detailed submission of the planned study and subsequent vetting and approval by the IMB by means of a project authorisation and (3) Individual authorisations: All individuals performing scientific procedures on animals must be adequately trained and must hold an individual authorisation. Likewise, individuals carrying out the role of project manager under a project authorisation (sometimes known as 'P.I.s') as well as those involved in the euthanasia of animals must hold an individual authorisation. All research involving animals is regulated by the College's BioResources Unit (BRU) and the Animal Research Ethics Committee (AREC). Animal studies are permitted by the College only when it is clear that such work will positively contribute to the advancement of knowledge intended to 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.

2.2.4 Research using genetically modified organisms

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, http://www.epa.ie/licensing/gmo/) 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 EPA in accordance with the requirements of the Contained Use legislation, seeking the agency's consent before commencing work with GMOs.

2.2.5 Research using stem cells

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 (http://www.dohc.ie/working_groups/Current/nacb/Ethical_Scientific_Legal_Issues.pdf?direct=1). 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 International Society for Stem cell Research (ISSCR) guidelines (2006, http://www.isscr.org/home/publications/guide-clintrans). 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 an appropriate Level 2 College research ethics committee in the context of compliance with international ISSCR ethical guidelines. TCD formally limits the permitted range of experimentation involving hES cells, to those defined as category 1 and category 2 section (10.2e) in Section 10 of the ISSCR Guidelines.

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.

2.3 Trinity College Research Ethics Structures

All researchers are required to conduct their research to the highest ethical standards and each individual researcher is responsible for ensuring good ethical practice. In order to permit maximum flexibility and efficiency and to ensure that Research Ethics Committees (RECs) are fit for purpose it is required that individual Faculties and Schools as well as other non-Faculty units (including administrative and service departments whose members may undertake research) must have appropriate ethical review and approval processes in place. Each School/unit is required to detail how its members can obtain ethical approval for high- or low-risk research projects.

All Schools/units must have a research ethics approval policy in place. It is recommended that ideally each School should have its own REC that has the authority to consider what are deemed to be low-risk projects. These RECs are termed Level 1 RECs. Schools/units that routinely engage in high-risk research should have or have access to one or more RECs qualified to consider such research projects. RECs that can grant approval for both high- and low-risk research projects are termed Level 2 RECs. If a School/unit does not have its own standing REC it should have a formal agreement with an appropriate REC (e.g. another School or Faculty REC and/or the AREC) that can provide approval for its staff.

Each unit has a designated Research Ethics Officer (or more than one in Schools with large numbers of projects requiring approval) who is responsible for the oversight and implementation of research ethics policies in the School and who is a point of reference for staff queries concerning research ethics. This individual may be the Director of Research and/or another individual with experience in research ethics. Level 1 RECs with the authority for granting approval for low-risk research should be comprised of a minimum of 3 members of College academic staff, and be chaired by the School Research Ethics Officer. Ideally, membership should include at least one member from outside the School (e.g. another School). Level 2 RECs with the authority to grant approval for both high- and low-risk research should be comprised of sufficient members of staff relevant to all the disciplines to be served, as well as specialist, external lay and legally qualified members. Details of the criteria for Level 1 and 2 research ethics committees may be found at: https://www.tcd.ie/research/dean/assets/pdf/criteria-for-research-ethics-committees.pdf. The precise membership of committees should be determined by the REC in consultation with the Research Ethics Policy Committee (REPC).

2.3.1 College research ethics policy committee (REPC)

This committee, functioning as a standing subcommittee of the College Research Committee, serves 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 functions independently of but in co-ordination with Faculty, School or Unit research ethics committees.

Membership

The membership of the REPC will include the Chair (to be appointed by the Research Committee on the recommendation of the Dean of Research), the Dean of Research, the Associate Dean of Research (Secretary to the Committee), two nominees from each Faculty, an internal member with legal expertise, at least one external member, the College Secretary (or nominee), a representative of the Graduate Students union and the Senior Dean.

Roles & responsibilities

- To recommend research ethics policy to the College Research Committee for adoption and implementation.

- To consider for approval extant Research Ethics Committees (RECs) and the formation of new RECs, at levels 1 and 2.
- 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 policy in College.
- To be responsible, where appropriate, for liaison with external organizations.
- To superintend the provision of relevant research ethics 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 a regular basis to review notifications from RECs and to consider any submissions made in relation to review of research ethics policy in College, furnishing an annual report to the Research Committee on research ethics policy.
- Requisite notifications from approved RECs 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 procedures
    - identification of unmet policy needs
    - proposals and appeals considered
- To recommend policies pertaining to research integrity to the College Research Committee for adoption and implementation.

Approval & Appeals

The REPC does not normally have a role in approving individual research ethics applications. Rather, routine review of research ethics policy compliance is devolved to approved RECs; and, subject to the remainder of this section, any decision of any REC on such matters is final.

In exceptional circumstances, and at the discretion of the REPC, the Chair of the REPC may convene a Research Ethics Appeals Committee (REAC) for the purpose of considering an appeal by the promoter of a research proposal against the result of an application to a Level 2 REC following the exhaustion of that committee's appeals process. Such an REAC shall consist of five

members (including a Chair), none of whom may be members of the Level 2 REC the decision of which is being appealed, though they may be members of other Level 1 or Level 2 RECs. In that appeal, the decision of that REAC shall be final.

Meetings

The REPC will meet at least twice per year, or more frequently if the business requiring its attention should so dictate. The quorum for meetings shall be one third of the membership plus one. Other College Officers or external experts may be invited to attend meetings to assist the committee in the attainment of its objectives. Draft minutes of meetings shall be circulated to the Research Committee for noting and/or discussion as necessary.

2.3.2 Research ethics committees based in or affiliated with Trinity College Dublin

A comprehensive list of the current RECs within TCD and their level of operation may be found at: https://www.tcd.ie/research/dean/ethics/

2.3.3 Processes of review

While recognizing that the research ethics review bodies of College have specific and established processes, it is required that all ethical review committees will 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 required that all research ethics review forms 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 annual submissions of review / approval statistics to the Research Ethics Policy Committee.

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

College recognizes that our collaborating institutions worldwide conduct research under established ethical procedures and policies. When appropriate, to facilitate collaboration Trinity College research ethics committees are granted the discretion to recognize reciprocity of recognition of ethical approvals granted in collaborating institutions through a fast-tracked ethical approval process. Each Trinity research ethics committee will have its own specific policies for such circumstances.

3. Integrity

3.1 Preamble

Research Integrity covers many issues including research misconduct, conflict of interest and policies for inquiring into allegations of research misconduct. Policies in Trinity College relating to research integrity are guided by the national policy statement Ensuring Research Integrity in Ireland (https://www.tcd.ie/research/dean/assets/pdf/Publication%20version%20Research%20Integrity%20statement%20170713.pdf) and by adhering to this document Trinity College makes the following commitments:

1. We are committed to ensuring the highest standards of integrity in all aspects of our research, founded on basic principles of good research practice to be observed by all researchers and research organisations.
2. Education and promotion of good research practice are the foundations of research integrity. We are committed to maintaining a national research environment that is founded upon a culture of integrity, embracing internationally recognised good practice and a positive, proactive approach to promoting research integrity. This will include support for the development of our researchers through education and promotion of good research practices.
3. We are committed to working together to reinforce and safeguard the integrity of the Irish research system and to reviewing progress regularly.
4. We are committed to using transparent, robust and fair processes to deal with allegations of research misconduct when they arise.

3.2 General Guidelines

The European Code of Conduct for Research Integrity (http://www.allea.org/Content/ALLEA/Scientific%20Integrity/Code_Conduct_ResearchIntegrity.pdf) specifies eight basic principles that underpin all research integrity and good practice in carrying out research. The principles outlined below are taken from the national policy statement and must be adhered to by all researchers:

- ☐ ***Honesty*** in presenting research goals and intentions, in precise and nuanced reporting on research methods and procedures, and in conveying valid interpretations and justifiable claims with respect to possible applications of research results.
- ☐ ***Reliability*** in performing research (meticulous, careful and attentive to detail), and in communication of the results (fair and full and unbiased reporting).
- ☐ ***Objectivity****:* interpretations and conclusions must be founded on facts and data capable of proof and secondary review; there should be transparency in the collection, analysis and interpretation of data, and verifiability of the scientific reasoning.

- ***Impartiality* and *independence*** from commissioning or interested parties, from ideological or political pressure groups, and from economic or financial interests.
- ***Open communication***, in discussing the work with other scientists, in contributing to public knowledge through publication of the findings, in honest communication to the general public. This openness presupposes a proper storage and availability of data, and accessibility for interested colleagues.
- ***Duty of care*** for participants in and the subjects of research, be they human beings, animals, the environment or cultural objects. Research on human subjects and animals should always rest on the principles of respect and duty of care.
- ***Fairness,*** in providing proper references and giving due credits to the work of others, in treating colleagues with integrity and honesty.
- ***Responsibility for future science generations.*** The education of young scientists and scholars requires binding standards for mentorship and supervision.

In addition, we recognise that research should always be designed and conducted in accordance with ethical principles, and with appropriate review processes in place to ensure this.

3.3 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 College 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 particularly 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 College, researchers must refrain from any conduct or action in their role as a researcher employed by or working in the College which would unfairly detract from the good name of the institution and any relevant professional body to which they may belong.

3.3.1 Determination of research misconduct.

The College will investigate all allegations of Research Misconduct using the procedures outlined in accordance with its established disciplinary procedures. 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. Any member of College who believes that an act of research misconduct has occurred or is occurring should address their concerns in the first instance to the appropriate Head of School/Unit or, where the Head is the subject of the complaint, to the Faculty Dean/line manager, for consideration under the normal College disciplinary procedures. The Head of School/Unit should inform the Dean of Research of any such cases.

Trinity College Dublin 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. Investigations into allegations of research misconduct will adhere to the principles outlined in the European Code of Conduct for Research Integrity and the policy statement on Ensuring Research Integrity in Ireland. Such investigations will be conducted in accordance with the established College Disciplinary Procedure
(at http://www.tcd.ie/hr/assets/pdf/procedure_disciplinary_procedure_staff.pdf) and in accordance with the principles of natural justice. Researchers found to be guilty of research misconduct will be subjected to the appropriate disciplinary sanction in accordance with this procedure.

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.

Complaints in relation to dignity and respect issues will be dealt with separately under the College Dignity and Respect Procedures (detailed at http://www.tcd.ie/hr/assets/pdf/dignity-and-respect.pdf). Complaints upheld under this procedure will be dealt with under the College Disciplinary Procedure as appropriate.

3.4 Conflict of Interest

The text below sets out the definition of research 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.

3.4.1 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.

3.4.2 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 research 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 research 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 College.

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.

4. Good Publication Practice

4.1 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 (http://publicationethics.org/international-standards-editors-and-authors) or the Vancouver Requirements (http://www.icmje.org/recommendations/). In all research, the College expects that authors do not publish libelous 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.

4.2 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 on 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 author 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

Trinity College Dublin has an institutional responsibility to ensure integrity and ethical practice in the conduct of research. This responsibility devolves to those in faculties, institutes, schools and disciplines, research centres, and to those affiliates leading research. In the case of graduate and undergraduate research, responsibility devolves to the supervisor in overseeing the student's research project. The supervisor has a duty of care to ensure integrity and ethical practice in research as well as a pedagogical responsibility to help develop the new researcher's understanding of appropriate research practices. A code of responsibilities is available for supervisors, based on the IUQB Guidelines (http://www.iuqb.ie/info/iuqb-good-practice-guides.html), indicating the frequency of contact, responsibilities regarding scrutiny of primary data, the broader development needs of research trainees and so on. Policies for the supervision of research students are detailed in the 'Supervision of Students- Best Practice Guidelines booklet (https://www.tcd.ie/Graduate_Studies/staff/supervision/guidelines/Supervision%20Guidelines.pdf) issued by the TCD Graduate Studies Office. Information regarding regulations and eligibility to supervise research students is available at http://www.tcd.ie/calendar/part2/.

It is mandatory that supervisors supervise all stages of the research process, including outlining or drawing up a hypothesis, preparing applications for funding, protocol design, data recording and data analysis. The supervisor is expected to ensure that students and new researchers understand and adopt best practice as quickly as possible. Supervisors should facilitate their researchers in undertaking appropriate training, for example in research design, regulatory and ethics approvals and consents, equipment use, confidentiality, data management, record keeping and data protection.

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 the absence of specific legal or external requirements, College guidelines mandate the secure retention of primary data for a period of ten years after completion of a research project.

6.3 Guidelines (taken from the Policy Statement on Ensuring Research Integrity in Ireland)

Data should be recorded in a clear and accurate format. Particular attention should be paid to the completeness, integrity and security of these records.

Data should be organised in a manner that allows ready verification either in paper or electronic format. Original data should be authenticated, in order to protect the College and researcher against allegations of falsification of data.

Research data and records may be discoverable in the event of litigation. This means that the research data and records may be accessed by the university and its legal advisers, to determine their relevance to any litigation process.

Research data related to publications should be made available for discussion with other researchers, except where confidentiality provisions prevail. Confidentiality provisions relating to research data and records will apply in circumstances where the College or the researcher has made or given confidentiality undertakings to third parties or where disclosure would involve the unreasonable disclosure of information relating to the personal affairs of any person (including a deceased person) or when confidentiality is required to protect the intellectual property rights. The published National Principles for Open Access (http://www.iua.ie/wp-content/uploads/2012/10/National-Principles-on-Open-Access-Policy-Statement-FINAL-23-Oct-2012-v1-3.pdf) encourage the deposition of research data in open access repositories linked to publications, whenever this is feasible. This should lead

to greater integrity in the gathering, analysis and presentation of data as it may be open to scrutiny by peers, globally.

Researchers who are leaving the College and who wish to retain data, or copies of data, must get permission from their Head of Unit 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.

Statutory Obligations
Researchers should be aware that under the Freedom of Information Act 1997 (Freedom of Information Act, 1997), a university or other research performing institution is required to allow persons access to documents of the institution (documents which are in the institution's possession) under defined circumstances. Researchers must at all times be aware of the provisions of, and operate in accordance with, the Data Protection Act, 1988 and the Data Protection (Amendment) Act, 2003 which, amongst other things, restricts the usage of sensitive and personal data.
In order to ensure research integrity through compliance with Data Protection legislation, researchers should:
i. Obtain and process the personal data fairly
ii. Keep it only for specified and lawful purposes
iii. Process it only in ways compatible with the purposes for which it was volunteered initially
iv. Keep it safe and secure
v. Keep it accurate and up to date
vi. Ensure it is adequate, relevant and not excessive
vii. Retain it no longer than is necessary for the specified purpose or purposes
viii. Give a copy of his/her personal data to any individual on request

6.4 Codes of Practice

- Where the nature of a Unit's research involves primary data, the Head of Unit 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 Unit. This code must be publicly available and published on the Unit'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 Units 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 Unit's 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 Unit is implemented by those concerned.
- Researchers or others in a Unit wishing to remove or dispose of research data may only do so with the approval of the Head of Unit. The School's Code of Practice should provide clarity on what data can be taken from College when a PI or researcher leaves the College and determine how transfer of ownership of data occurs.

For electronically generated data:

- Data should be backed-up regularly; duplicate copies should be held 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 including encryption and password protection.

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.

6.5 Data Management

The Principal Investigator (PI) in a research project plays a key role in ensuring that appropriate data management processes are created and adhered to both for the duration of the project and for the full lifecycle of the data generated during the project.

The PI should:

- Take a leadership role in data management – the PI is the data steward and is accountable for all aspects of data management and data security;
- Put in place a data management plan for the project to cover the data lifecycle (Managing and Sharing Research Data: A Guide to Good Practice, Corti et. al., 2014, ISBN: 9781446267264):
    1. Discovery and planning;
    2. Initial data collection;
    3. Final data preparation and analysis;
    4. Publication and sharing;
    5. Long term management.

- The data management plan should address the following:
    - Classify the data to be collected as part of the research. Data should be classified as public, or university internal, or personal, personal sensitive, or confidential data and information (see the College Cloud Policy for the definition of these terms);
    - Plan consent for data sharing and reuse;
    - Plan data collection;
    - Find and discover existing data sources;
    - Define and document data handling methods/protocols appropriate to the type of data collected. For example, in medical research where personal or personal sensitive data is collected from consenting subjects, it may be appropriate to develop and trial detailed SOPs prior to data collection;
    - Identify appropriate storage and, if appropriate, information management systems for the full data lifecycle;
    - Identify roles and responsibilities for data management and appropriate access controls for each project member.
    - A data manager should be appointed where personal, personal sensitive, or confidential data and information is being collected and processed;
    - Use the defined methods and protocols to collect initial data sets
    - Determine what data needs to be stored. At a minimum, source data, important intermediate data, and results data should be preserved along with the workflow(s) used in the project;
    - Ensure use of appropriate metadata (data about data) to contextualize the data. Data without context is almost useless. The PI needs to consider how data will be curated so it is accessible and reusable when the researcher(s) have left the College;

- Ensure that any third parties subcontracted to participate in the project and handle data be included in and adhere to the data management plan;
- Adequate training should be provided to ensure that all members of the project team understand the data management plan, any standard operating procedures, and their roles and responsibilities in respect of data management;
- All members of the project team, as defined in the data management plan should formally sign off that they have read, understood, have received adequate training if appropriate, and agreed to abide by the plan and any standard operating procedures developed for data handling.

A template for a data management plan which includes further definitions and information can be found at http://www.tcd.ie/ITSecurity/policies/edm.doc.

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. In all cases where personal data are collected under the auspices of the College, the College is the Data Controller. The Acts place a duty of care on the College, as the Data Controller in favour of those individuals about whom we process data.

This guidance note is designed to provide staff, who collect personal data for the purposes of research, 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 guidance is not a definitive statement of Data Protection law and should not be relied upon as legal advice. If you have any specific questions or concerns in relation to any matters pertaining to personal data, please contact the College Solicitor / Information Compliance Officer.

This guidance note should be read in conjunction with the College's data protection policy and with the other data protection guidance which is 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. This could be a third party who has entered into a contract with the College to store and analysis data on the College's behalf. In this case the College will remain the Data Controller and the third party will be the data processor.

• ***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 an 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. More stringent conditions apply to the processing of sensitive personal data which requires the explicit consent of the data subjects.

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 advised[1] 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:

- *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. 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 personal 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. All transfers of data must be done under contract.

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 the 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 Guidance 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. 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. . 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 units undertaking research acting as agents for external bodies

On occasions, College units 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 unit 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 unit 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 unit 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 unit 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 unit undertaking the work). The College unit 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.

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

Appendix 3- Selected relevant websites

For guidelines on biomedical research see (i) the Declaration of Helsinki (http://www.wma.net/) and (ii) the Belmont report (http://videocast.nih.gov/pdf/ohrp_belmont_report.pdf).

For guidelines on research involving pharmaceuticals see ICH (http://www.ich.org/)

Research guidelines for research involving children (http://www.tcd.ie/childrensresearchcentre/assets/pdf/CRC_Ethical_Doc.pdf)

Research involving genetically modified organisms (http://www.epa.ie/licensing/gmo/)

National Policy Statement Ensuring Research Integrity in Ireland (https://www.tcd.ie/research/dean/assets/pdf/Publication%20version%20Research%20Integrity%20statement%20170713.pdf)

The European Code of Conduct for Research Integrity (http://www.allea.org/Content/ALLEA/Scientific%20Integrity/Code_Conduct_ResearchIntegrity.pdf)

College Disciplinary Procedure (http://www.tcd.ie/hr/assets/pdf/procedure_disciplinary_procedure_staff.pdf)

College Dignity and Respect Procedures (detailed at http://www.tcd.ie/hr/assets/pdf/dignity-and-respect.pdf)

Guidelines on publication and authorship can be found at the Committee on Publication Ethics (http://publicationethics.org/international-standards-editors-and-authors) and the International Committee of Medical Journal Editors (http://www.icmje.org/recommendations/)

College's Data Protection website (http://www.tcd.ie/info_compliance/dp/.)