



UNIVERSITY *of* LIMERICK
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CONFLICTS of INTEREST
PROTOCOL and PROCEDURES
related to Research activities
at
University of Limerick.

May, 2009.

University of Limerick

Conflicts of Interest – Protocol and Procedures related to Research.

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University of Limerick

Protocol and Procedures for Conflicts of Interest

1. **Background.**

- 1.1. Universities and their employees engage in a wide range of activities. The traditional academic roles of teaching and supervising students and conducting academic research are nowadays supplemented by commercial collaborations including publicly funded research, consultancy, commercial research and development, intellectual property licensing and involvement in ‘spin-out’/ Campus companies.
- 1.2. UL recognises that involvement in such commercial activities carries many advantages, including the practical application of new technologies, the provision of additional sources of research funding, insights into commercial and societal needs, and the receipt of royalty income for UL, its Departments, and the inventors.
- 1.3. These activities can, and do, produce positive benefits, but they also have the potential for diverting UL and its employees from their primary educational, research, and service missions. In particular, Conflicts of Interest can arise when the interests of a commercial venture, from which a UL researcher derives direct benefit, differ from the interests and primary obligations of UL as a whole, or when the commercial venture consumes an undue share of the researcher’s attention. UL believes it to be essential that its researchers should manage or avoid, and be seen to manage or avoid such conflicts. Moreover the Funding Agencies (SFI, EI, HRB and others) seek assurance that universities are properly managing conflicts as a condition of grant funding.
- 1.4. This Protocol sets out the UL position on Conflicts of Interest related to Research and provides guidelines as to how potential and/or actual Conflicts of Interest, and of Commitment, should be managed.
- 1.5. This Protocol applies to all employees of the University, and to all Honorary, Adjunct, Emeritus, Visiting personnel and Postgraduate Students, engaged in research work at the University, collectively **Researchers**.
- 1.6. **The full prior disclosure** of interests is clearly an important (and in many cases, a sufficient) mechanism for the management of Conflicts of Interest. **Researchers**, i.e. all UL employees, and all Honorary, Adjunct, Emeritus and Visiting personnel and Post Graduate Students engaged in research at the University, are required to complete the ‘Annual Declaration of Interests’ return in October of each year – **Register of Interest** (refer to Annex 2 of this document).
- 1.7. Whilst this Protocol describes, and provides, guidelines for many of the situations in which conflicts occur / can occur, it is not meant to be exhaustive. **The primary obligation rests with the Researcher** to recognise situations in which he or she has an existing and/or potential conflict of interest, and to disclose and discuss that conflict with his/her Dean / Head of Department (or Institute Director).

2. **Types of Conflicts.**

2.1 “Conflict of Interest” is defined as:

“A conflict between the *private* interests and the *official* responsibilities of a person in a position of trust.”

The damage caused by such conflicts can be considerable. For example, should the media (Press/Radio/TV) cast doubt on the validity of the research findings due to the researcher being discovered to have had a conflict of interest, there could be considerable reputation damage to the researcher, and to UL.

The above illustration highlights another important issue, namely that the definition is not restricted to those cases in which an individual actually betrays that trust: it can be just as damaging for the conflict to exist or appear to exist. Thus this Protocol is a mechanism for protecting UL researchers against criticism or compromise by ensuring that they recognise, and disclose, such conflict situations, and take steps to avoid and manage them.

Some of the principles set out in this Protocol relate to what might be better described as “conflicts of duty” (e.g. where one’s duty as a UL researcher, conflicts with one’s duty say as director of a spin-out or campus company). The term “Conflict of Interest” thus includes conflicts of duty, rights, obligations, interests and similar conflicts, whether as an individual or as a representative of UL.

2.2 The main categories of conflict of interest related to Research are:

- Educational Mission (especially in regard to supervision)
- Research Integrity
- Conflicts of Commitment and Loyalty
- Financial Conflicts

2.3 The need for a comprehensive set of guidelines has been made more acute by the increasing, and welcome, tendency by researchers to form spin-out /campus companies as a mechanism for bringing the results of research to market. Those involved often have multiple roles in such companies, for example as a Director, a shareholder and/or a consultant. Fulfilling these multiple roles in a company can create (or appear to create) a conflict with the researcher’s primary obligations and allegiance to UL. The Protocol addresses conflicts involving spin-out and campus companies as well as many other situations where conflicts may arise. Other general examples include:

- a) The use of the University’s research and/or administrative facilities to pursue personal business, commercial or consulting activities.
- b) Any attempt to restrict rights governing the timing and contents of publications, save in circumstances approved by the University to protect

privacy, commercially sensitive proprietary information, and/or patentable inventions.

- c) Involvement in externally-funded activity that might infringe the right of a student engaged in the activity to complete the degree for which he or she is registered and/or to publish freely or seek patent protection for his or her findings (save in the circumstance referred to in (b) above).
- d) A financial interest held by an individual in an external enterprise engaged in activities closely related to that individual's field(s) of research in the university.
- e) A personal involvement in any company, which is in, or in the process of, negotiating a contract with the university
- f) Over-dependency on a particular company for research funding – which may result in that company either formally or informally influencing the direction of the research or dissemination of results.

The above categories are intended to be illustrative and are not exhaustive.

3. **The UL Position.**

3.1 **UL is committed to the principle that the activities of its researchers should not give rise to situations in which its researchers have, or appear to have, conflicts of interest.** At the same time, UL recognises that procedures seeking to eliminate all potential conflicts could also prevent many of the activities (e.g. spin-out/campus companies) that universities now wish to encourage. Accordingly, rather than seek to prohibit all activities that might give rise to a conflict of interest, this Protocol, and its related Procedures, provide for a three-fold approach:

- Disclose always
- Manage the conflict
- Prohibit the activity when necessary to protect the public interest, or the interest of UL, or that of its researcher.

3.2 The key goal is to segregate the decision-making about the financial activities and the research/teaching activities, so that they are separately and independently managed. UL is particularly concerned to ensure that the activities of its researchers do not create conflicts in the areas of UL's Educational Mission and Research Integrity, as these areas are of fundamental importance to UL as an institution dedicated to teaching and research.

4. **Conflicts in the Educational Mission.**

4.1 Principles

UL's primary mission is the education and training of students, thus those of UL's researchers involved in education, training, supervision or directing the work of students, should ensure that the education they provide is appropriate to the student.

Special care must be taken to ensure that the choice of a student's research project, and the direction of that research is not, and does not appear to be, influenced by a supervisor's financial interest.

Whilst the following guidelines refer to research students, many of the same points are also applicable to junior members of academic staff and Post Doctoral Research assistants.

4.2 Conflicts and their management.

As a general rule, UL would prefer not to enrol a student where:

- The student receives support from (is sponsored by) a company in which the proposed academic supervisor has a Significant Financial Interest (refer to Annex 3 for Definition of Significant Financial Interest).
- The results arising from, or IP generated in the course of, the research project are related to the research activities of a company in which the supervisor has a Significant Financial Interest.

UL believes that such situations are difficult to monitor and that both the supervisor and the university are vulnerable to allegations that the student's research (and advice given on other issues, e.g. IP protection) was directed in a way that was not in the student's best interest.

One approach to the management of a conflict of this nature is to identify an alternative member of academic staff, with no Significant Financial Interest in the sponsoring company, to act as the supervisor for the student. In such cases the individual with a conflict of interest should not be involved in the project except through the alternative supervisor.

However, UL recognises that it is also to the student's advantage to be supervised by the appropriate person with the greatest relevant expertise, and that in a very few circumstances this may require that a student is supervised by an academic with a Significant Financial Interest in the sponsoring organisation. In these circumstances permission must be sought by the Dean / Head of Department from the Committee on Conflicts of Interest (refer to Clause 8). Where such permission is granted specific safeguards should be applied e.g.:

- a) Before embarking on a research project, the student must be provided by the supervisor with a clear description of the source of the sponsorship for the research to be undertaken; any personal financial interest the supervisor has in the sponsoring company; any restrictions that might be imposed on the scientific communication of the data by the sponsor, and, any rights that the sponsor may have to any intellectual property generated in the course of the project.
- b) The alternate Supervisor will not have any connection with, or interest in, the sponsoring company.

5. **Conflicts of Research Integrity.**

5.1 Principles

Researchers should maintain the highest standards of scientific integrity in the conduct of research.

The complete, objective and timely, dissemination of new findings through publication is essential for research integrity. In this context, '**publication**' means any means of dissemination of the research finding, including publication in a journal, information placed on the web, conference presentation or any other kind of scientific communication.

The potential for personal gain must not jeopardise, nor appear to jeopardise, the integrity of research activities, including the choice of research, its design, the interpretation of results, or the reporting of such results.

5.2 Conflicts and their management

Conflicts of interest can arise in a number of situations, for example:

- The researcher has a Significant Financial Interest in the company sponsoring the research, this being exacerbated if the value of the researcher's Significant Financial Interest may be affected by the outcome of the research.
- The researcher is an inventor of patents whose value may be affected by the outcome of the research.
- The researcher holds a position in an enterprise (e.g. as a Director) that may wish to restrict (or otherwise manage) adverse research findings for commercial reasons.

The preservation of research integrity must be largely dependent on self-regulation. The primary way to encourage appropriate conduct is to promote and maintain a climate consistent with high ethical standards. The fundamental factor in ensuring the quality of research and research practices has to be the honesty of the individual investigator.

However, where a researcher has, or appears to have, a conflict of interest (for example, because he or she has a Significant Financial Interest in a research sponsor), integrity in designing, conducting and reporting the research may be insufficient to protect the researcher and the university from suspicion and consequent reputation damage. In such cases researchers must take special measures to put themselves beyond suspicion.

The first step for managing such conflicts is disclosure.

Where a researcher has a conflict of interest, he/she should:

- Before the research project is authorised (i.e. a contractual arrangement agreed) disclose to, and seek written consent from, his/her Dean / Head of Department who may refer to the Committee on Conflicts of Interest if he or she has any doubts. The disclosure should be in the form of a written memorandum that states the nature of the research; the personnel to be involved in conducting the research; the potential conflict, and the method proposed to manage that conflict.

- Play no part whatsoever in the negotiation of the financial terms of the research contract, either as an agent of UL or of the sponsor.
- At the time of submission of a publication to a journal, comply with any conflict of interest policy of the relevant journal.
- Make a similar form of disclosure on all other forms of publication.

Conflicts of this kind should be managed or avoided by:

- Declining the opportunity to conduct the research; instead arranging for the work to be carried out by another researcher in UL or elsewhere as may be appropriate, or
- Appointing a co-investigator who has control over the design and analysis of the research and its results, or
- establishing an oversight committee.

Clinical research is a special case requiring greater scrutiny, given the very significant financial consequences of research outcomes, and the potential harm to persons engaged in clinical trials, or under treatment. In some cases UL may prohibit a researcher from acting as Principal Investigator. In addition to the guidelines laid out in this Protocol, researchers should comply with any additional requirements as laid down by the **University Research Ethics Committee (ULREC)**.

6. **Conflicts of Commitment / Loyalty.**

6.1 Principles

Researchers owe their primary commitment and allegiance to UL. Membership of external Committees, Boards, Advisory Groups, etc. (External Appointments) infers an obligation (and sometimes a statutory duty) to act in the best interest of the external body. These duties may overlap with the duties and obligations researchers have to UL. Where an External Appointment for a UL employee is authorised under the **UL Personal Consultancy Policy**, or otherwise allowed by UL, this does not absolve the researcher from ensuring that he or she continues to give their primary commitment and allegiance to UL.

6.2 Conflicts and their management

For UL employees the rules applying to the acceptance of external appointments and the conduct of non-academic work, including limits on the amount of time that may be devoted to such activities are set out in the **UL Personal Consultancy Policy**. The scheduling of commitments to such external bodies should be such that they do not result in significant rescheduling of lectures, tutorials or other supervisory or management duties.

Where a researcher is involved in founding a new company, he or she may be induced to dedicate more time to it than is consistent with his/her duties to UL. This risk can be reduced by ensuring that appropriate people are employed by the company to manage and direct both its business and scientific activities, with, in the case of a UL employee, his/her role being limited to consultancy. Alternatively, UL employees may be able to arrange unpaid leave of absence from UL for a period of time so that they can dedicate themselves full-time to the company.

In exceptional circumstances, it may be acceptable to UL to permit academic staff to devote significant time (over and above that permitted under the **UL Personal Consultancy Policy**) to an external appointment; for example where such absence can be shown to be short-term and non-disruptive to the employee's other duties, and be of clear benefit to UL. Such cases should be notified to the Dean / Head of Department in timely fashion, giving full details of the nature of the activity, and the timing and duration of the external commitment. The Dean / Head of Department will refer all such applications to the Committee on Conflicts of Interest (Clause 8) to seek advice as to the appropriateness of granting or denying permission.

In all cases, UL employees must disclose in writing and discuss any potential conflicts with their Dean / Head of Department:

- Prior to the commencement of such commitment.
- When circumstances change in a way that result in changes to the conflict (either as a result of change to that person's responsibility in UL, changes in the nature of the relationship between the external company and UL, or changes in the commitment to the external body). This can present a significant challenge since circumstances often change gradually and with little formality. It is nevertheless important, for the person's own protection, that his / her Dean / Head of Department is informed, in advance, of any changes to the relationship.

7. **Conflicts of Financial Interest.**

7.1 Principles

Researchers have a responsibility to respect and promote the financial interests of UL. Researchers should, wherever possible, ensure that UL:

- Receives appropriate financial benefits from the provision of research services, including consultancy and other services conducted through UL.
- Receives appropriate financial benefits from the use or commercialisation of UL's Intellectual Property.
- Receives appropriate financial benefits from the use of other UL resources and assets, including equipment, technical staff and facilities.
- Makes responsible use of its financial resources in relation to the purchase of goods and services.

7.2 Conflicts and their management

A Researcher's relationship with another organisation e.g. as a shareholder of a spin-out / campus company or other commercial entity, may create financial responsibilities to that organisation which conflict with his or her financial responsibilities to UL.

Such potential conflicts should be managed by:

- Seeking formal permission from his/her Dean / Head of Department describing the nature of the relationship. If the Dean / Head of Department believes that the conflicts created by the proposed arrangement are manageable and that the use of any UL resource will not conflict with academic priorities he/she may approve the arrangement in writing. If the

Dean / Head of Department is in any doubt as to whether a conflict exists, he/she may refer the matter to the Committee on Conflicts of Interest for advice. If approval is given, then the arrangement will be formalised and an appropriate fee will be levied for any resource used.

- In the case of research contracts with external organisations, in which the researcher has, or expects to have, a financial interest, being negotiated by UL (normally by the Technology Transfer Office on behalf of the university) the researcher should not play any part whatsoever in such negotiations unless specifically invited to do so by the TTO.
- Disclosing (if necessary under a Confidentiality / Non -Disclosure Agreement) and seeking a waiver from UL in respect of all inventions or other IP generated by the individual as part of a private consultancy.
- Where the researcher provides consultancy services, by conducting that consultancy, if appropriate, through UL.
- Where the purchase of any goods or services is to be sanctioned by a researcher from a business in which that researcher has any Significant Financial Interest, then such interest should be declared via the Dean / Head of Department to the Vice President Finance.

On occasions, UL itself may be involved in an activity in which a researcher has a conflict of interest. For example, UL may own shares in a spin-out / campus company in which the researcher also owns shares. Depending on the circumstances, the researcher's shareholding may give rise to a Conflict of Interest. Researchers should be aware that the fact that UL may benefit from an activity (e.g. as a shareholder) does not in any way mitigate or reduce that person's obligation to declare his/her interest under this Protocol.

Increasingly, students themselves start businesses whilst still at university. Academic researchers in a position to judge the quality of that student's work or to evaluate the student in any way, should not take a Financial Stake, or hold a Formal Position in such a student-run, owned or controlled venture whilst the student is enrolled at UL. **Financial stake** means equity, share option or any form of financial interest in such venture. **Formal position** means as member of the Board of Directors, or acting as a paid consultant, or employee or executive of the venture.

8. **Committee on Conflicts of Interest.**

- 8.1 This Protocol applies to all employees of the University and to all Honorary, Adjunct, Emeritus, Visiting personnel, and Postgraduate Students engaged in research work at the University, collectively **Researchers**.
- 8.2 A **Committee on Conflicts of Interest** shall be appointed by the President to manage, and adjudicate on, issues arising from the application of this Protocol.
- 8.3 Membership shall include:
- Vice President, Academic and Registrar.
 - Vice President, Research.
 - Director, HR.

- Plus such other appointees as the President deems appropriate.

The Chair of the Committee will be nominated by the President. Appointments shall be for a three (3) year term.

8.4 The Committee shall have the following Terms of Reference:

- a) To respond to requests from Deans / Heads of Department for advice in relation to a member of their Faculty / Department as to whether a conflict of interest, as defined by this Protocol, exists or may exist, and /or how it might best be managed in the interests of the University, and of the individual.
- b) To consider, for approval, all cases referred by Deans / Heads of Departments involving the proposed supervision of a sponsored student by an academic researcher with a Significant Financial Interest in the sponsoring organisation. All such requests to be considered in accordance with the conditions set out in this Protocol.
- c) To consider, for approval, all cases referred by Deans / Heads of Departments involving conflicts of research integrity if a particular research project were to be accepted. All such cases must be determined before a contractual arrangement is agreed.
- d) To consider, for approval, all cases referred by Deans / Heads of Departments where a researcher's proposed relationship with another organisation creates a conflict of interest.

8.5 Issues for consideration by the Committee should, in the first instance, be sent to the Director, Research Support Services who will convene the meetings of the Committee, and whose office will provide the Committee Secretariat. All decisions of the Committee shall be recorded by way of Minute. Copies of the relevant decision shall be distributed to both the Dean / Head of Department raising the issue, the researcher involved, and the Vice President Research.

8.6 The Committee will report to the President by means of the submission of its Minutes, and by an Annual Report to the Executive Committee summarising in general terms (to retain a high level of confidentiality), the issues it considered in the preceding year.

8.7 References to Heads of Department (which include Institute Directors) apply to the relevant Dean for Heads of Departments/ Institute Directors, the President for the Deans and Vice Presidents, and the Governing Authority for the President.

9. Review.

9.1 The terms of this Protocol will be reviewed from time to time to reflect experience of its operation.

May, 2009.

Examples of activities that are generally **not allowable**, or that require **prior written approval** (and may be subject to overview).

A. Activities that are generally not allowable:

- A researcher acting as academic supervisor for an industry –funded student where the researcher concerned has a Significant Financial Interest in the sponsoring company.
- A researcher taking any financial stake, or holding a formal position, in a student-run, owned or controlled company while the student is enrolled at UL where the researcher is in a position to judge the quality of that student's work or to evaluate the student in any way.
- A researcher taking any part in the negotiation of a contract between UL and a company, where the researcher has a Significant Financial Interest in the company.
- A researcher publishing, or formally presenting, research results, or providing expert commentary on a subject, without disclosing any Significant Financial Interest in a company that may benefit from the results being reported or opinions expressed.
- A researcher using UL resources and assets (equipment, technical staff and facilities) for personal gain.
- A researcher commenting on a company's products or innovations when the researcher has a commercial interest. There should also be a recognition that a conflict of interest could also arise where a researcher, involved with a commercial company, chooses to comment negatively on a competitor company or a competitor company's products.
- Use of the University of Limerick's name to endorse a product that has been researched or developed by a researcher working in a private or consultative capacity for an external company.

B. Activities that may be allowable after disclosure, review and approval by the Head of Department (who may refer to the Committee on Conflicts of Interest for advice).

- A researcher acting as academic supervisor for a Student where the research results are related to the research or commercial activities of a company in which the supervisor has a Significant Financial Interest.
- A researcher acting as Principal Investigator on a project funded under contract by a company, where the researcher concerned has a Significant Financial Interest in the company.
- A researcher carrying out research, the outcome of which may affect the value of Patents or other Intellectual Property owned by the researcher.
- A researcher holding a position in a company (e.g. as a Director) where the company may, for commercial reasons, wish to restrict (or otherwise manage) adverse research findings generated by the researcher concerned.
- A researcher taking administrative action within UL, which is beneficial to a company in which he/she has a Significant Financial Interest.

REGISTER OF INTEREST

of

Financial Interests, Directorships, Partnerships, Consultancies, Trusteeships, Trade Engagements, Other Remunerated Positions, and Membership of External Committees.

The Register of Interest applies to all UL employees, and to all Honorary, Adjunct, Emeritus, Visiting personnel, and Post Graduate Students, engaged in research at UL.

Introduction.

In keeping with its academic aims and purposes, UL encourages close liaison between its staff and industry, commerce and Government departments through the acceptance by staff of personal Directorships, Partnerships, Consultancies (including Private Clinical Practice, where appropriate), Trusteeships, Trade Engagements and membership of official committees.

UL encourages such interaction, but is mindful of its obligations to provide safeguards, wherever possible, against anything arising from these links, which could be detrimental to UL, or to individual employees. One area of concern is that of potential conflicts of interest; another is legal liability and indemnity insurance cover.

Where the possibility of conflict of interest exists, particularly that of a Financial nature, it is universally accepted that prior declaration by all parties of their interests is essential. A **Register of Interests** is kept of the personal interests of UL employees, both full and part time, and of other appropriate personnel engaged in research, which may overlap with the interests of UL. Thus researchers, in addition to declaring their Financial interests are also asked to provide details of Directorships, Consultancy undertakings and other remunerated positions, as well as Membership of external committees whose work may be related to that of UL, e.g. Research Councils, government departments, professional bodies, and training organisations.

Employees, and other appropriate persons, could also be engaged in trading activities or other remunerated positions, without necessarily holding consultancies etc, in which there could be deemed to be a conflict of interest with activities they engage in on behalf of UL.

The **Register** is maintained by the Office of the Vice President Research. Persons with bona fide and substantial reasons to inspect declarations shall be allowed access to the information filed at the discretion of the chairperson of the Committee on Conflicts of Interest.

Annual Return

All Employees and all Honorary, Adjunct, Emeritus and Visiting personnel and Post Graduate students working on Sponsored Research Contracts stipulating that all Conflicts of Interest are declared, are required to complete and submit an Annual Return of Interests in October of each year.

Prior to submission the Return should be discussed with the individual's Head of Department. The completed return should then be sent to the VPR for compliance with Funding Body contractual terms and subsequent inclusion in the Register of Interests.

Failure to declare an interest may become a disciplinary matter. It is therefore important that Persons would declare any interest if they are in any doubt about its relevance or materiality to the work they are undertaking at UL.

Forms:

- 1. Declaration of Interests.**
- 2. Directorships, Partnerships, Consultancies
Trusteeships, Traderships, or Employment
(other than UL).**
- 3. Membership of External Committees.**

Copies of the Forms may be downloaded from the **Code of Good Practice in Research** on the Research Office website.

Annex 3.

A Significant Financial Interest.

For the purposes of this Protocol a **Significant Financial Interest** includes :

- **Shares** / Share options / Warrants and other securities and interests (collectively referred to as “shares”) in a company held by a Researcher, his or her close family members (husband / wife / partner / children / siblings / mother / father), and associated entities where the Researcher exercises voting control.

The current value of Shares shall not exceed 13,000 euro at any time, or amount to more than 10% of the equity of the company.

These limits shall not apply in the case of shares held in a company listed on a recognised Stock Exchange, and/or where no relationship or connection, explicit or implicit, exists between the acquisition of the shares and any research to be conducted by the Researcher at the university on behalf of the company.

- **Payments for services**, including Consulting fees.

Consulting fees shall not exceed 13,000 euro in any twelve month period.

This limit shall not apply where permission to engage in Consultancy, under the terms of the **UL Personal Consultancy Policy**, has been received by a UL employee, and/or where it can be reasonably demonstrated that the payment of any fee is not related or contingent on the award of any research contract .

- **Payments of Fees**, Directors fees, Stipends, Honoraria, payments-in-kind.

Directorships and other appointments received by UL employee’s outside UL (i.e. not as a UL “appointee”) are subject to the terms of the **UL Personal Consultancy Policy**. Where payments arise in respect of such appointments, provided the appointments have been

notified to the university in accordance with the policy / procedure current at the time, they shall be allowable.

- **Payments in respect of IP**, (licence fees, royalties and revenue sharing).

UL employees are required to declare payments received in respect of all inventions or other IP generated in the context of their private consultancy.

This requirement does not apply to payments received by an individual under the terms of the **UL Intellectual Property Policy**.