CONFLICTS OF INTEREST POLICY



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Service of the United States Department of Health and Human Services

1. Overview

- 1.1. It is the policy of the University of Dundee to conduct business in an honest and ethical manner consistent with the University's Values, the Nine Principles of Public Life in Scotland and applicable law and regulation.
- 1.2. As part of this overarching policy, the University requires Staff to take appropriate steps to identify and prevent any Conflicts of Interest that may arise or have the potential to arise in the course of conducting business on behalf of the University.
- 1.3. However if a conflict cannot be prevented then Staff will require to take appropriate steps to mitigate and manage such conflicts.

2. Purpose

2.1. This policy sets out the University's expectations of its Staff in respect of the identification and management of Conflicts of Interests and the controls that the University has in place to facilitate this.

3. Who does this policy apply to?

3.1. This policy applies to all individuals working for or on behalf of the University at all levels and grades, whether permanent, fixed-term or temporary, and wherever located and any other person who performs services for, or on behalf of, the University.

4. What is a Conflict of Interest?

- 4.1. A "Conflict of Interest" is a situation where one or more persons or entities have competing interests and the serving of one interest may involve detriment to another.
- 4.2.A Conflict of Interest under this policy includes both an actual Conflict of Interest (i.e. a Conflict of Interest that has arisen) and a potential Conflict of Interest (i.e. a Conflict of Interest that may arise given particular facts and circumstances).
- 4.3. It also includes a perceived Conflict of Interest (i.e. a situation which may give rise to the perception of a Conflict of Interest), even where a Conflict of Interest may not in fact exist.
- 4.4. Failure to identify and appropriately manage Conflicts of Interest could result in inappropriate or adverse consequences for the University, Students, Staff and Third Parties who deal with the University.

5. Examples of Conflicts of Interest

Conflicts of Interest relating to the University can be broadly described as scenarios where:

• a Staff Member's interest in the outcome of a particular activity or endeavour differs from the University's interest;

- a Staff Member (or, where applicable, a Family Member or Close Personal Relationship) receives a financial or other significant benefit as a result of the Staff Member's position at the University that is inappropriate in nature;
- a Staff Member has the opportunity to influence the University granting business or making administrative and other material decisions in a manner that leads to personal gain or advantage for the Staff Member or a Family Member or Close Personal Relationship;
- a Staff Member's existing financial or other interest or previous engagement in an endeavour or activity or relationship with another person, impairs or could impair their judgment or objectivity in carrying out their duties and responsibilities to the University;
- a Staff Member favours the interest of one part of the University over another, which is inconsistent with the best interest of the University:
- a Conflict of Interest arises in connection with a transaction or arrangement entered into between the University and a person of significant influence or between University Related Entities due to the close relationship between the parties; or
- an individual member of Staff has a competing interest in the distribution of effort between employment obligations to the University and to outside professional activities and Outside Business Interests.

6. What is not acceptable?

Conflicts of Interest, if inadequately managed, could result in the following outcomes which are deemed unacceptable by the University:

- the University and/or a member of Staff failing to comply with their legal or regulatory obligations;
- the University and/or a member of Staff failing to fulfil a duty of care, trust or loyalty owed to another person or entity such as a Student or Third Party;
- a Staff member's professional judgement and objectivity being compromised and/or hindering the proper discharge of their duties and responsibilities;
- a member of Staff engaging in unethical conduct;
- the University or member of Staff obtaining improper advantage or treatment or giving rise to the appearance of impropriety and consequent reputational damage, including as it relates to the manner in which business is awarded to or by the University; and/or
- the University being brought into disrepute and subject to adverse publicity and reputational damage.

7. Responsibilities

- 7.1. As part of the University's approach to conflicts management, the prevention, management and reporting of Conflicts of Interest as set out in this policy are the responsibility of all those working within the University community or under our control.
- 7.2. The University requires the following categories of Staff to carry out the relevant actions as set out below.

A. All Staff

All Staff are responsible for being alert to, identifying and managing Conflicts of Interest on an ongoing basis in relation to themselves and others and are required to:

- comply with this policy, Rules and other applicable policies and procedures relating to the identification, documentation, escalation and management of Conflicts of Interest;
- act with integrity and exercise good judgment and discretion in accordance with the University's Values and the Nine Principles of Public Life in Scotland;
- act with the requisite degree of independence and objectivity when discharging their responsibilities at the University;
- avoid, wherever possible, situations giving rise to Conflicts of Interest due to any of the following:
 - o personal financial interest;
 - o Family Members or Close Personal Relationships including but not limited to recruitment of Staff and/or applications for study at the University;
 - o previous, current or potential future involvement in an activity or endeavour (whether at the University or externally); and/or
 - o different roles and responsibilities at the University.
 - o and, in particular, refrain from participating in the recruitment process of staff, including shortlisting, selection and interview, where a Family Member or Close Personal Relationship has applied or is likely to apply; and
 - avoid acting in any way to influence the consideration of student applications to study at the University from Family Members or Close Personal Relationships.
- immediately notify their line manager and/or Legal of the existence and general nature of a Conflict of Interest;
- immediately disclose Conflicts of Interest to the Chairperson/Convener when participating in decision-making within a committee or working group setting;
- within a committee of Court or Senate or other authorised group setting within the University (such as steering committee on a project) declare their interest and, if the

Chairperson/Convener so determines, remove themselves from the decision-making process and not seek to influence such decisions any further. Where the Conflict of Interest arises from the Chairperson/Convener they shall be under an obligation to declare it to the group/committee and they shall refer themselves to the University Secretary or Legal for advice and decision;

- not be in a supervisory, subordinate or control relationship (having influence over conditions of employment) with closely related persons including Family Members or Close Personal Relationships;
- not misuse information obtained in the course of working at the University including for personal benefit;
- manage work-related information on a "Need to Know" basis, respecting information barriers and duties of confidentiality at all times;
- challenge and escalate promptly issues of concern to their supervisors and Legal so that Conflicts of Interest may be appropriately reviewed, managed and resolved;
- upon joining the University and on a periodic basis thereafter, complete all Annual Declarations required by the University; and
- being aware of how their actions could be perceived in respect of Conflicts of Interest and to act in the best interest of the University at all times so that the University does not suffer reputational damage;
- comply with applicable Rules which require transactions and arrangements between the University and a Related Party to be carried out on an independent, arms-length basis.

B. Supervisors

Staff who act in a supervisory capacity are required to:

- actively seek to identify, mitigate and, to the extent required by the University document Conflicts of Interest in their area of responsibility, including in connection with any current or planned activities;
- assess any Conflicts of Interest reported to them to determine if a Conflict of Interest exists (or might reasonably be perceived to);
- determine, after consulting Legal and other control functions as required, the best course of action to resolve, manage or avoid the Conflict of Interest, including further escalation to a higher management authority where necessary or the (temporary or permanent) withdrawal of oversight of a given matter or activity from the Staff member concerned;
- review on an annual basis or more regularly, if required, any reported Conflicts of Interest to ensure these are being managed in accordance with any agreed resolution; and

 allocate responsibilities to Staff who report to them in a manner that does not lead to Conflicts of Interest and avoid allocation of responsibilities which will compromise the independence of control functions of the University.

C. Senior Management

Members of Senior Management are responsible for overseeing the identification, documentation, escalation and management of all Conflicts of Interest as they arise within their relevant areas of responsibility at the University.

Members of Senior Management are required to:

- sponsor and encourage an appropriate culture which emphasises the importance of ethical treatment of persons involved in a Conflict of Interest and the fair handling of Conflicts of Interest;
- be engaged in the implementation of policies, procedures and arrangements for the identification, documentation, escalation, management and ongoing monitoring of Conflicts of Interest:
- be engaged in the clear communication of policies, procedures and expectations and the sharing of best practice throughout the University;
- adopt a holistic view to identifying potential and emerging Conflicts of Interest within and across the University and to facilitate informed judgements with respect to materiality and the manner in which conflicts are handled;
- raise awareness and promote adherence of Staff in completing regular training both at induction and in the form of refresher training;
- sponsor systems and controls to document, track, manage and mitigate Conflicts of Interest risk, and regularly review their effectiveness;
- consider the implications and take corrective action, where required, in connection with performance measurements or incentive schemes that may incentivise a Staff Member to act contrary to the duties and responsibilities owed to the University; and
- utilise management information to remain sufficiently up-to-date and informed in connection with the matters listed above.

D. University Executive Group (UEG)

Key obligations for members of UEG in connection with Conflicts of Interest are:

• To generally act in the best interest of the University and ensure that procedures are in place so that transactions considered by UEG relating to the University and/or a Third Party are generally undertaken only on an arm's length basis.

- To ensure that business decisions are unaffected by Conflicts of Interest and to therefore:
 - proactively identify Conflicts of Interest resulting from their executive management position (whether as a member of the management or the supervisory function) and disclose such Conflicts of Interest as required by the applicable terms of reference; and
 - o Material Conflicts of Interest, individually and collectively, must be adequately documented, communicated to, discussed and duly managed by the UEG;
- In general, to not be involved financially in any kind of business which is in competition with the University without prior approval of the Principal and the consent of the Chair of the Audit Committee. Where such approval is granted this shall be reported to and documented by the Audit Committee promptly with regular reporting to Court.
- To not represent the University in dealings with himself or herself, or with a Third Party represented by himself or herself, unless the Chair of the Audit Committee permits such representation on the basis of consent and such consent is granted. Any consents granted by the Chair of the Audit Committee shall be reported to and documented by the Audit Committee promptly with regular reporting to Court.

8. Conflicts of Interest management

- 8.1. The University addresses specific actual or potential conflicts through one or more of the following options:
- Application of the measures and precautions set out in this policy; and/or
- Declining to act.
- 8.2.All decisions as to the appropriate management of any Conflict of Interest should be based on three principles, namely:
- To comply with the terms of this policy;
- To secure fair and equitable treatment of all parties involved, and
- To mitigate any legal, regulatory or reputational risk to the University.

9. Process for raising concerns and management (General)

- 9.1. Conflicts of Interest should be identified, declared and managed within the first line where possible in accordance with this policy.
- 9.2. For first line concern raising/declarations generally a Staff Member should contact their line manager in the first instance.
- 9.3. The following are escalation points after the line manager stage or where escalation to a line manager may not be appropriate.

Area	Escalation
Committee or Group	Declarations or concerns should be raised to

	the Chairperson or Convener who will then escalate in line with this policy as required.
Directorate	Declarations or concerns should be raised to the Director who will then escalate in line with this policy as required
School	Declarations or concerns should be raised to the Dean of School who will then escalate in line with this policy as required.

- 9.4.Where a Conflict of Interest is declared the individual School, Directorate, Committee or Group will require to keep records of such. These records shall be kept and will be made available to Academic & Corporate Governance on request.
- 9.5. Where a Conflict of Interest or a potential Conflict of Interest has been disclosed, and is either:
 - 9.5.1. subject to the mandated requirements; or
 - 9.5.2.cannot reasonably be managed by the individual School, Directorate, Committee or Group as to mitigate the risk of inappropriate influence as set out in this policy;

the relevant business area shall discuss a possible resolution with the University Secretary on advice from Legal.

9.6. Any matter unresolved by the University Secretary shall be referred to the Audit Committee for advice; in cases of particular difficulty the matter shall be referred to the Court for final resolution.

10. Mandated requirements in respect of certain identified Conflicts of Interest

Notwithstanding the generality of this policy the following process has been mandated by the University in respect of the following categories of Conflicts of Interest:

10.1.Outside Business Interests

- 10.1.1. The University permits Staff to maintain Outside Business Interests as long as:
 (i) the Outside Business Interest does not create an actual or potential Conflict of Interest; (ii) the Outside Business Interest does not affect the ability of Staff to perform their professional responsibilities within the University, including obligations under their employment contracts with the University.
- 10.1.2. No Staff Member shall establish an Outside Business Interest regardless of whether or not compensation is received or the Staff Member is asked to engage in such activity by the University without the express approval of their line manager, the University Secretary and/or Legal.
- 10.1.3. If approval is received, the Staff Member shall require to comply with the terms and conditions of this policy including but limited to Family Members or Close Personal Relationships and it is the Staff Member's responsibility to notify

- Legal immediately if any Conflict of Interest or potential Conflict of Interest arises in the course of the Outside Business Interest.
- 10.1.4. Generally, the University will not approve an Outside Business Interest other than where activities related to it are in compliance with the University's policies and procedures, reflect the interests of the University as a whole and/or that are not in competition with those of the University.

10.2. Holding of directorships and shares by Professional Services Staff

- 10.2.1. For the purpose of these rules "Professional Services Staff" are defined as staff of the University's professional services within both Directorates and Schools.
- 10.2.2. Unless formally nominated by the University to do so, Professional Services Staff shall not serve in a personal capacity as a director or other officer of a company or commercial enterprise, the establishment of which arose out of or was connected with work done in the University, or any company or commercial enterprise in a contractual relationship with the University, where the Professional Services Staff Member was concerned or connected with placing or negotiating the contract in question.
- 10.2.3. Any Professional Services Staff Member nominated by the University to serve as the director of a company shall be deemed to accept the nomination in the discharge of his or her duties as an employee of the University, and shall decline to accept any director's fee.
- 10.2.4. No Professional Services Staff Member shall hold any shares in a company, the establishment of which arose out of, or was connected with, work done in the University, or any company in a contractual relationship with the University, where the Professional Services Staff Member was concerned or connected with placing or negotiating the contract in question unless such shares have been acquired following the listing of the company on a recognised stock exchange.

11. Annual Declarations

- 11.1.1. Individuals occupying the following positions shall be required to submit an annual declaration of external interests:
 - Members of Court and supporting officers;
 - The Principal & Vice-Chancellor
 - Vice-Principals
 - Deans and Associate Deans
 - Directors of Directorates;
 - School Managers;
 - Other administrative officers with significant budgetary or procurement responsibilities

11.2. A record of all declarations made shall be maintained centrally by the University Secretary or their nominee.

12. Consequences for Breach of this policy

- 12.1. Any member of Staff who breaches this policy (which includes a failure to notify) may face disciplinary action, which could result in suspension or dismissal for gross misconduct. We reserve our right to terminate our contractual relationship with non-employee Staff if they breach this policy.
- 12.2. Repeated violations are considered on a cumulative basis.

13. Communication

13.1. The University's approach to managing Conflicts of Interest will, where appropriate, be communicated to Third Parties.

14. Monitoring and review

- 14.1. The Audit Committee has a general responsibility for monitoring the operation and effectiveness of Conflicts of Interest arrangements and will receive appropriate reports on any Conflicts of Interest activity.
- 14.2. The UEG has a responsibility to ensure that internal control systems and procedures are monitored and also subject to regular review to provide assurance that they are effective in countering any risks of non-compliance with this policy. Annex 2 lists the systems and controls that the UEG has in place to mitigate and manage Conflicts of Interest arising within the business of the University.
- 14.3.All Staff are aware that they are responsible for the success of this policy and ensure they use it to disclose any suspected danger or wrongdoing.

Annex 1 - Definitions

Definition	Meaning
Chairperson/Convener	A chairperson or convener of a committee or
	Group or equivalent;
Close Personal Relationship	any of the following: a) a romantic or sexual relationship of a Staff Member; b) a personal business, commercial or financial relationship of a Staff Member; c) a personal friend of a Staff Member or d) a cohabitee of a Staff Member.
Conflict of Interest	a situation where one or more persons or entities have competing interests and the serving of one interest may involve detriment to another.
Court Committee Member	A member of any board or committee of the University Court or Senate.
Directorate	A directorate within the professional services of the University from time to time.
Family Member	in relation to a Staff Member, a spouse, civil partner, domestic partner, children or stepchildren, parent or parent-in-law, sibling or sibling-in-law, grandparent, aunt, uncle, nephew, and niece.
Group	A group convened for the purposes of conducting University business.
Legal	the University's Legal department headed by the Director of Legal.
Outside Business Interest	Any commercial or business interest or activity undertaken by Staff outside their day to day role at the University which is likely to (i) conflict with their obligations under their contract of employment (ii) create an actual or potential Conflict of Interest; (iii) bring the University into disrepute; and/or (iv) otherwise be disclosable to the University under the University's policies and procedures including without limitation, establishing a company, forming a limited partnership, other external business interest, directorships, board memberships, external employment and paid political office appointments.
	The following are not considered Outside Business Interests: any work or activity undertaken with local community organisations; for example, local churches, homeowners associations, school boards rotary clubs, local charities or other

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	community organisations. The definition also
	does not include any voluntary work outside
	of your day to day role at the University.
Related Party/Entity	any person or entity who is considered a
	related party of the University under
	applicable corporate law of the entity's
	country of incorporation. Examples include a
	parent, subsidiary or fellow subsidiaries.
Rules	any laws, regulations, rules, supervisory
	expectations, codes of conduct/ethics, and
	standards of good or best practice relating to
	Conflicts of Interest applicable to the
	University.
School	A school of the University
Senior Management	those Staff who are responsible for, or have
	significant influence over, the direction and
	day-to-day management of the University, its
	Schools and/or Directorates (including
	members of UEG, UMG and all other
	management positions) and/or a Related
	Entity;
Staff/Staff Member	any of the following: a) a permanent or
	temporary employee of the University; b) an
	authorised representative or agent of the
	University; or c) a Court Member
Student	
Third Party	any individual or organisation that Staff come
	into contact with during the course of their
	work and the running of the University's
	business, and includes actual and potential
	students, intermediaries, referrers of
	students, staff, work, grants, suppliers,
	distributors, contractors, business contacts,
	agents, advisers, government, funding
	councils, regulators and public bodies
	(including their advisers, representatives and
	officials), politicians and political parties.
UMG	The University Management Group as
	constituted from time to time (and its
	successor)
	Successori

Annex 2 - University Controls to Manage Conflicts of Interest

Committee Covernous s	Fook committee of the University is a serviced
Committee Governance	Each committee of the University is required
	to have terms of reference in place. These
	terms must include the requirement for
	members of committees to consider
	potential Conflicts of Interest when
	determining the composition of the
	committee, taking into account the tasks and
	responsibilities of that committee. Further,
	the terms of reference must require
	committee members to disclose potential
	Conflicts of Interest on an ongoing basis to
	the Chairperson/Convener and for the
	Chairperson/Convener to take appropriate
	action to resolve such Conflicts of Interest.
Escalation	The University operates internal escalation
Escalation	processes for Conflicts of Interest, with each
	•
	School and Directorate having the
	responsibility of defining and documenting
	their respective processes. The escalation
	processes are required to enable the Conflict
	of Interest to be escalated on a timely basis
	and considered at an appropriate level of
	seniority and by the correct stakeholders to
	arrive at the most appropriate resolution.
Legal	as a 2nd Line of Defence function, is the risk
	controller for the Conflicts of Interest. In this
	capacity, Legal is responsible for the
	development of related policies, the testing
	of controls implemented by the University
	and the regular risk assessment of Conflicts
	of Interest risk management by the
	University.
Segregation of Functions and Duties	The University structurally segregates Legal
	from its business to allow for their
	independence. The University also operates
	an internal control environment underpinned
	by a "Three Lines of Defence" framework that
	requires the independence of control
	functions, including Legal.
Whistlablowing	The University provides appropriate channels
Whistleblowing	through the Whistleblowing Policy for the
	,
	reporting/whistleblowing of Conflicts of
	Interest within the University where a Staff
	Member considers this to be the appropriate
	channel to draw the matter to the attention
1	of the University.

Annex 3 - The University's Values

Our values

Valuing People, Working Together, Integrity, Making a difference and Excellence

Communication underpins all our values

- Take personal responsibility for ensuring communication in your sphere is effective.
- Communicate effectively and clearly using appropriate channels.
- A conversation is often better than email.
- Listen well so you can understand before responding.
- Be polite and courteous in all circumstances.
- Praise first before giving constructive feedback.
- Challenge absent or poor communication appropriately and ensure that no one is left out of the loop.

Valuing people

- Treat everyone with equal respect, valuing their contribution to the University.
- Make time to listen to, help and support others.
- Be aware that you might have unconscious biases and try to identify and overcome them.
- Be liberal with thanks and praise.
- Recognise and reward achievement.
- Acknowledge the contribution of others towards individual success.
- Recognise and respect differences, actively promoting inclusion.

Working together

- One Dundee: seek what is best for the wider University community as well as your team.
- Actively seek ways of working together across boundaries to address the University's key challenges.
- Foster partnership working between students and staff.
- Ensure every member of the University community is included and feels part of the bigger picture.
- Share good practice generously.
- Maintain calm and perspective in stressful situations.
- Counter cynicism by encouraging productive discussion and problem solving.
- Positively challenge divisive behaviour.

Integrity

- Behave ethically and professionally, with the best interests of the University at heart.
- Be open, honest and fair.
- Keep your word and be trustworthy.
- Be accountable for actions and decisions.
- Respect confidentiality when appropriate.
- Be open to challenge without defensiveness and willing to challenge without aggression.
- Have the courage to question actions that are inconsistent with University values.

Making a difference

- Remember that our common purpose is to transform lives locally and globally.
- Encourage and support fellow students and colleagues to be transformative.
- Commit to making a real difference through your work, inspiring others with your passion and enthusiasm
- Focus on working well with others to get results.

- Encourage and enable professional development.
- Embrace change.

Excellence

- Aim to be leading in what you do as we strive to be Scotland's leading University.
- Nurture creativity and innovation.
- Demonstrate consistently strong personal performance so that others can rely on you.
- Benchmark yourself and your team against the best.
- Gather feedback to improve performance and close feedback loops.
- Provide encouragement and seek support to improve.
- Be honest with yourself and others about performance that is less than excellent.
- Challenge mediocrity and be prepared to take, and accept, difficult decisions in pursuit of excellence.

Annex 4 - The Nine Principles of Public Life in Scotland

DUTY

Holders of public office have a duty to act in the interests of the public body of which they are a Board member and to act in accordance with the core tasks of the body.

SELFLESSNESS

Holders of public office should act solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends.

INTEGRITY

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might seek to influence them in the performance of their official duties.

OBJECTIVITY

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

ACCOUNTABILITY AND STEWARDSHIP

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

OPENNESS

Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

HONESTY

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

LEADERSHIP

Holders of public office should promote and support these principles by leadership and example.

RESPECT

Holders of public office must respect fellow members of their public body and employees of the body and the role they play, treating them with courtesy at all times.

Annex 5 - Specific Conflict of Interest Guidance related to Research Funded by the Public Health Service of the United States Department of Health and Human Services

The University has approved a policy and guidance to meet the requirements set out for research funded by the Public Health Service (PHS) of the United States Department of Health and Human Services that applies also to research funded by any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to: the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

The guidance is available online from: [Insert URL].

FINANCIAL CONFLICT OF INTEREST POLICY FOR RESEARCH FUNDED BY THE PUBLIC HEALTH SERVICE OF THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES

SCOPE & INTRODUCTION

- This policy an addendum to the University's Code of Practice on Conflict of Interest1 governs financial conflicts of interest (FCOI) and shall apply only to, in general terms,
 University and NHS Tayside employees who are applying to receive grant funding from
 the Public Health Service (PHS) of the United States Department of Health and Human
 Services (HSS).
- 2. Specifically, the policy applies to the Principal Investigator or any other person regardless of title or position who is responsible for the design, conduct or reporting of research funded by any component of PHS, including University contractors, collaborators and consultants, where deemed appropriate by the University.
- 3. For the purposes of this policy, the term 'Investigator' is used throughout to describe those employees who are deemed to fall under the scope of this policy.
- 4. The University shall designate responsibility for ensuring implementation of this policy according to a separate process schedule.
- 5. The University may suspend all relevant activities until the financial conflict of interest is resolved or other actions deemed appropriate by the University are implemented.
- 6. Any material breach of any part of this policy, as determined by the University, may constitute cause for disciplinary action.

DEFINITIONS

- 7. Audit Committee means the University committee that provides advice to the University Court in relation to, amongst other matters, the effectiveness of internal control systems and corporate governance.
- 8. Clinical Trial means any PHS-funded research study that involves interaction with human subjects and the concurrent investigation of the use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.
- 9. Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse.
- 10. Financial Conflict of Interest means a Significant Financial Interest (or, where the University requires disclosure of other Financial Interests, a Financial Interest) that the University reasonably determines could directly and significantly affect the design, conduct or reporting of Research.

¹ http://www.dundee.ac.uk/academic/court/policy/conflict_of_interest.htm

11. Financial Interest means anything of monetary value received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., shares, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the University;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, Financial Interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her University responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

- 12. Investigator means any individual who is responsible for the design, conduct, or reporting of Research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students.
- 13. Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Services, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.
- 14. Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge and encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug), and which is funded by PHS.

- 15. Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator's University Responsibilities, and:
 - a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds £2,500; or
 - b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds £2,500; or
 - c) if with a non-publicly traded company, is an equity interest of <u>any</u> value during the 12 month period preceding or as of the date of disclosure; or
 - d) is income exceeding £2,500 related to intellectual property rights and interests not reimbursed through the University, or
 - e) is reimbursed or sponsored travel related to their University responsibilities.
- 16. University responsibilities means the Investigator's professional responsibilities associated with his or her University appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

INFORMING & TRAINING INVESTIGATORS

- 17. Investigators will conduct their affairs in such a way as to avoid or minimise conflicts of interest, and will respond appropriately when they arise. To that end, this policy describes situations that may generate conflicts of interest related to Research and the mechanisms for Investigator training and disclosure.
- 18. The University will inform Investigators of the existence of this policy, their disclosure responsibilities and the responsibilities which the University has to comply with. In the event of a grant application to a PHS component, an Investigator will be directed to this policy and the FCOI training which they must undertake prior to submission of the grant application. Every Investigator as defined by this policy has an obligation to become familiar with, and abide by, the provisions of this policy.
- 19. The University expects Investigators employing new staff to the University to take responsibility on behalf of the University to cascade down the existence of this policy to such new staff (who qualify as Investigators for the purpose of this policy) and ensure that they are directed to the FCOI training which they must undertake prior to engaging in Research. The University will identify new staff funded by PHS grants and direct new staff to this policy and the FCOI training, ensure evidence of training is collected and recorded, and ensure disclosure forms are issued.
- 20. After initial training on FCOI, assuming that they continue to be PHS funded, Investigators will be re-trained in the FCOI training every 4 years, or at such other time as this policy may be revised, or when any Investigator is discovered to have been in breach of this policy or in breach of any management plan put in place following a disclosure.
- 21. An Investigator who has undertaken FCOI training will submit evidence of completion of the training to the University so that a record can be maintained and reminders issued in relation to update training.

22. If any situation should arise which raises potential questions of conflict of interest, an Investigator should discuss the situation with the University in the first instance.

DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

- 23. Investigators are required to disclose outside financial interests as defined above at grant application stage, on an annual and on an ad hoc basis, as described below. The University will arrange for the distribution of disclosure forms to Investigators identified in the course of managing the grants application process. The University shall designate responsibility for soliciting receipt, processing, reviewing and retaining disclosure forms. The University will ensure completed disclosure forms are received within 10 days of the Investigator receiving the forms, after which time the University will put the grant application process on hold.
- 24. Disclosure forms must be completed whether there is a disclosure or not. Even where no disclosures are made, an Investigator must sign a disclosure form to acknowledge that they have read and understood this policy.

a) Grant Application for PHS Funding & Subsequent Annual Disclosures

All Investigators must disclose their Significant Financial Interests to the University no later than at the time of a grant application in relation to a proposal for Research. In the event of a successful application, following formal award, University staff identified as Investigators must make a disclosure on an annual basis, on the anniversary of their application disclosure. All forms should be submitted to the University no less than 10 days prior to the anniversary date.

b) Ad hoc Disclosures, Appointed Staff & New Significant Financial Interest

Certain situations require ad hoc disclosure. Employees deemed to be Investigators through their appointment to a post which is PHS-funded must disclose their Significant Financial Interests to the University, within 30 days of their initial appointment.

Investigators must submit to the University an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within 30 days of discovering or acquiring such a new Significant Financial Interest.

c) Travel

Investigators must disclose reimbursed or funded travel related to their University responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the funder/organizer, the destination, the duration, and, if known, the monetary value. The University will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's Research.

EVALUATION, IDENTIFICATION OF CONFLICT & MANAGEMENT

- 25. If the disclosure form reveals a Significant Financial Interest, it will be evaluated promptly by the University to determine whether it constitutes a Financial Conflict of Interest. The University provides guidelines as to financial Conflict of Interest in the Code of Practice.
- 26. A Financial Conflict of Interest will exist when the University determines that a Significant Financial Interest **could directly and significantly** affect the design, conduct, or reporting of Research.
- 27. Where a Financial Conflict of Interest is identified, the University will take action to manage the Financial Conflict of Interest including the reduction or elimination of the conflict, as appropriate. The University may consult the Audit Committee for guidance in specific cases, or in the application of this policy to particular situations.
- 28. If the University determines that a Financial Conflict of Interest can be managed, a management plan must be developed and implemented, which the affected Investigator must formally agree to in writing before any Research goes forward.
- 29. The University will periodically review the ongoing activity, make arrangements to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of Research results, and to otherwise oversee compliance with the management plan.

CLINICAL TRIALS and CLINICAL RESEARCH Significant Financial Interests Related to Clinical Trials and Clinical Research

- 30. Clinical Trials and Clinical Research involves particularly sensitive issues if the Investigator has a related Financial Interest.
- 31. In addition to any disclosure which is required above, the Investigator must disclose Significant Financial Interests to the University at the time of any application for study sponsorship by the University and/or relevant Health Board. A copy of the Investigator's disclosure form should be submitted along with the Research protocol.
- 32. In the event of a determination by PHS of non-compliance with reporting and/or management requirements as prescribed by PHS regulations, which relates to a financial conflict of interest involving a PHS-funded Clinical Trial or other clinical Research, the Investigator will disclose the financial conflicts of interest in each public presentation of the results of the affected Research and will request an addendum to previously published presentations.

REPORTING

- 33. The University will submit initial reports of those Significant Financial Interests which are determined as Financial Conflicts of Interest to PHS at the very least prior to the expenditure of PHS funds.
- 34. Initial reports shall be made within 60 days of the identification of a new employee as an Investigator for the purposes of this policy (i.e. through being newly appointed).

- 35. Wherever funding for the Research is made available from a prime PHS-awardee, all reports shall be made to the prime awardee.
- 36. Additionally, the University will submit reports within 60 days of any subsequently identified financial conflict of interest.
- 37. Annual update reports will be made, in relation to each Investigator, within 60 days of the anniversary of the initial report, at the same time as submitting the annual progress report. These updates will provide an outline of the status of any previously reported financial conflict of interest and any changes to the management plan, where applicable.

INVESTIGATOR'S FAILURE TO COMPLY

Suspension of Research & Disciplinary Action

- 38. In the event of an Investigator's failure to comply with this policy (or failure to comply with a previous decision of the University), the University may suspend all relevant Research activity, and/or take enforcement and/or disciplinary action against the Investigator, and/or implement any other sanction, action or actions deemed appropriate by the University, until such time as the matter is resolved and/or is managed to the satisfaction of the University.
- 39. Any decision by the University to suspend or take any action against the Investigator will be described in a written explanation to the Investigator, and the Investigator will be notified of the right to appeal. The University will promptly notify the PHS component which awarded a grant to the Investigator of the decision and actions taken.
- 40. Where the funding for Research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

Retrospective Review & Bias

- 41. Where the University determines that a Financial Conflict of Interest was not identified or managed in a timely manner, or an Investigator failed to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or where there is a failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the University will (within 120 days of determination of any failure to comply) complete and document a retrospective review of the Investigator's activities and the Research project to determine whether non-compliance resulted in bias in the design, conduct or reporting of Research.
- 42. Documentation of the retrospective review shall include the project number, project title, Principal Investigator, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.
- 43. The University will update any previously submitted report to the PHS or the prime PHS-awardee relating to the Research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review, which will include

- implementation of a management plan, will be completed within 60 days of identification of a Financial Conflict of Interest which was not previously identified.
- 44. If bias is found, the University will promptly notify the PHS component which made the grant award and submit a mitigation report. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the Research project and the management plan including actions to be taken to eliminate or mitigate the effect of the bias.

SUB-RECIPIENT AWARD

45. In the event that the University is a prime PHS awardee and is collaborating with subrecipients, the University will establish a written agreement with the subrecipient to ensure compliance with this policy or an equivalent policy of the subrecipient institution. The University will obtain a certificate from the subrecipient that their FCOI policy complies with PHS regulations. The written agreement between the University and a subrecipient will ensure that suitable reporting of FCOI's is carried out in relation to subrecipient Investigators.

RECORDS

46. The University will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee; unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

CONFIDENTIALITY

47. To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the University may be required to make such information available to the PHS component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the University, if requested or required. If the University is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

PUBLIC ACCESSIBILITY

- 48. This policy is available to the public on the University's website at Academic and Corporate Governance.
- 49. Information relating to identified financial conflicts of interest under this policy will be made available on written request to the University Secretary.
- 50. Information to be made available to the public concerning any financial conflict of interest shall include:

- The Significant Financial Interest that was disclosed;
- The determination that has been made that the disclosure relates to Research; and
- The determination that has been made that there is a Financial Conflict of Interest.
- 51. The information to be made available shall be updated annually, within 60 days of any newly identified financial conflict of interest and shall remain available for at least three years from the date the information was most recently updated.