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| **Document Title:** | Cardiff University Research Integrity -Compliance with External Conflict of Interest Requirements (‘the Policy’) |
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| **Version Number:** | **V 1** |
| **Document Status:** | **Final** |
| **Date Approved:** | **26/03/2021** |
| **Approved By:** | **Council** |
| **Effective Date:** | **26/03/2021** |
| **Date of Next Review:** | **31/03/2021** |
| **Superseded Version:** | **This is a sub-policy of the Disclosure of Interest Policy** |

**Document History**

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| **Version** | **Date** | **Author/Consulted** | **Notes on Revisions** |
| 1 | March 2021 |  | New policy |
| 2 |  |  |  |

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**Research Integrity - Compliance with External Conflict of Interest Requirements**

**Introduction**

As an institution in receipt of public and other funds, the University has a duty to fulfil the highest standards of corporate governance. Cardiff University is therefore committed to the accepted principles of public life which embrace selflessness, integrity, objectivity, accountability, openness, honesty and leadership.

The University encourages staff to engage in appropriate external activities and in keeping with its academic aims and purposes, the University encourages liaison between its staff various external organisations including involvement with charities and government departments, business and community boards, providing expert advice, media commentary, professional practice, schools outreach, international projects and collaborations with the commercial world, including consultancy, collaborative research and development, and commercialisation of intellectual property (IP) through licensing and ‘spinout’ companies. The University also allows staff to be engaged in general paid and unpaid activities (subject to prior approval).

In encouraging such interaction, the University is mindful of its obligation to provide safeguards, wherever possible, and in order to manage the associated risks to an acceptable level, all staff, students and others working in the University (including grant holders and honorary researchers) are required to recognise and disclose activities that might give risk to actual or perceived conflicts of interest.

This policy is specific to compliance with External Conflict of Interest Requirements made by funders and must be read alongside the University’s overarching Declaration of Interest Policy.

**Declaration of interest**

Researchers are in receipt of public and private funding and must uphold levels of transparency and accountability in relation to declaration of interest. There may be specific examples where declaration/conflicts of interest may be relevant for researchers including (but not limited to) the following circumstances:

**External work & appointments** (external work, starting a new business, consultancy, board member, advisory work, directorships etc) – Approval should be sought from the Head of HR Operations and the relevant line manager for outside work and the holding of outside appointments, as set out in the regulations and the associated policy.

**Spin out companies** - All academics involved in the formation of a new spinout should complete a conflict of interest management plan[[1]](#footnote-1), which is to be reviewed by Research and innovation Services and approved by the Director of Research and Innovation before the initial investment can go through.

**Intellectual property** - If a researcher has a financial interest in the licensee (or proposed licensee) of University intellectual property they should disclose this, and step back from the negotiations, which should be managed by the Deputy Director and Head of Commercial Development.

**Publishing** - Authors submitting a manuscript should disclose any ‘significant financial interest’ or other relationship with the manufacturers of any commercial products or providers of commercial services discussed in the manuscript and any financial supporters of the research. The intent of such disclosures is not to prevent an author with a significant financial or other relationship from publishing a paper but to provide readers with information upon which to make their own judgements. Those acting in peer review or advisory roles (eg related to grant proposals, journal manuscripts, research policy) should also disclose any conflicts of interest.

**Grants/negotiating contracts** - Staff and students should declare all interests when applying for grants, negotiating contracts etc. In particular, financial conflicts need to be declared to avoid doubts being cast over the validity of research, and subsequent potential reputational damage.

**Employing family members** – particular care should be taken to when employing family members/those in close personal relationships. All decision-making around recruitment of staff must be in line with the University’s Recruitment and Selection Policy.

**Close family/personal relationships with students** - staff with a close personal or familial relationship with a student or a student’s family should not be involved in decisions about that student’s admission, supervision or academic progress, or the award of any studentships, prizes or other grants to the student.

**Use of University resources** - Members of staff should not make use of University resources when undertaking consultancy work or work for external organisations, unless express permission has been granted by their line manager and Head of School/Department. Similarly, resources from an external organisation should not be used in the individual’s role at the University unless express permission has been granted by their line manager and Head of School/Department as this could be interpreted as endorsement by the University of that resource.

**Procurement/contract negotiation -** If a member of staff has a conflict of interest (e.g. arising from a personal relationship or an outside appointment) relating to the procurement of goods and services, they cannot be involved in the purchasing decision or contract negotiation.

In addition to the requirements of the University under the Declaration of Interest Policy and procedure, some funders may require direct notification of certain interests, and/or reserve the right to review a plan for managing a conflict of interest, and/or prohibit grant holders from undertaking certain activities.

**US National Institutes of Health (NIH): financial conflict of interest**

The 2012 US Department of Health and Human Services regulations on disclosing and reporting conflicts of interest for researchers funded via its Public Health Service (which includes the NIH) include specific requirements regarding financial conflicts of interest.

**Scope**

The requirements highlighted in this section apply to all investigators funded by the NIH (or via a sub-contract with a university, where the research in question is funded by the NIH). For the purposes of this policy, an investigator is defined as:

“Investigator” means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants.

**Definitions**

Per the regulations, a Financial Conflict of Interest exists when the Institution, through its designated official(s), reasonably determines that an Investigator’s Significant Financial Interest is related to a NIH-funded research project and could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

The regulation covers all financial interests that have monetary value, whether or not the value is readily ascertainable.

The 2011 revised regulation defines a “Significant Financial Interest” as follows:

“(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

(i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution’s FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution’s FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.”

For further definitions, please see Section D of the NIH FAQs:

<https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=question53049>

**Responsibilities of the Investigator**

***Training***

All investigators in receipt of NIH funding must complete the University’s Research Integrity Training (which includes a section on Financial Conflicts of Interest) when they commence employment with the University and prior to engaging in any research. Any investigator engaged in research related to PHS-funded grants must undertake training at least every 4 years.

***Disclosure***

Investigators must disclose to their institutions annually all of their significant financial interests (and those of the Investigator’s spouse and dependent children) related to their institutional responsibilities. A significant financial interest need not necessarily represent a financial conflict of interest, but must be disclosed by the investigator to the relevant head of department or faculty to determine whether this presents any possible conflict of interest which needs to be reported to the NIH.

A declaration of a 'significant financial interest’ should be made initially to the Investigator’s Head of Department or School (or in the case of a Head of Department or School, to the COO or PVC of the College) via the declaration of interest form. This must be done:

1. No later than at the time of application for PHS-funded research
2. At least annually during the period of the award
3. Within 30 days of discovering or acquiring a new significant financial interest

The declaration form is available in appendix 1.

Where a conflict is identified and a management plan agreed with the NIH, the Investigator must produce annual updates on how the conflict is being managed

NIH-funded investigators are also required to familiarise themselves with the University’s policy on conflict of interest.

**Responsibilities of the University**

***Reporting and Managing Significant Financial Interests***

When a significant financial interest is disclosed, the Head of Department/School should review the declaration and evaluate whether it could present a financial conflict of interest. Where it is decided that a financial conflict of interest could exist then this should be referred to the University Secretary together with a plan for how the conflict can be reduced, eliminated or managed. The University Secretary will then liaise with Research and Innovation Services, who will submit the plan to the NIH via their electronic Research Administration (eRA) Commons financial conflicts of interest module.

The University will report any financial conflicts of interest to the NIH:

1. Prior to the expenditure of funds
2. Within 60 days of identification for an Investigator who is newly participating in the project
3. Within 60 days for new, or newly identified, FCOIs for existing Investigators
4. At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
5. Following a retrospective review to update a previously submitted report, if appropriate.

The University must report to the NIH additional information, as required by the NIH, on identified financial conflicts of interest and how they are being managed.

***Public Accessibility***

The University is required to make certain information accessible to the public concerning identified financial conflicts of interest held by senior/key personnel as detailed on the NIH website (Section G): <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=header11122>

***Subrecipients***

Where there are subrecipients of any NIH awarded grant, the University will review the subrecipient’s financial conflict of interest policy to ensure it meets the minimum requirements set-out in this policy. Where the policy does not meet the minimum requirements then a written agreement will be established to ensure that the subrecipient follow’s the University’s own policy as detailed here.

***Non-compliance***

Instances of non-compliance with this policy will be reported to and reviewed by Open Research, Innovation and Ethics Committee and disciplinary action taken as necessary. A retrospective review must be completed and documented within 120 days on the University determining that there has been non-compliance with this policy.

The University will report all instances of non-compliance with this policy including any issues related to a financial conflict of interest management plan to the NIH.

Where non-compliance is identified the University will ensure that the Investigator discloses their financial conflict of interest at each public presentation of the research findings and request an addendum to any previously published presentations.

***Records Management***

The University will maintain all financial conflict of interest records, including any management or resolution plans, for a period of at least 3 years from the date the final expenditure report is submitted to the NIH or from other dates as set out in the regulations, where applicable.

1. A conflict management plan that sets out the agreed strategy for managing a disclosed conflict, including the review dates, responsibilities of discloser, reviewer and others, and identifies any options for amendment that may be required in the future. [↑](#footnote-ref-1)