****

***Associated Forms (word) for***

**POLICY ON FINANCIAL CONFLICTS OF INTEREST (FCOI)** **FOR RESEARCH FUNDED BY THE PUBLIC HEALTH SERVICES OF THE UNITED STATES OF AMERICA DEPARTMENT OF HEALTH AND HUMAN SERVICES**

|  |  |
| --- | --- |
| **Policy Title** | **Policy on Financial Conflicts of Interest (FCOI)** **for Research Funded by the Public Health Services of the United States of America Department of Health and Human Services** |
| **Scope** | **Applies to Investigators applying for/or funded by the United States of America Public Health Services** |
| **Owner** | **Research and Innovation Services** |
| **Approving Committee** | **Principal's Office** |
| **Policy approved date** | **18 May 2016** |
| **Policy effective from date** | **Immediate** |

**APPENDIX to The University of St Andrews POLICY ON FINANCIAL CONFLICTS OF INTEREST FOR RESEARCH FUNDED BY THE PUBLIC HEALTH SERVICES OF THE UNITED STATES OF AMERICA DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**University of St Andrews: PHS Disclosure Forms**

All investigators applying for funding from any US Department of Health & Human Services organisation have to comply with the St Andrews Financial Conflicts of Interest (‘FCOI’) Policy[[1]](#footnote-1) by making declarations regarding FCOIs, Significant Financial Interests (‘SFIs’) and undertaking training[[2]](#footnote-2) before the submission of an application.

In this context, ‘Investigators’ means anyone who is or would be responsible for the design, conduct, or reporting of the application/project e.g. Principal Investigators (PIs) and Co-Investigators (Co-Is), as well as any other similarly responsible individuals, including honorary staff, students, technicians, external collaborators or consultants. It is the role of the individual and the degree of independence with which that individual works, rather than their title, that determines whether they fall within the definition of an ‘Investigator’.

All Investigators must familiarise themselves with the FCOI Policy and make the declarations below and sign and return this form to Research and Innovation Services [(](http://www.st-andrews.ac.uk/researchfundingsupport/contactingtheteam/)researchintegrity@st-andrews.ac.uk) **before** an application may be submitted (this form may be signed and e-mailed as a pdf). Where an application has more than one Investigator, they may make their declarations collectively on one form or on separate forms. The University will not authorise any application until all Investigators have completed a declaration and taken any necessary action.

**PART I: PHS Pre-Submission Declaration Form - Investigators**

**Declaration by Investigators when submitting applications for funding by US Department of Health & Human Services organisations, such as the NIH, the National Cancer Institute and the National Institute of Allergy & Infectious Diseases.** This declaration is required for all applications, including those that are routed via other organisations, e.g. universities in the US.

|  |  |
| --- | --- |
| **Information required** | **Project Details** |
| Title of project |  |
| Funding organisation (e.g. NIH) |  |
| Name of lead organisation, where applicable |  |
| Details of any external collaborators, including subcontractors, consultants  |  |

**Declaration by Investigator/s**

I/we have read and understood the responsibilities and requirements for Investigators regarding FCOIs and SFIs and agree to abide by them should the application be successful.

I/we have (each) completed the NIH online tutorial.

I/we have (each) completed an SFI disclosure form (PART II) and submitted it in line with University requirements.

**Declaration made by ................................................................ (Print Name) Date ..............................**

**Signature............................................................**

**PART II: St Andrews PHS Disclosure of Significant Financial Interests (SFI) form – Investigators**

(submit **to** researchintegrity@st-andrews.ac.uk at **application stage** and **annually** on 1st August for the duration of the project**)**

|  |  |
| --- | --- |
| **Information required** |  |
| **Project Title** |  |
| **Investigator’s name and role within the project** |  |
| **Principal Investigator/s and Lead Institution on Grant** |  |
| **Project Title and grant reference** |  |
| **Internal Grant Code** |  |
| **Name of the entity/ies with which the Named Investigator has an SFI. If none, enter ‘N/A’** |  |
| **Nature of any financial interest** (e.g. equity, consulting fee, travel reimbursement, honorarium)For sponsored travel reimbursement, the minimum information to include is:* Purpose of the trip
* Name of the sponsor/organiser
* Destination
* Duration

**If none, enter ‘N/A’** |  |
| **Value of the SFI (US dollar ranges are permissible)**$0 - $4,999; $5K - $9,999; $10K - $19,999Amounts between $20K and $100K by increments of $20KAmounts above $100K by increments of $50KIf the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value, a statement is required**If none, enter ‘N/A’** |  |
| **Other relevant information****If none, enter ‘N/A’** |  |
| **Date of disclosure** |  |

**PART III St Andrews PHS Review of SFIs – Vice Principal (Research and Innovation)**

|  |  |
| --- | --- |
| **Post-review comments by Vice-Principal (Research and Innovation)** where **the SFI/s are considered to be a Financial Conflict of Interest.** If the SFI/s constitute an FCOI a management plan will be developed by the VP Research and the Investigator including reporting to PHS or to the funded partner. |  |
| **Post-review comments by the Vice-Principal (Research and Innovation)** where **the SFI/s are not considered to be a Financial Conflict of Interest** in order to record why the SFI/s were not considered to be a Financial Conflict of Interest linked to the PHS-funded project.If the SFI/s are not considered FCOIs or if there is a nil return, this data should now be reported to PHS or to the funded partner. |  |
| **Date of completion** |  |

This form must be retained for at least 3 years after the University has submitted the final statement of expenditure for the relevant PHS-funded project (or such other timescale as specified by the PHS), because the information it contains will need to be made available within 5 days should the University receive a request to provide such information under the PHS FCOI policy.

1. The University of St Andrews POLICY ON FINANCIAL CONFLICTS OF INTEREST FOR RESEARCH FUNDED BY THE PUBLIC HEALTH SERVICES OF THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES [↑](#footnote-ref-1)
2. Training is available via this link <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> [↑](#footnote-ref-2)