**THE INSTITUTE OF CANCER RESEARCH: ROYAL CANCER HOSPITAL**

**POLICY**

**Conflicts of Interest and Competing Financial Interests in Research**

|  |  |  |
| --- | --- | --- |
| Committee Approval:  …………………………. | Author and Position: Dr Angela Kukula  Director of Enterprise | |
| Approval Date:  ………………………….. | Department: Enterprise Unit | |
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1. **Introduction**

The ICR encourages members of its staff to consider research funding from a wide range of sources and to engage in a wide variety of external activities, such as serving on government, business and community boards, providing expert advice, media commentary, professional practice, outreach and collaborations with the commercial world, including via consultancy, research collaboration, knowledge exchange and intellectual property transactions. The ICR considers such funding and activities to be to the benefit of the ICR, the individual concerned and ultimately to cancer patients. However, on occasion they may give rise to conflicts of interest whether potential, actual perceived or alleged.

Competing or conflicting interests in research are those, whether of a financial nature or otherwise, that, could influence the objectivity and impartiality with which research is conducted or results interpreted or which could undermine objectivity, integrity or perceived value of a piece of research.

All ICR officers, staff and students are required to recognise and disclose activities that might give rise to conflicts of interest or the perception of conflicts and to ensure that such conflicts are properly managed or avoided. If properly managed, such activities can usually proceed as normal whilst at the same time protecting the integrity and reputation of the ICR and its researchers.

It is therefore the ICR’s policy to encourage and promote external activities whilst ensuring that when conflicts or perceived conflicts of interest arise they are disclosed, acknowledged, and in relevant cases, properly managed.

1. **Scope**

This Policy provides a standard by which all ICR personnel must abide. It applies to both the conduct of research and the publication of any results arising from research at ICR. It is the responsibility of each individual at ICR to recognise situations in which he or she has a conflict of interest, or might reasonably be seen by others to have a conflict, to disclose that conflict to the appropriate person and to take such further steps as may be appropriate to manage the conflict.

1. **Recognising competing or conflicting interests**

A conflict of interest arises where the commitments and obligations owed by an individual member of staff or student to the ICR or to other bodies, for example a funding body, or the integrity of research results are likely to be compromised, or may appear to be compromised. There can be situations in which the appearance of conflict of interest is present even when no conflict actually exists. Thus it is important for all officers, staff and students when evaluating whether a conflict of interest exists to consider how it might be perceived by others.

1. **Declaration of Competing Political, Financial and other Interests**

Any personal political, financial or other interests should be declared if circumstances are such that any undeclared interests could question the integrity of ICR research, jeopardise ICR funding, embarrass the researcher and/or ICR were they to become publicly known at any time.

In particular the following should be declared:

* Political interests;
* Personal financial interests(including share options and equities but excluding shareholdings in pooled funds such as unit trusts unless they are specific to the operations of ICR or benefit ICR);
* Non-financial interests;
* Access to non-public information;

Conflicts of interest may be financial or non-financial or both. Further information about the different types of conflict and the procedures to follow in declaring them are as follows:

* 1. **Positions of political or other influence**

ICR officers, staff and students must declare to the Director of Enterprise at the ICR if they or a member of their immediate family (spouses, partners or dependent children) are:

* An elected or appointed government official
* An employee of or acting on behalf of government, a government agency, or enterprise performing a governmental function
* A political party member, officer, employee or candidate
* Someone acting on behalf of a political party or a candidate for political office
* A consultant, employee or person acting on behalf of a public international organization
* A representative of government in any other capacity.

[Note that government covers all levels and sub-divisions of government, including local and national government and administrative, legislative and executive government.]

And if declaring any of the above, researchers should also declare whether they or anyone they are making the declaration on behalf of have decision making authority or official influence over

* Pharmaceutical or other medicine product licences
* Conditions under which pharmaceutical products are imported, marketed, distributed or sold;
* Price/reimbursement or formulary listing of pharmaceutical products or medicines;
* Approval or authorisation of clinical trials or other research and development undertakings;
* Government funding of research or higher education institutions.

Declarations of the type set out above may also be requested by research sponsors to enable them to comply with the US Foreign Corrupt Practices Act (“FCPA”). The above declarations should therefore also be made to research sponsors and to any regulatory body if requested. Research sponsors may also request information about other ICR employees or officers other than those directly involved in the research; such requests should be referred to the Enterprise Unit.

* 1. **Personal financial interests**

A personal financial interest, for the purposes of this Policy, is one where there is or appears to be opportunity for personal financial gain, financial gain to close family members, or where another party might take the view that financial benefits might affect that person's actions.

Personal financial interests include anything of monetary value; including but not limited to:

* Payments for services
* Consultancy arrangements
* Equity interests (e.g. stocks, stock options or other ownership interests)
* Royalties from intellectual property rights

All such personal financial interests should be declared in confidence to the Director of Enterprise at the ICR.

The level of financial interest is not the determining factor as to whether a conflict should be disclosed. Any financial interest, however small should be disclosed. A conflict may arise if the interest might provide, or be reasonably seen by others, to provide an incentive to the individual which influences their decisions or causes them to act in a particular way

* 1. **Non-financial interests**

Non-financial interests which may come into conflict, or be perceived to come into conflict, with a person's obligations or commitments to the ICR or to other bodies, for example funders of research should also be declared. Such non-financial interest may include any benefit or advantage, including, but not limited to, direct or indirect enhancement of an individual's career, education or gain to immediate family. Any such non-financial conflicts of interest should be declared in confidence to the Director of Enterprise at the ICR.

* 1. **Use of non-public information**

When negotiating or carrying out research collaborations with commercial companies, ICR researchers may have access to commercially sensitive and confidential information, it is imperative that any such information is kept confidential and not discussed or used other than is strictly necessary to carry out the research – doing otherwise may jeopardise the collaboration and place ICR in breach of its confidentiality obligations to the commercial partner. Any approach to provide such information to a third party should be declared to the Director of Enterprise.

It is possible that when the results of research collaborations are announced to the public that they may have an effect on the share price of any company who is sponsor or otherwise involved in the work. It is illegal for someone with potential access to non-public information to trade in the shares of a company based on that information before it is made public. Doing so may result in fines or even a custodial sentence. It may also be a disciplinary offence at ICR due to the adverse effect it would have on ICR’s reputation. ICR researchers that have information about potential collaborations or the results of collaborative work that have not yet been publicly announced should take professional advice before trading in the shares of any company involved until the results have been publicly announced.

1. **Timing of disclosure**

The general rule is that disclosure should be made *at the time the conflict first arises, or it is recognised that a conflict has arisen or might be perceived*, in writing to the Director of Enterprise. If the Director of Enterprise has an interest in the matter it shall be referred instead to the Chief Operating Officer.

1. **Consequences of a declaration**

The Director of Enterprise (or COO if applicable) will discuss the actual or potential conflict with the individual concerned and may consult with his or her Head of Division, the Director of Finance or the CEO as required. Many situations will require nothing more than a brief written record of the declaration and the discussion be held in the ICR’s records.

Some instances will however need to be dealt with by agreeing how the conflict can be actively managed. The approach agreed will be documented and copies provided to the relevant parties and a copy held in the ICR’s records. One or more of the following strategies may be appropriate to manage the conflict of interest:

* not taking part in discussions of certain matters;
* not taking part in decisions in relation to certain matters;
* referring to others certain matters for decision;
* resolving not to act as a particular person's supervisor;
* divesting or placing in trust certain financial interests;
* publishing a notice of interest;
* standing aside from any involvement in a particular project; and/or
* declaring an interest to a particular sponsor or third party.

It is the responsibility of those affected to comply with the approach that has been agreed. If an approach cannot be agreed the matter will be escalated to the Chief Executive Officer of the ICR.

* 1. **Disciplinary Procedures**

A member of staff may be subject to ICR’s Disciplinary Policy and Procedure if they fail, whether deliberately or otherwise, to adhere to this policy.

In particular, a member of staff may be subject to ICR’s Disciplinary Policy and Procedure if they:

* do not adhere to this policy
* fail, whether deliberately or otherwise, to make a declaration, where one should have been made;
* are considered or alleged to have made a false declaration;
* do not adhere to agreed measures to manage a conflicting or competing interest;
* as an author, are alleged by a publisher to have made a false declaration or not to have declared significant competing interests,
* as the lead author, make a group declaration that subsequently proves to be false for an ICR or non-ICR employee, having not taken reasonable measures to ensure the veracity of the statements of other authors.

If an author’s scientific judgement is believed to have been compromised by committing a breach of this policy, this will be investigated under ICR’s ‘Procedure for the Investigation and Management of Complaints arising from Fraud or Misconduct Medical and Scientific Research’.

If a false declaration is found to have been made by a non-employee as lead author, the matter will be reported to their employer.

1. **Specific guidance**

The following sets out procedures applying to specific circumstances in which significant interests should be declared and conflicts managed:

* 1. **Declaration of competing financial or other interests in the publication of research results.**

In the interest of maintaining integrity of research through a policy of transparency, ICR researchers must provide either a declaration of competing interests, or declare that there are no competing interests, or declare they are unable to provide information about competing interests because an agreement with a third party prevents it when reporting the results of their research.

Competing interests in research are those that could influence the objectivity and impartiality with which research is conducted or results reported or interpreted. Any personal political, financial or other interests should be declared in a research publication if circumstances are such that any undeclared interests could embarrass the author and/or ICR were they to become publicly known either during the research or after the results of the research are published.

For the purposes of this policy, published research includes papers, articles, reviews and book chapters. It does not include conference abstracts unless declaration is required by the conference organisers.

* + 1. **Types of competing interest that should be declared**

Competing interests which should be declared in research publications might include any of the following:

* + - 1. **Funding**

Research support of any value (including salaries, equipment, supplies, reimbursement for attending symposia, and other expenses) by organisations that may gain financially through the publication of the results of research.

* + - 1. **ICR Interests**

Where ICR has an interest in a company that may gain financially through the publication of the results of research (this would be principally through shareholdings in start-up companies) and where ICR has a financial interest in a product that may be increased in value through the publication of the results of research. The Enterprise Unit maintains a list of start-up companies, companies and products in which the ICR has an interest.

* + - 1. **Employment**

Recent (that is, while engaged in the research project), present or anticipated employment by any organisation that may gain financially through the publication of the research.

* + - 1. **Personal financial interests**
         1. stocks or shares in companies that may gain financially through publication (excluding shareholdings in pooled funds such as unit trusts unless they are specific to the operations of ICR or provide a benefit to ICR).
         2. consultation fees or other forms of remuneration (such as payment as a Board Director or advisor) from organisations that may gain financially through the publication of research results perhaps because the organisation owns patents or patent applications whose value may be affected by publication. Consultancy agreements should be declared as an interest even if the consultant does not take personal payment for the consultancy but receives payment in kind, such as the benefit of travel to conferences, and consultancy agreements should also be declared even if the consultant puts the payment in a discretionary budget.
         3. payments to the individual via ICR’s Rewards to Inventors Scheme, whether or not these payments are put in a discretionary budget, that may be increased because the financial return on that invention is increased by publication.
    1. **Statement of Disclosure**

Any actual or potential conflicts of interest in published work should where possible be disclosed in the manuscript. Whether disclosed in the manuscript or not, authors should make a statement of disclosure to their Head of Division (or their nominee) prior to submitting the manuscript for publication, preferably using the proforma declaration attached at Appendix 1

***The following Statements of Disclosure are to be used as appropriate in research publications:***

* I certify that I have no affiliations with or financial or other involvement with any organisation or entity with a financial interest in or in financial competition with the subject matter or materials discussed in the manuscript.
* I certify that I hold no position of political or other influence which may have a bearing on the subject matter or materials discussed in the manuscript
* I decline to provide information about competing financial, political and other interests as an agreement to which I am a party prevents me from doing so.
* I certify that all positions of political or other influence that I hold and which may have a bearing on the subject matter or materials discussed and all of my affiliations with or financial or other involvement (e.g. employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, royalties) with any organisation or entity with a financial or other interest in or in financial competition with the subject matter or materials discussed in the manuscript are completely disclosed below or in an attachment.  In addition, positions of political or other influence and all financial and material support for this research and work are clearly identified in the manuscript.

If a journal has its own policy this will not supersede the requirement to complete ICR's proforma declaration and if there is a difference between the journal’s policy and ICR’s policy, where possible, ICR’s policy on declaring competing interests should be adopted.

Where a journal does not have its own policy then staff must complete ICR’s proforma declaration. The proforma is provided as an appendix to this policy

A completed declaration (ICR proforma or copy of a journal's declaration) must be submitted to the Head of Division for consideration together with any proposed publication.

When approved, a copy of the ICR proforma declaration must be sent to the Director of Enterprise of ICR where it will be held as a record to protect ICR and its researchers from accusations of impropriety.

Researchers should retain copies of their declarations for at least five years. This procedure will be subject to audit by Internal Audit.

If an author is not free to make a declaration, such as due to a confidentiality agreement with a sponsor, then the first consideration must be whether to publish at that time1.  If it is decided to proceed, permission should be sought from the sponsor to make a declaration.  If permission is not forthcoming, a statement must be made declining to provide information about competing interests.  The decision to publish research in such circumstances should only be made if any undeclared competing interests will not lead to embarrassment if they became known after the work is published.

If an association with a sponsor compromises the individual’s freedom to carry out and publish academic research then the conflict must be resolved by, for example:

* selling equity held in the sponsoring company (subject to taking advice on potential insider trading)
* refusing payments from the sponsor company for other services
* resigning from position held with the sponsor company (including advisory board positions)
* naming a new principle investigator for the relevant research,

If ICR stands to gain financially or otherwise then this should also be declared even if the individual is not involved in the benefit.

* + 1. **Group Declarations**

It is a lead author’s responsibility to ensure that a group declaration is made and to take reasonable measures to ensure the veracity of the subsidiary authors’ statements. It is reasonable to expect external authors to comply with this requirement as making a declaration of competing interests in published research is becoming normal practice. If there is any uncertainty as to what are reasonable measures in a particular set of circumstances, then the Head of Division should be consulted.

The wording of a group declaration may be agreed with the co-authors as far as is possible so as to be in line with ICR’s requirements. If the declaration is not required by the journal, then it must be sent to the Director of Enterprise for the record.

Where ICR personnel are subsidiary authors, they should endeavour to ensure a group declaration is made. However, they should make certain that their own declaration is filed using either the journal’s declaration or ICR proforma as appropriate.

* 1. **Managing Competing Financial Interests and other conflicts of interest for ICR Employees that Act as Chief or Principal Investigators for Clinical Trials**

This section applies to any ICR employee that takes on the role of Chief Investigator or Principal Investigator for a clinical trial and anyone listed on a co-investigator list associated with a clinical trial. The Chief Investigator, in relation to a clinical trial conducted at more than one trial site, is the authorised health care professional, whether or not he is an investigator at any particular site, who takes primary responsibility for the conduct of the trial. The Chief Investigator assumes full responsibility for the treatment and evaluation of human subjects in the trial, and for the integrity of the research data and results. A Principal investigator is the authorised health care professional who is responsible and accountable for conducting a clinical trial at a particular trial site.

* + 1. **Prohibited Financial Interests**

ICR employees who act as Chief Investigator or Principal Investigator for a clinical trial must not hold the following financial interests while the trial is being conducted and up to the time that the trial results are published and such financial interests should not be held by their spouse, partner or dependent children:

* Any ownership interest, stock options or shareholding in a non-listed company, if that company is the sponsor or beneficiary of the trial.
* Any shareholding or stock options in a listed company, if that company is the sponsor or beneficiary of the trial.
* Any personal financial interest in the product being tested in the trial (other than benefits through the ICR’s rewards to inventors scheme), such as a personal royalty interest in the product or personal payments due on a successful outcome of the trial.
  + 1. **Financial Interests that must be Declared**

ICR employees who act as Chief Investigator or Principal Investigator for a clinical trial must declare the following financial interests to the Sponsor of the clinical trial, to the Director of Enterprise at the ICR and to any other body that asks for such a declaration. The declaration should also be made if the financial interests are held by spouses, partners or dependent children.

* Any benefits through the ICR’s Rewards to Inventors scheme that will be received relating to the product being tested in the trial even if such payments are put in a discretionary budget.
* Any research support, including compensation in the form of equipment or other in-kind support, received from the company that is the sponsor or beneficiary of the trial during the period of the trial and for one year after its completion and that is not related to studies associated with the trial.
* Any paid consultancy carried out for the company that is the sponsor or the beneficiary of the trial during the period of the trial and for one year thereafter even if the payment is put into a discretionary budget or if the payment is received in kind.
* Any other payments or benefits in kind from the company that is the sponsor or the beneficiary of the trial during the period of the trial and for one year thereafter.

If ICR employees who act as Chief Investigators or Principal Investigators for clinical trials are asked by the Sponsor of the clinical trial to have no competing financial interests then all financial interests listed above, if they exist, must be terminated before such an undertaking can be given.

* + 1. **Other Interests that must be declared:**

ICR employees who act as Chief Investigator or Principal Investigator for a clinical trial must declare the following interests to the Sponsor of the clinical trial, to the Director of Enterprise at the ICR and to any other body that asks for such a declaration. The declaration should also be made if the interests are held by spouses, partners or dependent children:

* If they are:
  + An elected or appointed government official
  + An employee of or acting on behalf of government, a government agency, or enterprise performing a governmental function
  + A political party member, officer, employee or candidate
  + Someone acting on behalf of a political party or a candidate for political office
  + A consultant, employee or person acting on behalf of a public international organization
  + A representative of government in any other capacity.
  + Note that government covers all levels and sub-divisions of government, including local, and national government and administrative, legislative and executive government.
* And if declaring any of the above also declare if they or anyone they are making the declaration on behalf of have decision making authority or official influence over
  + Pharmaceutical or other medicine product licenses
  + Conditions under which Pharmaceutical products are imported, marketed, distributed or sold;
  + Price/reimbursement or formulary listing of Pharmaceutical products or medicines;
  + Approval or authorisation of clinical trials or other research and development undertakings

Declarations of the type set out above may also be requested by Sponsors to enable them to comply with the US Foreign Corrupt Practices Act (“FCPA”) and may require information about ICR employees other that the Principal of Chief Investigator. Any requests for information about ICR researchers other than the Principal of Chief Investigator in order to comply with FCPA should be referred to the Enterprise Unit

* 1. **Declaration of Significant Financial Interests in NIH Research**

Where research is funded in whole or in part by the US National Institutes of Health (NIH), all ‘Investigators’ must declare any ‘Significant Financial Interests (SFIs)’ which may *reasonably appear to be related to the Investigator’s institutional responsibilities* to the Director of Enterprise. Investigators must also declare the SFIs of their spouse/ civil partner and dependent children.

* + 1. **Definitions**

For the purpose of this section:

* + - 1. **‘Investigator’**

Means any person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by the NIH, or proposed for such funding. This includes the PI and all postdocs, graduate students and scientific officers, but does not include those solely in technical/support roles;

* + - 1. **Significant Financial Interests (SFIs)**

means all financial interests in excess of $5,000 in the previous 12 months from a publicly-traded or non-publicly traded entity, including remuneration, equity interests, income related to IP rights, or reimbursed/sponsored travel (except from an academic, medical or government source); SFIs do not include salary, royalties or IP rights from the ICR, income from non-commercial seminars or academic or governmental advisory committees, or income from investment vehicles where the investigator is not in direct control of investment decisions (e.g. pension).

* + 1. **Investigator responsibilities**
       1. Before the commencement of the study and at a maximum of 4- year intervals thereafter, all Investigators must complete the NIH online tutorial regarding financial conflict of interest. This may be found at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
       2. Investigators must report all SFIs to the Director of Enterprise within 30 days of them arising or the investigator first becoming aware of them.
    2. **Consequence of declaration**
       1. Upon submission of an SFI, it will be reviewed by the Director of Enterprise who will decide whether it is related to the NIH funding.
       2. If it is not related to the NIH funding or does not constitute an actual or potential financial conflict of interest, no further action will be taken, but a record of the SFI and the reason for the decision will be kept.
       3. If the SFI does or may constitute an NIH-funding-related financial conflict of interest:
          1. A plan for managing the conflict will be agreed in accordance with section 6
          2. The SFI and the plan for managing the conflict will be reported to NIH
          3. Annual reports on how the conflict is being managed must be provided to NIH which will be produced in conjunction with the Director of Enterprise.

It is important that SFIs are reported to the Director of Enterprise as soon as they arise. In cases where the conflict is not reported promptly, the reporting and management requirements may become more onerous.

If the above procedures are not adhered to, there could ultimately be a loss of funding to the Investigator and the ICR.

* + 1. **ICR as a sub-contractor**

The above procedures apply to both collaborators and sub-contractors. ICR is often a sub-contractor in collaborative NIH awards but is still bound by all NIH regulations including those relating to financial conflict of interest. The lead institution has a responsibility to ensure that the sub-contractor is complying and the ICR may be required to make a contractual undertaking that it is.

**Notes**

1. Collaborations or contracts should not be entered into where disclosure (e.g. minimum disclosure of existence, company and type of agreement) is prevented indefinitely.  However, it is likely that any Agreement would include a clause whereby the company concerned would wish to see a form of words to be used by ICR regarding any collaboration.  This would need to be taken into account when declaring any collaboration with a company.  The wording should be agreed when negotiating the agreement or immediately thereafter.  In any event it needs to be sufficiently timely to allow for full disclosure at the appropriate time.  It is never appropriate to enter into consultancies that prevented their minimum disclosure.
2. This policy should be read in conjunction with The Bribery and Corruption Policy 2011

**Appendix 1**

THE INSTITUTE OF CANCER RESEARCH: ROYAL CANCER HOSPITAL

**DECLARATION OF COMPETING INTERESTS**

PROFORMA FOR THE DECLARATION OF COMPETING FINANCIAL INTERESTS IN PUBLISHED RESEARCH

# 

**Name(s) of Author(s): ……………………………………………………………**

**……………………………………………………………**

**Title of Paper**: **……………………………………………………………**

**……………………………………………………………**

*Delete following statement as appropriate:*

1. I certify that I have no affiliations with or financial or other involvement with any organisation or entity with a financial interest in or in financial competition with the subject matter or materials discussed in the manuscript.

2. I certify that I hold no position of political or other influence which may have a bearing on the subject matter or materials discussed in the manuscript.

3. I decline to provide information about competing financial/political/other (*delete as applicable*) interests as an agreement to which I am a party prevents me from doing so.

4. I certify that all positions of political or other influence that I hold may and which may have a bearing on the subject matter or materials discussed in the manuscript and all of my affiliations with or financial or other involvement (e.g. employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, royalties) with any organisation or entity with a financial or other interest in or in financial competition with the subject matter or materials discussed in the manuscript are *(delete as appropriate)*:

i) completely disclosed below,

ii) completely disclosed in an attachment.

In addition, all positions of political or other influence and all financial and material support for this research and work are clearly identified in the manuscript.

Signature(s) of Author(s): **……………………………………………………………**

**……………………………………………………………**

Date: **……………………………………………………………**

**Official Use Only**

**Date Rvd:**

**Initials:**

**Appendix 2**

THE INSTITUTE OF CANCER RESEARCH: ROYAL CANCER HOSPITAL

**DECLARATION OF COMPETING INTERESTS**

PROFORMA FOR THE DECLARATION OF COMPETING FINANCIAL INTERESTS and other conflicts of interest for icr employees acting as chief or principal investigators for clinical trials

# 

# 

|  |  |
| --- | --- |
| Name |  |
| Division |  |
| Email |  |

1. I declare that neither I nor my spouse, partner or dependent children hold any of the following prohibited financial interests:
   1. Any ownership interest, stock options or shareholding in a non-listed company which is a sponsor or beneficiary of a trial for which I am the chief investigator or a principal investigator;
   2. Any shareholding or stock options in a listed company which is a sponsor or beneficiary of a trial for which I am the chief investigator or a principal investigator (other than from investment vehicles where I am not in direct control of investment decisions (e.g. pension))
   3. Any personal financial interest in the product being tested in any trial for which I am the chief investigator or a principal investigator (other than benefits through the ICR’s rewards to discoverers scheme), such as a personal royalty interest in the product or personal payments due on a successful outcome of the trial.
2. Delete as applicable

[EITHER]

I declare that neither I nor my spouse, partner or dependent children hold any of the following financial interests that must be declared:

* 1. Any benefits through the ICR’s Rewards to discoverers scheme that will be received relating to any trial for which I am the chief investigator or a principal investigator
  2. Any research support, including compensation in the form of equipment or other in-kind support, received from the company that is the sponsor or beneficiary of the trial for which I am the chief investigator or a principal investigator and that is not related to studies associated with the trial.
  3. Any paid consultancy carried out for the company that is the sponsor or the beneficiary of for which I am the chief investigator or a principal investigator including payments in kind
  4. Any other payments or benefits in kind from the company that is the sponsor or the beneficiary of the trial for which I am the chief investigator or a principal investigator

[OR]

I declare that either I or my spouse, partner or dependent children hold the following financial interests:

|  |  |
| --- | --- |
| Financial interest (delete if not applicable) | Details |
| Any benefits through the ICR’s Rewards to discoverers scheme that will be received relating to any trial for which I am the chief investigator or a principal investigator |  |
| Any research support, including compensation in the form of equipment or other in-kind support, received from the company that is the sponsor or beneficiary of the trial for which I am the chief investigator or a principal investigator and that is not related to studies associated with the trial. |  |
| Any paid consultancy carried out for the company that is the sponsor or the beneficiary of for which I am the chief investigator or a principal investigator including payments in kind |  |
| Any other payments or benefits in kind from the company that is the sponsor or the beneficiary of the trial for which I am the chief investigator or a principal investigator |  |

1. Delete as applicable

[EITHER]

I declare that neither I nor my spouse, partner or dependent children are:

* 1. An elected or appointed government official
  2. An employee of or acting on behalf of government, a government agency, or enterprise performing a governmental function
  3. A political party member, officer, employee or candidate
  4. Someone acting on behalf of a political party or a candidate for political office
  5. A consultant, employee or person acting on behalf of a public international organization
  6. A representative of government in any other capacity.

Note that government covers all levels and sub-divisions of government, including local, and national government and administrative, legislative and executive government.

[OR]

1. I declare that either I/my spouse/ my partner/ a dependent children am/is:
2. An elected or appointed government official
3. An employee of or acting on behalf of government, a government agency, or enterprise performing a governmental function
4. A political party member, officer, employee or candidate
5. Someone acting on behalf of a political party or a candidate for political office
6. A consultant, employee or person acting on behalf of a public international organization
7. A representative of government in any other capacity.

Note that government covers all levels and sub-divisions of government, including local, and national government and administrative, legislative and executive government.

And

1. The person declared in section 3 above does/does not (delete as applicable) have any decision making authority or official influence over:
2. Pharmaceutical or other medicine product licences
3. Conditions under which Pharmaceutical products are imported, marketed, distributed or sold;
4. Price/reimbursement or formulary listing of Pharmaceutical products or medicines;
5. Approval or authorisation of clinical trials or other research and development undertakings
6. I declare that the information I have provided indicates all actual or potential competing financial interests and other conflicts of interest with regard to trials for which I am the chief investigator or a principal investigator.
7. I agree to disclose promptly to the ICR (and within 30 days of acquiring) any financial or other interests that may arise after submission of this form that may constitute an actual or potential competing interest.
8. I understand that the information provided on this form will be held and processed by the ICR for the purposes of :
   1. recording declarations of financial and other interests:
   2. managing conflicts and reporting and responding to trial Sponsors as needed;

subject to the provisions of the Data Protection Act 1998.

1. I understand that the ICR may be obliged to make information available concerning identified actual or potential conflicts of interest to Sponsors to enable them to comply with the US Foreign Corrupt Practices Act (“FCPA”). I understand that such data may be provided by the ICR and. I consent to the ICR disclosing my data in this way.

Information of the type set out above may also be requested by Sponsors about ICR employees other that the Principal or Chief Investigator. Any requests for information about ICR researchers other than the Principal or Chief Investigator should be referred to the Enterprise Unit

If you want to supply any additional details or clarify any points, please add them in the space below or attach additional sheets

Signed: **……………………………………………………………**

Date: **……………………………………………………………**

**Official Use Only**

**Date Rvd:**

**Initials:**

**Please return the form in hard copy or by email to the Director of Enterprise**

**Appendix 3**

THE INSTITUTE OF CANCER RESEARCH: ROYAL CANCER HOSPITAL

**DECLARATION OF COMPETING INTERESTS**

PROFORMA FOR THE DECLARATION OF SIGNIFICANT FINANCIAL INTERESTS IN RESEARCH FUNDED BY THE US NATIONAL INSTITUTES OF HEALTH

# 

|  |  |  |  |
| --- | --- | --- | --- |
| Name |  | | |
| Division |  | | |
| Title of NIH Research Project |  | | |
| NIH Institute funding the research (e.g., National Cancer Institute) |  | | |
| Project start date |  | NIH grant reference number |  |
| Email |  | | |

**Actual or Potential conflicts of Interest**

The purpose of this declaration is to ensure that Significant Financial Interests are disclosed and, if these are considered to present a Financial Conflict of interest, that these are managed or eliminated.

Please please information on any significant financial Interest

|  |  |  |
| --- | --- | --- |
| Name of organisation in which you (or a close family member) have a significant financial interest | Details of significant financial interest (e.g., directorship, consultancy, shareholding, etc.) | Approximate value (£) of the significant financial interest |
|  |  |  |
|  |  |  |
|  |  |  |

**Declaration**

1. I declare that the information I have provided indicates all Significant Financial Interests with regard to my position at the Institute of Cancer Research.
2. I acknowledge that I am obliged to disclose promptly to the ICR (and within 30 days of acquiring) any Significant Financial Interest that may arise after submission of this form.
3. I understand that the information provided on this form will be held and processed by the ICR for the purposes of :
   1. recording declarations of Significant Financial Interest:
   2. assessing and identifying Financial Conflicts of Interest as required by the NIH
   3. managing such conflicts and reporting and responding to the NIH accordingly;
   4. providing information on declarations and any identified Financial Conflicts of Interest to NIH

subject to the provisions of the Data Protection Act 1998.

1. I understand that the ICR is obliged by [NIH regulations](http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf) to make information available concerning identified Financial Conflicts of Interest by a written response to any requestor within five business days of receiving such a request. I understand that such data may be provided by the ICR and. I consent to the ICR disclosing my data to any requestor in this way.
2. I consent to the ICR sharing information with NIH about this disclosure.

Signed: **……………………………………………………………**

Date: **……………………………………………………………**

**Official Use Only**

**Date Rvd:**

**Initials:**

**Please return the form in hard copy or by email to the Director of Enterprise**

If you want to supply any additional details or clarify any points, please add them in the space below or attach additional sheets

|  |
| --- |
|  |

The full text of the NIH’s regulations (entitled Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors) is available at:

<http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf>

Frequently Asked Questions about the NIH’s regulations on Financial Conflicts of Interest are available at:

<http://grants.nih.gov/grants/policy/coi/coi_faqs.htm> .

The regulations define ‘Significant Financial Interest’ as follows:

“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.

iv) 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 institutional responsibilities. Excludes travel reimbursed or sponsored by Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical centre, or a research institute affiliated with Institution of higher education.

Investigator is defined as 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 US Public Health Service (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants.