Policy Directive

Ethics & Research Governance: Conflicts of Interest

Document Number: SWSLHD_PD2017_030

Functional Sub-Group: Research and Ethics Office

Summary: This policy outlines the process for identifying and managing conflicts of interest

Approved by: Policy & Compliance Committee

Publication (Issue) Date: November 2017

Next Review Date: November 2020

Replaces Existing Policy: N/A

Previous Review Dates: N/A

Compliance with this policy directive is mandatory.
Contents

1. Introduction..................................................................................................................... 3

   The risk addressed by this policy: ........................................................................... 3

2. The Aims / Expected Outcome of this policy: .......................................................... 3

3. Policy Statement ........................................................................................................... 3

4. Principles........................................................................................................................ 4

   4.1. Identifying a conflict ...................................................................................... 4

   4.2. Declaring a real/potential/perceived conflict of interest ................................ 5

5. Recording of Conflicts of Interest .................................................................................... 5

   5.1. Staff members .............................................................................................. 5

   5.2. Departments/Units providing services for human research projects ........ 5

   5.3. Human Research Ethics Committee .................................................................. 5

   5.4. Institution (SWSLHD) and institutional leaders .............................................. 6

   5.5. Staff/committee/institutional leaders who become aware of another person’s possible conflict of interest .............................................................. 6

6. Recording of Conflicts of Interest.................................................................................... 6

7. Assessing a possible declared conflict of interest in human research ....................... 7

8. Managing Conflicts of Interest .................................................................................... 7

9. Performance Measures.................................................................................................. 8

10. Definitions ..................................................................................................................... 8

11. References and Links..................................................................................................... 9

12. Attachments: .................................................................................................................. 9

   12.1. Declaration of a Conflict of Interest .......................................................... 10

   12.2. SWSLHD HREC Member/external advisor Declaration and undertaking .. 12

   12.3. Member Statement of Interest and Associations ........................................ 13

Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Amendment Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2017</td>
<td>Amended to reflect current practice and guidelines for the process of managing conflicts of interest in research.</td>
</tr>
</tbody>
</table>
1. Introduction

South Western Sydney Local Health District (SWSLHD) is committed to providing a fair, ethical and accountable environment for the conduct of human research within the District.

Conflicts of interest in human research deserve special scrutiny because of their potential to affect the rights and welfare of human subjects. In particular, such conflicts may arise when research is undertaken that is sponsored by, or involves a product of, an entity with which an investigator or other persona may have an external relationship.

The integrity and fairness of the decisions and actions taken by staff, members of the Human Research Ethics Committee and the Institution could be undermined if, when performing their respective duties, a conflict between work and private interest exists or appears to exist.

**The risk addressed by this policy:**

- Breach of the NSW Health Code of Conduct
- Unethical practice in research
- Breach of the South Western Sydney Local Health District Research Code of Conduct

2. The Aims / Expected Outcome of this policy:

- All staff involved or providing services in human research will conduct themselves in an ethical manner and uphold the integrity of research involving humans.

3. Policy Statement

Conflicts of interest are not necessarily wrong or unethical, however it is important to appropriately identify/disclose and effectively manage any actual, perceived or potential conflict of interest situations.

This policy specifically relates to:

- Staff members who undertake human research, for example, Principal Investigators, Associate Investigators, members of a research team
- Staff members who provide services for human research projects
- Members of the Human Research Ethics Committee (also refer to SWSLHD HREC Standard Operating Procedure)
- Institution (SWSLHD) and institutional leaders

In relation to clinical research, conflicts of interest occur at different levels, for example, among investigators, conflicts may be related to the financial gains to participate in...
pharmaceutical sponsored trials, to potential academic career improvement and also to personal interests such as the financial support for trips to international conferences. Research institutions also have conflicts of interest, as the sponsored projects may help increase their budgets, both directly and indirectly, for example, improvement of physical infrastructure of laboratories or outpatient clinics etc. Human Research Ethics Committee (HREC) members may also be conflicted from time to time including the possible pressures exerted on them by researchers, possibly sponsors and other relationships.

A conflict of interest may arise when a person, due to external and/or internal influences, may not (or could not) act;

- Equally;
- Fairly; and
- With integrity and honesty.

4. Principles

4.1. Identifying a conflict

When undertaking and/or reviewing a human research project, staff/committee members/institutional leaders should ask themselves the following questions to help decide if a conflict of interest exists or could be perceived by any person to exist:

- Are there personal financial incentives such as payment of fees and/or honorariums for sitting on committees or other interests in relation to the research such as consultancies?
- Are there unreasonably high financial gains to my department/unit/institution from undertaking this research or providing services for the research project?
- Do I, a relative, friend or associate stand to gain/lose in any way from the SWSLHD decision/action in relation to the research?
- Am I in a position to influence decision making about the research that is related to a potential private benefit?
- Have I made any promises or commitments to persons or others in relation to the research should it be undertaken?
- Have I received a benefit or hospitality from someone who stands to lose or gain from the SWSLHD’s decision/action in relation to the research?
- Am I a member of an association or professional organisation, or do I have particular ties and affiliations with research sponsors, organisations or individuals, who stand to lose or gain from the SWSLHD’s consideration of the research?
- Could there be benefits for me in the future that could cast doubt on my objectivity?
- If I do participate in assessment or decision-making, would I be happy for my colleagues and the public to be aware of any association or connection?
- Would a fair and reasonable person perceive that I was influenced by personal interest in performing my role in the research or public duty?
- Do I need to seek advice or discuss the matter with an objective party?
- Am I confident of my ability to act impartially?
- Do I need to declare a matter?

Should situations result in the identification of potential or real conflicts of interest, these do NOT necessarily imply wrong-doing or inappropriate activities. However, in research settings, they can compromise, or be perceived as compromising, important academic values, research integrity, or the SWSLHD mission. It is essential for all staff, students, committee
members and institutional leaders to understand how these divergent interests can become a problem.

4.2. Declaring a real/potential/perceived conflict of interest

Staff/committee members/institutional leaders must declare any real/potential/perceived conflict of interest (whether pecuniary or non-pecuniary). Staff/committee members/institutional leaders are also expected to declare any circumstances that could result in a third party reasonably perceiving a conflict of interest to exist.

The Chief Executive SWSLHD has delegated authority to the HREC to assess declarations of conflicts of interest in human research and deciding what action (if any) is necessary.

A declaration of a potential/real conflict of interest must be submitted to the HREC for review as soon as is possible after the potential/real conflict has been identified.

Persons submitting a declaration must do so using the Declaration of conflict of interest form (Attachment 1). This form is available on the SWSLHD ethics and research governance web page at: http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html

5. Recording of Conflicts of Interest

5.1. Staff members

(who undertake human research, for example, Principal Investigators, Associate Investigators, co investigators, members of a research team) reporting their own real/potential/perceived conflict of interest

Principal Investigators, Associate Investigators, co investigators, members of a research team should inform the Human Research Ethics Committee when submitting their research proposal for ethical review or during an ongoing project at the first available opportunity. If a member of the research team has real/potential/perceived conflict of interest it should be reported to their Principal Investigator and discuss the matter. The conflicted person should complete the Declaration of a Conflict of Interest form describing the real/perceived/potential conflict of interest and the form should be signed by the Principal Investigator.

5.2. Departments/Units providing services for human research projects

Heads of departments/units or others providing services for human research projects should also consider whether there is any potential or real conflict of interest in providing the services requested, either pecuniary or non-pecuniary.

The conflicted person should complete the Declaration of a Conflict of Interest form describing the real/perceived/potential conflict of interest and the form should be signed by the Head of the department/unit undertaking the services.

This should be submitted to the HREC as soon as practicable after the request is made to provide the services.

5.3. Human Research Ethics Committee

This section should be read in conjunction with HREC SOP 011. This SOP outlines the procedures for dealing with a declaration made by a HREC member.
All HREC members are required to complete the Declaration and Undertaking (Appendix 2) and Statement of Interest form (Appendix 3) prior to the commencement of their tenure.

All HREC members are required to declare any real or perceived conflict of interest at the commencement of each meeting or alternatively this may be made in writing to the Chairperson prior to the meeting. The full discussion and outcome (positive and negative) will be recorded in the minutes of each meeting.

If the Chair of the HREC discloses a real or perceived conflict of interest then the Deputy Chair will lead the discussion on that matter.

External advisors/experts providing reviews and/or advice to the HREC must also complete the Declaration and Undertaking form prior to receiving any documentation/information from the Executive Officer, HREC about the research.

5.4. Institution (SWSLHD) and institutional leaders
Institutional conflict of interest involving human research may arise in a situation in which the financial or other interests of SWSLHD or the personal interests of the institutional leaders might affect or reasonably appear to affect institutional processes for the design, conduct, reporting, review, oversight and approval/authorisation of human research.

The institutional leader should complete the Declaration of a Conflict of Interest form describing the real/perceived/potential conflict of interest. This should be submitted to the HREC as soon as practicable after the conflict has been recognised.

5.5. Staff/committee/institutional leaders who become aware of another person’s possible conflict of interest.
Staff/committee members/institutional leaders have an obligation under the Australian Code for the Responsible Conduct of Research 2007 to report possible conflicts of interest that will have the potential to bring the health service into disrepute. If staff members are aware that another staff member has a potential conflict of interest in human research that has not been disclosed, they should report the matter to the Human Research Ethics Committee as appropriate.

If the report of a possible conflict of interest involves corrupt conduct, maladministration and/or serious and substantial waste of public resources then the Protected Disclosures Act 1994 provides certain protections against reprisals. See Public Interest Disclosures (PD2016_027)

Members of the general public or participants of human research are also able to make a complaint if they have reason to believe that research management or a research team member has a conflict of interest.

6. Recording of Conflicts of Interest
Conflict of Interest Registers are to be maintained for:
a) HREC
b) Researchers, those providing services to research, institution and institutional leaders
These Registers will be managed by the Manager, Ethics & Research Governance Office and will be a record of all real/perceived/potential conflicts.
The Register is to incorporate as a minimum and as appropriate, the following information:

- name of the person declaring the conflict of interest
7. Assessing a possible declared conflict of interest in human research

Declarations of possible conflicts of interest in human research are assessed in the first instance by the Human Research Ethics Committee either at the next HREC Executive Committee meeting or full HREC meeting, following receipt of the Declaration of Conflict of Interest by the Manager, Ethics & Research Governance Office.

The HREC will consider all relevant information and may determine that:
- the potential for a conflict of interest is remote and requires no further action other than to record that the matter has been reviewed; or
- the situation presents a conflict of interest and that the conflict must be resolved, and
- how the conflict of interest is to be resolved

8. Managing Conflicts of Interest

The Manager, Ethics and Research Governance Office, will provide written feedback to the person involved within 5 working days of the HREC reviewing the declaration.

When the disclosure of the real/perceived/potential conflict of interest is related directly to the ethical review of a research proposal by the HREC, either single or multicentre research, then the HREC assessment of the declaration will be acknowledged in the letter from the HREC to the Coordinating/Principal Investigator following review of that research proposal. For multicentre research, Coordinating Principal Investigators will then be responsible for informing Research Governance Officers at other sites about the deliberations of the HREC, in accordance with the NSW Ministry of Health policy directive: Research - Authorisation to Commence Human Research in NSW Public Health Organisations [PD2007_043] http://www.health.nsw.gov.au/policies/pd/2010/PD2010_056.html

If the person disagrees with the outcome the matter is to be discussed between the person involved and the Chair, HREC to seek resolution.

Reporting potential or actual conflicts may involve disclosing personal information. This information will be handled in such a way that privacy is appropriately managed having regard to the circumstances.

The assessment process will be fully documented, refer to section 6 Record Keeping.

If the HREC resolves that the situation does present a conflict of interest, the HREC will decide whether the proposed activity may proceed, how and whether a plan is required to manage the conflict.

The disclosure of a potential/real conflict of interest will be recorded in the Conflict of Interest Register for Human Research. This Register will be maintained by the Manager, Ethics and
Research Governance Office. Recording in this Register is an important first step however this does not necessarily resolve the conflict. It may be necessary to further assess the situation and determine whether one or more of the following strategies (but not limited to) is required:

- Disclosure in relevant publications and presentations
- Disclosure of the conflict in consent forms
- Restrictions on the role of the conflicted person in the research to be undertaken, for example:
  - by restricting a researcher in obtaining informed consent, serving as a Principal Investigator on a project, or performing data analysis
- Remove the conflicted person from participating in the research or reorganise the involvement of that person so as to remove the conflict
- If it is not practical to restrict involvement in the research, an alternate person may be able to take on the relevant role.
- Relinquishing the interest which prompted concerns about the conflict of interest, for example:
  - relinquishment of benefits such as shares, consultancies, travel, accommodation expenses and the like for an individual or
  - relinquishment of benefits to the organisation such as unreasonably high financial gain above the cost of undertaking the research
- Restrict the conflicted person from any role in the research
- Non approval of the research altogether if the conflict is of significant magnitude and cannot be resolved in any other manner.

9. Performance Measures

The HREC will establish a case-by-case mechanism to monitor the implementation of any plan to resolve a conflict of interest in accordance with the NSW Ministry of Health Conflicts of Interest and Gifts and Benefits, Document Number PD 2015_045.

At a minimum this will include periodic review by the HREC such as the provision of an annual report by the conflicted person.

Appendix
1. Declaration of Conflict of Interest form
2. HREC Member/external advisor Declaration and Undertaking form

10. Definitions

List any words that may be open to interpretation unless specifically defined.

<table>
<thead>
<tr>
<th>Conflict of Interest</th>
<th>“it is likely that a staff member or a committee member could be influenced or perceived to be influenced, by a personal interest when carrying out their public duty”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pecuniary interest</td>
<td>An interest that a person has in a matter because of a reasonable likelihood (or expectation) or appreciable financial gain (or loss) to the person (or to another person with whom that person is associated)</td>
</tr>
</tbody>
</table>
Non-pecuniary interest is any private interest, which does not pertain (or relate) to money.

11. References and Links

Related Policy Directives / Guidelines

<table>
<thead>
<tr>
<th>Policy Ref.</th>
<th>Description</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>MoH – PD2015_049</td>
<td>Code of conduct</td>
<td>Link</td>
</tr>
<tr>
<td>MoH – Pd2015_045</td>
<td>Conflicts of Interest and Gifts and Benefits</td>
<td>Link</td>
</tr>
<tr>
<td>MoH – PD2016_027</td>
<td>Public Interest Disclosures</td>
<td>Link</td>
</tr>
<tr>
<td>SWSLHD_PD2015_002</td>
<td>South Western Sydney Local Health District Research Code</td>
<td>Link</td>
</tr>
<tr>
<td>SWSLHD_PD2016_005</td>
<td>Research &amp; Ethics - Responding to Allegations of Research Misconduct</td>
<td>Link</td>
</tr>
</tbody>
</table>

Articles / Research / Resources

<table>
<thead>
<tr>
<th>Description</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Health &amp; Medical Research Council/Australian Research Council/Australian Vice-Chancellors’ Committee <em>National Statement on the Ethical Conduct of Human Research 2007</em></td>
<td>Link</td>
</tr>
<tr>
<td>National Health &amp; Medical Research Council/Australian Research Council <em>Australian Code for the Responsible Conduct of Research 2007</em></td>
<td>Link</td>
</tr>
</tbody>
</table>

12. Attachments:

1. Declaration of a Conflict of Interest Form
2. SWSLHD HREC Member/external advisor Declaration and Undertaking
3. Member Statement of interest and Associations

Author: Manager, Research and Ethics Office (Ms Annamarie D’Souza)

Reviewers: Research and Ethics Office Steering Committee
Declaration of a Conflict of Interest Form

This form is to be completed by any staff member who has a real or perceived conflict of interest or a potential conflict of interest in undertaking their obligations in relation to human research. The relevant SWSLHD policy on Conflict of Interest is located at: http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html

DISCLOSURE

Please complete your answers in block letters.

Name: .........................................................................................................................

Department: .............................................................................................................

Title of research project: ..........................................................................................

Role in research project: ............................................................................................

I declare a:

REAL   ☐     POTENTIAL ☐     PERCEIVED ☐

CONFLICT OF INTEREST

Note: Tick all applicable boxes (more than one box may be ticked)

Please provide a brief outline of the nature of the perceived/real conflict

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

Please detail the arrangements proposed to resolve/manage the conflict

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________
Signed: .................................................................

Date: ............................

Endorsement of
(tick whichever is applicable)

Chief Investigator  □

Head of Department providing services for the research  □

I, (insert full name) ................................................................. have reviewed the disclosure (and plan where applicable) and:
("delete as appropriate")

- Believe that a plan to manage the conflict of interest is not required and that no further action is necessary in relation to this matter.

- Believe that the plan outlined in the disclosure will mitigate or remove the conflict of interest but will continue to monitor the situation.

- Cannot adequately resolve the conflict of interest with the staff member concerned and request the matter to be reviewed by the HREC for resolution.

Signature: .....................

Position: .....................

Date: ............................
12.1. SWSLHD HREC Member/external advisor Declaration and
undertaking

I………………………………………….. undertake that:

1. All matters of which I become aware during the course of my work on/for the HREC
will be kept confidential;

2. Any real/potential/perceived conflicts of interest, which exist or may arise during my
tenure/provision of advice on/to the HREC will be declared; and

3. I have not been subject to any criminal conviction or disciplinary action, which may
prejudice my standing as a HREC member or as an external advisor

……………………………..
Signature

……………………………..
Date
12.2. Member Statement of Interest and Associations

Member Statement of Interest and Associations

Name: ________________________________

EMPLOYERS

I am currently employed by the following companies:

A. ________________________________
B. ________________________________
C. ________________________________
D. ________________________________
E. ________________________________

DIRECTORSHIP/CONSULTANCIES (whether Public or Private)

I, and/or the persons associated with me, hold the following directorships/consultancies, whether remunerated or not:

A. ________________________________
B. ________________________________
C. ________________________________
D. ________________________________
E. ________________________________

PECUNIARY INTEREST IN HEALTH AND ASSOCIATED FIELDS

I have the following interests, financial or otherwise, the nature of which gives rise to, or may be seen to give rise to, a conflict of interest with my public duty:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

I certify that the information provided in this statement properly reflects, as far as I am aware, my registrable interests and that the information provided is in accordance with the guidelines for declaring interests.

_________________________________________ Date: / / 

Signature (employee)