

## Policy Directive



# Ethics and Research Governance: Conflicts of Interest

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<b>Functional Sub-Group:</b>	Research Directorate
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## Review Process

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## Approval Process

<b>Committee Name</b>	<b>Endorsement/Approval Date</b>
Research and Ethics Steering Committee, SWSLHD	1 February 2021
SWSLHD Policy and Compliance Committee	27 April 2021

## Revision History

<b>Version</b>	<b>Amendment Notes</b>
April 2021 SWSLHD_PD2021_004	Reviewed with minor amendments for clarity and to update reference documents.
November 2017 SWSLHD_PD2017_030	Amended to reflect current practice and guidelines for the process of managing conflicts of interest in research.

## 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 person may have an external relationship.

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

### **The risks addressed by this policy:**

- Breach of the NSW Health Code of Conduct
- Unethical practice in research
- Breach of the SWSLHD Research Code of Conduct

## 2. The Aim/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 HREC (also refer to SWSLHD HREC Operations Manual)
- Institution (SWSLHD) and all institutional directors.

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. 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 or 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 the research 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 (Form 1).

### **5. Recording conflicts of interest**

#### **5.1. Staff members**

Those 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 and members of a research team should inform the HREC 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 discussed, documented and reported to their Principal Investigator and the matter discussed.

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 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 Conflict of Interest* form (Form 1) 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 (HREC)**

This section should be read in conjunction with SWSLHD HREC Operations Manual, HREC 011: Declaration of interest. The Operations Manual outlines the procedures for dealing with a declaration made by an HREC member.

All HREC members are required to complete the *SWSLHD HREC Member/External Advisor Declaration and Undertaking* form (Form 2) and *Member Statement of Interest and Associations* form (Form 3) prior to 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 an HREC member declares a conflict of interest for an application, they will be requested to leave the HREC meeting while the application is being discussed/reviewed by the Committee.

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 *SWSLHD HREC Member/external advisor 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 where 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.

An 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, 2018 to report possible conflicts of interest that have the potential to bring SWSLHD 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 HREC.

If the report of a possible conflict of interest involves corrupt conduct, maladministration and/or serious and substantial waste of public resources, then the Public Interest Disclosures

Act 1994 provides certain protections against reprisals. Also see NSW Health PD2016\_027 Public Interest Disclosures.

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.

Members of the general public are able to make a complaint by contacting the SWSLHD Research Directorate via email: [SWSLHD-ethics@health.nsw.gov.au](mailto:SWSLHD-ethics@health.nsw.gov.au) or via phone contact: 02 8738 8304.

## 6. Recording of conflicts of interest

Conflict of Interest Registers are to be maintained for:

- HREC
- 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:

- full name of the person declaring the conflict of interest
- to whom the conflict was declared (name and position)
- date of declaration
- organisation or individual involved
- brief description of the matter
- proposal for managing the conflict
- date of review of declaration and action taken/comments.

The minutes of the HREC meeting at which the declaration is presented will include a full and accurate record of the discussion and outcome of the declaration.

## 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 HREC either at the next HREC Executive Committee meeting or full HREC meeting, following receipt of the *Declaration of Conflict of Interest* by the Research Ethics and Governance Manager.

The HREC will consider all relevant information and may determine that either:

- 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, if so
- how the conflict of interest is to be resolved.



## 8. Managing conflicts of interest

The Research Ethics and Governance Manager will provide written feedback to the person involved within 5 working days of the HREC review of 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 Health policy directive [PD2010\\_056 Research - Authorisation to Commence Human Research in NSW Public Health Organisations.](#)

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 (see Section 6 above, "Recording of conflicts of interest"). If the HREC resolves that the situation does present a conflict of interest, the HREC will decide whether the proposed activity may proceed 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 & 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.
- Restrict the role of the conflicted person in the research to be undertaken, for example, restrict 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 alternative person may be able to take on the relevant role.
- Relinquish 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. Internal Audit

All conflicts of interest must be declared to Internal Audit, SWSLHD. Internal Audit maintains a District-wide register of all conflicts of interest in SWSLHD.

Once the attached Conflict of Interest Form is approved by the Chief Investigator or Head of Department, it must be forwarded to [SWSLHD-InternalAuditUnit@health.nsw.gov.au](mailto:SWSLHD-InternalAuditUnit@health.nsw.gov.au) with any relevant supporting documentation. The conflict will be maintained on the register for the research period or longer if specified in the form.

## 10. 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 NSW Health [PD2015\\_045 Conflicts of Interest and Gifts and Benefits](#).

At a minimum, this will include periodic review by the HREC..

## 11. Definitions and Acronyms

<b>Conflict of Interest</b>	Where 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.
<b>HREC</b>	Human Research Ethics Committee
<b>Pecuniary interest</b>	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).
<b>Non-pecuniary interest</b>	Any private interest, which does not pertain (or relate) to money.

## 12. References and Links

### Related Policy Directives/Guidelines

MoH – PD2015_049	NSW Health Code of Conduct	<a href="#">Link</a>
MoH – PD2010_056	Research - Authorisation to Commence Human Research in NSW Public Health Organisations	<a href="#">Link</a>

MoH – PD2015_045	Conflicts of Interest and Gifts and Benefits	<a href="#">Link</a>
MoH – PD2016_027	Public Interest Disclosures	<a href="#">Link</a>
SWSLHD_PD2015_002	South Western Sydney Local Health District Research Code of Conduct	<a href="#">Link</a>
SWSLHD_PD2016_005	Research & Ethics - Responding to Allegations of Research Misconduct	<a href="#">Link</a>

### Articles/Research/Resources

National Health and Medical Research Council/Australian Research Council/Australian Government - <i>National Statement on the Ethical Conduct of Human Research 2007(Updated 2018)</i>	<a href="#">Link</a>
National Health and Medical Research Council/Australian Research Council/Australian Government - <i>Australian Code for the Responsible Conduct of Research 2018</i>	<a href="#">Link</a>
NSW Legislation <i>Public Interest Disclosures Act 1994</i>	<a href="#">Link</a>

### 13. Forms

Form 1	Declaration of Conflict of Interest	<a href="#">Link</a>
Form 2	SWSLHD HREC Member/External Advisor Declaration and Undertaking	<a href="#">Link</a>
Form 3	Member Statement of Interest and Associations	<a href="#">Link</a>