

## Human Research Ethics Committee

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### 1. Purpose

The Board of the WEHI has established a Human Research Ethics Committee (**HREC**) to provide ethical oversight, review and approval of research involving humans, human tissue, data or their derivatives at the WEHI and compliance with the National Statement on Ethical Conduct of Human Research (2018) and any amendments (**National Statement** or **NS**).

This Charter outlines the role and responsibilities of the HREC and meets the requirement of 5.2.1 and 5.1.27 of the National Statement.

This Charter should be read in conjunction with the National Statement. Where inconsistencies exist between this Charter and the National Statement the National Statement prevails.

### 2. Role and responsibilities

The primary function of the WEHI's HREC is to ensure that the WEHI's research is ethical, compliant and properly carried out, safeguarding the welfare and the rights of all research participants.

The Board takes the view that ethical research is best nurtured and protected by supporting scientists to see ethical reflection and conduct as a fundamental part of their professional responsibilities and of the WEHI's culture.

The HREC's key responsibilities are:

- To confirm on behalf of the WEHI that human research is conducted consistently with NS 5.1.2.
- To evaluate human research projects submitted to the HREC for review according to the National Statement.
- To oversee the ethical review processes of human research at the WEHI.
- To comply with all guidelines and legislation relevant to the research proposals considered.
- To protect the welfare, rights and safety of participants in the research projects it reviews.

### 3. Ethical review processes

The HREC supports the ethical review processes that the WEHI has established as detailed in the *Procedure - ethical review processes for human research*.

## **Risk**

The level of ethical review is determined by the level of risk inherent in the research project, as defined in Chapter 2 of the National Statement.

### **3.1. HREC Review – research involving more than low risk**

The following types of research require review by an HREC.

- all research that involves more than low risk
- women who are pregnant and the human fetus (NS Chapter 4.1)
- people highly dependent on medical care who may be unable to give consent (NS Chapter 4.4)
- people with a cognitive impairment, an intellectual disability, or mental illness (NS Chapter 4.5)
- Aboriginal and Torres Strait Islander Peoples (NS Chapter 4.7).

The WEHI currently accepts the review of the following human ethics committees:

- the WEHI HREC
- an HREC registered with the NHMRC and certified under the HREC National Certification Scheme.

### **3.2. Out of session review – low risk research**

Research involving no more than low risk that does not fall within a category under **NS section 4.1** may be reviewed out of session.

Applications for out of session reviews are made in the Human Research Database.

Out of session reviews are to be conducted by at least

- Chair
- Scientific Secretary or other member of the committee with an appropriate research background
- Any other personnel as deemed necessary by the Chair

#### **Considerations for out of session review**

In assessing out of session review applications the following must be considered

- NS Section 1, 3 and 4 (NS5.1.19 (b))
- take account of researcher's judgements as to whether their research is suitable for review by a non-HREC process (NS 5.1.19 (c))
- have due regard to privacy legislation (NS 5.1.19(d)).

#### **Documenting out of session review**

The HREC Convenor is responsible for maintaining records of all discussions related to out of session reviews and decisions.

#### **Reporting**

All decisions assessed through Out-of-session review are to be reported to the next HREC meeting.

### **3.3. Exempt from review – Negligible Risk**

Where submitted through the HRD the following are exempt from ethical review:

- amendments to existing projects involving only a change of project personnel who:
  - are not external investigators where their role would change the tissue/ data transfers currently being undertaken as part of the project and,
  - Are not the Principal Investigator.

- amendments where the changes are purely administrative and do not affect the ethical implications of the project.
- Data-only projects that meet the requirements under NS 5.1.22, where:
  - the research is negligible risk research
  - the research does not involve human tissue
  - the research only involves the use of existing collections of data or records that contain only non-identifiable data about human beings

#### **4. Members**

The Board appoints all members to the HREC which is constituted in accordance with NS 5.1.29-30.

The minimum membership of the HREC is eight and as far as is possible consist of an equal number of men and women. At least one third of the members should be from outside the WEHI (NS 5.1.29).

The core membership of the HREC is as follows (NS 5.1.30):

- Chairperson with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement.
- At least two lay people (one man and one woman) who have no affiliation with the IWEHI and who do not currently engage in medical, scientific, legal or academic work
- At least one person with knowledge of and current experience in the professional care, counselling or treatment of people
- At least one person who performs a pastoral care role in the community
- At least one lawyer, where possible one who is not engaged to advise the institution
- At least two people with current research experience that is relevant to the research proposals to be considered at the meetings they attend. These two members may be selected according to need from an established pool of inducted members with relevant expertise.

No member may be appointed to more than one of the above categories, but the Institute may establish a pool of inducted members who may attend meetings as needed to meet the HREC minimum requirements (NS 5.1.31).

One or more of the members above should be experienced in reflecting on and analysing ethical decision-making (NS 5.1.32).

A Committee member may not nominate an alternate.

#### **Additional duties**

The HREC will appoint one of its members as the Scientific Secretary.

This will be an individual with relevant clinical and research experience. The Scientific Secretary's responsibilities include explaining the science, procedures and/or treatments if necessary to lay committee members. The Scientific Secretary also acts as a valuable conduit to researchers offering and giving advice as necessary.

#### **Experts and observers**

The HREC may invite experts and/or seek additional advice on specific projects as required.

Staff involved in the administration of the HREC may attend meetings to support the committee at the discretion of the Chair. These staff will attend as observers and do not have voting rights.

#### **Researchers**

Researchers may request to be present for discussion of their proposed research.

#### **4.1. Appointment of members**

Members will be appointed to the HREC using an open and transparent process.

Selection will be as an individual based on their knowledge, qualities and experience. Members are not appointed as a representative of any organisation, group or opinion (NS 5.1.34-5.1.36).

### **Term**

Appointments to the HREC will be reviewed every three years (NS 5.1.34). Reviews will be conducted in conjunction with the HREC Chair, Head, Governance Risk and Compliance, and the HREC Convenor. Members maximum term is 12 years.

### **Notice of appointment**

All members to the HREC are to be provided with a written notice of appointment that states the terms of their appointment.

### **Remuneration**

Committee members are appointed on a pro bono basis and will not receive payment for membership nor attendance at meetings. The WEHI will reimburse reasonable expenditure incurred for bona fide HREC business activities.

### **Indemnification**

Committee members are indemnified by the WEHI in respect of any liabilities that may arise in the course of bona fide conduct of duties as members of the HREC.

## **4.2. Obligations of members**

### **Induction and training**

All members must participate in the HREC induction program. Each member is responsible for becoming familiar with the National Statement and consult other guidelines relevant to the review of specific research proposals. HREC members are expected to attend continuing education or training programs in research ethics at least every three years (NS 5.2.3). WEHI will pay for any conferences, training or similar undertaken in this manner.

All new members to the HREC will be provided with a mentor from the current membership to assist them in their transition to the committee.

### **Obligations in reviewing applications**

Each member of the HREC is responsible for deciding whether, in their judgement, a proposal submitted to the review body meets the requirements of the National Statement and is ethically acceptable.

### **Membership of HREC to be made public**

The membership of the HREC will be made public on the WEHI's website and intranet (NS 5.1).

## **4.3. Adverse events**

Researchers are responsible for reporting adverse events promptly to the HREC.

The HREC will promptly review any adverse events and take necessary action to ensure that the research continues to perform within the parameters of the National Statement.

## **5. Meetings**

### **5.1. Frequency of meetings**

The HREC shall meet a least five (5) times a year as agreed by the members. In determining the frequency of meeting the HREC should consider the impact of the number of meetings on the ability of researchers to commence their projects.

The Chair may call additional meetings at their discretion.

### **5.2. Attendance at meetings and quorum**

As far as possible, each HREC meeting should be arranged to enable at least one member in each membership category to attend (NS 5.2.30).

### **5.3. Preparation of papers and minutes**

#### **Papers**

All meeting papers will be circulated electronically to HREC members, at least seven (7) days prior to the meeting by the HREC Convenor.

#### **Minutes**

A draft copy of the minutes will be circulated electronically to members as soon as practicable after the meeting but no more than seven (7) days.

### **5.4. Decision making**

The following applies to decision making at the HREC consistent with NS 5.2.30-5.2.33.

Decisions by the HREC about whether a research proposal meets the requirements of the National Statement must be informed by an exchange of opinions from each of those who constitute the minimum membership. This exchange should ideally take place at a meeting with all those members present.

Where a member is not able to attend a meeting, they are encouraged to forward comments in writing to the HREC Convenor prior to the meeting to aid committee deliberation.

Where there is less than full attendance of the minimum membership at a meeting the Chairperson should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered.

#### **Decisions by general agreement**

The HREC should endeavour to reach decisions by general agreement. This need not involve unanimity.

#### **Timeliness**

The consideration and review of applications should be done in a timely manner.

#### **Decision outcomes**

The HREC will promptly notify researchers about decisions relating to outcomes. Decisions relating to approvals, rejections or withdrawal of ethical approval should be in writing and link the decision to the National Statement (NS 5.2.24).

## **6. Confidentiality**

All members, experts, observers and staff involved in the review of an application must maintain the confidentiality of its content and the deliberations of the HREC in relation to those applications.

## **7. Conflicts of interest**

All HREC meeting agendas will include the item *Declaration of any conflict of interest*.

Any committee member who has an interest that bears on any research coming before the review body should declare this interest when prompted by the Chair.

Types of interest may include:

- personal involvement or participation in research
- financial or other interest or affiliation
- involvement in competing research.

Where a conflict exists, the person may not participate in the deliberation on whether or not the project can be approved and will leave the room while the item is discussed.

Refer to NS 5.2.11, Chapter 5.4 and any guidelines issued by the NHMRC for more guidance on the management of conflict of interest.

## **8. HREC and researcher communication**

The HREC is committed to open communication between itself and researchers and a shared commitment to the review process.

The HREC will make itself available to staff and researchers to promote a clear understanding and raise awareness of the National Statement among researchers.

Where possible researchers will be given the opportunity to respond in person to issues about research proposals that have not be resolved by telephone or in writing (including email).

## **9. Fees**

The WEHI will not charge fees for submissions to the WEHI's HREC.

## **10. Receiving complaints from researchers or participants**

The WEHI has established procedures for receiving and promptly handling complaints or concerns about ethical issues arising in relation to the conduct of an approved research project or the handling of research proposals for review or the conduct/decisions of the WEHI's HREC through its *Policy and procedures for good scientific practice*.

All complaints are handled in a timely, sympathetic and confidential manner.

Information on the reporting process will be available on the WEHI's external website.

## **11. Human research policies**

The HREC will make recommendations to the Board on relevant human research policies to ensure that researchers understand their responsibilities under this Charter and the National Statement are clearly communicated to researchers.

## **12. HREC Convenor**

The HREC Convenor is responsible for:

- Supporting the scheduling of HREC meetings.
- Circulating electronically meeting papers to HREC members, at least seven (7) days prior to the meeting.
- Preparing and circulating draft minutes to HREC members within seven (7) days of the meeting.
- Maintaining the register of approved human research projects consistent with NS 5.2.26.
- Overseeing that researchers submit required reports on time.
- Supporting the development of appropriate policies and procedures to support the HREC.
- Coordinate the provision of education initiatives for HREC members and staff in relation to the ethical conduct of research involving humans.
- Ensuring that researchers are notified in writing of the Committee's decision as soon as practicable after the meeting at which the proposal was considered.
- Ensuring that all relevant reports are submitted on behalf of the WEHI in a timely fashion.
- Reviewing annual progress reports from HREC approved research projects. This review is to ensure the projects continue to conform to all ethical guidelines and legislation and that no new ethical issues have arisen (consistent with NS 5.5.2-5.5.5).

## **13. Reporting**

### **WEHI Board**

- The Chair will report regularly to the WEHI Board of Directors.
- The HREC Convenor will provide confirmed minutes of all HREC minutes to be presented to the Board.
- Immediately notify the Board where it determines to withdraw ethical approval of a research project consistent with NS 5.5.7-5.5.8.

### **Compliance**

The HREC is responsible for reporting regularly to the following bodies to ensure compliance. The HREC will undertake that:

- The HREC Convenor will report annually to the NHMRC on the HREC's activities for the preceding calendar year.
- The HREC Convenor will report annually to the Health Complaints Commissioner on its compliance with all relevant privacy legislation.

### Annual report

The HREC Convenor will prepare an annual report for the Board summarising the HREC activities for the year, which will be made available in the WEHI annual report (NS 5.1.16).

## 14. Review

This Charter will be reviewed annually at the first HREC meeting of each year. In reviewing the Charter the Board and HREC should consider the views outlined in (NS 5.1.14-15)

## 15. Supporting information

### Related Policies and Procedures

- Research Integrity Policy
- HREC Review Checklist

### Related Documents

- National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)
- Australian Code for the Responsible Conduct of Research 2018
- Safety monitoring and reporting in clinical trials involving therapeutic goods 2016
- Data Safety Monitoring Boards 2018
- Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)

### Legislation

- Privacy Act 1998
- National Health and Medical Research Council Act 1992

### Definitions

Term	Definition
<b>Human Research</b>	Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through: <ul style="list-style-type: none"><li>• taking part in surveys, interviews or focus groups;</li><li>• undergoing psychological, physiological or medical testing or treatment.</li><li>• being observed by researchers,</li><li>• researchers having access to their personal documents or other materials,</li><li>• the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath,</li><li>• access to their information (in individually identifiable, re-identifiable or nonidentifiable form) as part of an existing published or unpublished source or database.</li></ul>
<b>Low Risk</b>	Low risk research describes research in which the only foreseeable risk is on of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk. (NS Chapter 2.1)
<b>Negligible risk</b>	Negligible risk research describes research where there is not foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience. (NS Chapter 2.1)

## Human Ethics Committee Charter

	This includes the use of existing collections of data or records that contain only non-identifiable data about human beings. (NS 5.1.22)
<b>Principal Investigator (PI)</b>	The lead or head researcher for a research project.
<b>Research</b>	The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.

### Roles and Responsibilities

<b>Approval Authority</b>	Board
<b>Responsible Division/Department</b>	Governance, Risk and Compliance
<b>Policy Owner</b>	Human Research Ethics Committee
<b>Policy Author</b>	Human Ethics Officer and Committee Convenor

### Review cycle

<b>Initial review</b>	3 years
<b>Ongoing review</b>	3 years
<b>Next review</b>	2023

### Version History

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1.0						