



Government of **Western Australia**  
WA Country Health Service

# WA Country Health Service Human Research Ethics Committee Procedure



# Human Research Ethics Procedure

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## 1. Appointment of Members

### Reference Number: P1

**Purpose:** To describe the procedure for the appointment of members to WACHS HREC

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1. Members are appointed as individuals for their knowledge, qualities and experience.
2. Prospective members of the WA Country Health Service Human Research Ethics Committee (WACH HREC) are to be recruited in accordance with the WACHS [Human Research Ethics Committee Appointment Policy](#).
3. The Chief Executive (CE) or delegate, the Executive Director Medical Services (EDMS), may appoint a selection committee, which may include a representative of the WACHS HREC who is not an institutional member to interview prospective applicants, consult with the WACHS HREC members and make a recommendation to the CE or delegate. Prospective members may be invited to attend a meeting of the WACHS HREC as an observer and will be subject to a duty of confidentiality in relation to the proceedings of that meeting.
4. The Chair and the members are appointed after completion of the selection process and endorsement by the CE or delegate (in consultation with the WACHS Chair) and by the Minister for Health and will receive a formal letter of appointment.
5. The Deputy Chair is to be appointed by the Chair. In the absence of the Chair, the Deputy Chair is to perform the role and duties of the Chair.
6. A letter of appointment is to be issued to members once successfully appointed. The letter of appointment are to include the date of appointment, length of tenure, assurance that indemnity is to be provided in respect of liabilities that may arise in the course of their duties as a WACHS HREC member, the circumstances whereby membership may be terminated and the conditions of their appointment.
7. Members must agree to their names and membership categories being made available to the public, including being published on the WACHS HREC internet and intranet website.
8. Members are required to sign a confidentiality agreement upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the WACHS HREC will be kept confidential.
9. Members are also required to sign a member duties statement, outlining the duties required according to their membership category including a declaration that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a WACHS HREC member.

10. Upon appointment, members are to be provided with an induction pack containing the following documentation:
  - WACHS [HREC Terms of Reference \(TOR\)](#)
  - WACHS [HREC Procedures](#)
  - An up to date list of members' names and contact information including that of the WACHS HREC Ethics and QI Coordinator (EQIC) and Clinical Research Manager (CRM)
  - [National Health and Medical Research Council \(NHMRC\) National Statement on Ethical Conduct in Human Research 2007 \(National Statement\)](#)
  - Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders
  - [NHMRC Guidelines approved under Section 95A of the Privacy Act 1988](#)
  - [NHMRC Guidelines approved under Section 95 of the Privacy Act 1988](#)
  - [WA Health Research Governance Policy and Procedures \(2012\)](#)
  - [WA Health Single Ethical Review Standard Operating Procedures \(2013\)](#)
  - [WA Health Managing Conflicts of Interest Policy and Guidelines \(2010\)](#)
  - Any previous reports on the WACHS HREC's activities; and
  - Any other relevant information about the WACHS HREC's processes, procedures and protocols.
11. The fixed term appointment periods, regulations on the amount of consecutive terms served and conditions of appointment are outlined in the WACHS [Human Research Ethics Committee Appointment Policy](#).
12. Members are appointed to the WACHS HREC to provide category and geographical representation as outlined in the WACHS [Human Research Ethics Committee Appointment Policy](#).
13. New members are expected to attend available training sessions and review the contents of the induction pack as soon as practicable after their appointment. Existing members are expected to participate in training and education activities organised by WACHS. Reasonable costs associated with attendance at training and education sessions will be met by WACHS as recommended by the Public Sector Commission.

## 2. Orientation of New Members

### Reference Number: P2

**Purpose:** To describe the procedure for the orientation of new members

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1. New WACHS HREC members must be provided with adequate orientation.
2. Orientation may involve all or some of the following:
  - Introduction to other WACHS HREC members prior to the WACHS HREC meeting.
  - Informal meeting with Chair, EQIC and CRM to explain their responsibilities as a WACHS HREC member, the WACHS HREC processes and procedure.
  - An opportunity to attend a WACHS HREC meeting as an observer before their appointment takes effect.
  - 'Partnering' with another WACHS HREC member in the same category.
  - Priority given to participate in training sessions.

### 3. Preparation of Agenda

#### Reference Number: P3

**Purpose:** To describe the process and format of agenda for a WACHS HREC meeting

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1. The EQIC is to prepare an agenda for each WACHS HREC meeting.
2. All completed applications and relevant documents received through RGS by the EQIC and CRM will be included on the agenda for WACHS HREC consideration at its next available meeting.
3. The meeting agenda and associated documents is to be prepared by the EQIC and made available to all WACHS HREC members at least ten days prior to the next meeting.
4. Documentation received after the closing date will be included on the agenda and/or tabled at the meeting at the discretion of the Chair. Under no circumstances are new or incomplete applications for research to be tabled at the meeting if they are received after the closing date.
5. Agenda items are to include at least the following items:
  - i. apologies
  - ii. confirmation of quorum
  - iii. minutes of the previous meeting
  - iv. conflicts of interest
  - v. business arising from the previous minutes
  - vi. new applications
  - vii. amendments to approved protocols
  - viii. safety reports
  - ix. out of session activity
  - x. final reports
  - xi. complaints
  - xii. administration
  - xiii. other business
  - xiv. close and next meeting.
6. The agenda and all documentation is to remain confidential.

## 4. Conduct of Meetings

### Reference Number: P4

**Purpose:** To describe the format of meetings of the WACHS HREC.

1. The WACHS HREC is to meet on a regular basis, which will normally be at monthly intervals. Meeting dates and submission closing dates are to be publicly available.
2. Subject to paragraph P4.10 and the membership requirements set out in paragraph 5.1.30 of the National Statement, WACHS may implement a roster plan for members within the same category of membership to attend meetings.
3. Meetings are to be conducted at WACHS Central Office in Perth.
4. Members may attend WACHS HREC meetings in person or via teleconference or videoconference.
5. The Chair is to cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the WACHS HREC is to convene within five working days of the cancelled meeting to ensure all agenda items are considered.
6. Meetings are to be scheduled for an allocated time. If the business has not been completed within the allocated time, then the WACHS HREC may either continue the meeting until all agenda items have been considered or schedule an additional meeting. If an additional meeting is called for, then the meeting is to be held within five working days.
7. The WACHS HREC meeting is to be conducted in private, to ensure confidentiality and open discussion. Members are to be advised of the meeting room details in the meeting agenda.
8. Notwithstanding paragraph 6, the WACHS HREC may agree to the presence of visitors or observers to a meeting. The minutes are to note observers or visitors and the agenda items they were present for.
9. Where there is less than full attendance of the minimum membership [as set out in paragraph 5.1.30 of the National Statement being namely the chair/deputy chair, two lay people (one man and one woman), two researchers, one lawyer, one professional care and one pastoral care] at a meeting, the written views of those absent who belong to the minimum membership should be received prior to the meeting (if possible) through written submissions to the EQIC and considered.. These should normally be received at least three working days prior to the meeting so that copies may be made available in advance to members. The minutes are to record the submission of written comments.
10. A quorum must be present in order for the WACHS HREC to reach a final decision on any agenda item. A quorum will exist when at least six members are present, including one of each of the following categories: chair/deputy chair, lay person, researcher, lawyer, professional care and either pastoral care or Aboriginal<sup>1</sup> representative.

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<sup>1</sup> Within Western Australia, the term Aboriginal is used in preference to Aboriginal and Torres Strait Islander, in recognition that Aboriginal people are the original inhabitants of Western Australia. No disrespect is intended to our Torres Strait Islander colleagues and community.

11. If the meeting does not achieve a quorum, the Chair shall decide the meeting can proceed only in exceptional circumstances. In such circumstances, decisions made by the WACHS HREC must be ratified by at least one representative from those membership categories listed in paragraph 9 that were not present.
12. Any member of the WACHS HREC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the WACHS HREC should declare such interest. This will be dealt with in accordance with P 5.



## 5. Declaration of Interest

### Reference Number: P5

**Purpose:** To describe the procedure for managing declarations of interest by WACHS HREC members.

1. A WACHS HREC member is, as soon as practicable during the WACHS HREC meeting, to inform the Chair if he/she has an interest in a project or other related matter(s) considered by the WACHS HREC.
2. The WACHS HREC is to determine if this results in a conflict of interest for the member and if so, the member is to withdraw from the meeting until the WACHS HREC's consideration of the relevant matter has been completed. The member is not permitted to adjudicate on the research.
3. If the Chair identifies they have a conflict of interest, this is to be declared as soon as practicable, and they are to withdraw from the meeting until the WACHS HREC's consideration of the relevant matter has been completed. The Chair is not permitted to adjudicate on the research. The Deputy Chair is to assume the role as Chair during this time, or in the event the Deputy Chair is unavailable, the Chair is to nominate an Acting Chair.
4. All declarations of interest, conflicts of interest and the absence of a member during the review of the research where there is a conflict of interest will be minuted.
5. Any breach of the above process and consequently, the [WA Health Managing Conflicts of Interest Policy and Guidelines \(2010\)](#) (Section 3. Breaches of the Conflict of Interest Policy) is to be handled in accordance with the [WA Health Discipline Policy with Explanatory Notes and Template Letters \(2016\)](#) whereby a member may have their appointment to the WACHS HREC terminated.

## 6. Preparation of Minutes

### Reference Number: P6

**Purpose:** To describe the process and format for minutes of a meeting of the WACHS HREC

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1. The EQIC is to prepare and maintain minutes of all meetings of the WACHS HREC.
2. The format of the minutes are to include at least the following items:
  - i. attendance
  - ii. apologies
  - iii. confirmation of quorum
  - iv. minutes of the previous meeting
  - v. conflicts of interest
  - vi. business arising from the previous minutes
  - vii. new applications
  - viii. amendments to approved protocols
  - ix. safety reports
  - x. out of session activity
  - xi. final reports
  - xii. complaints
  - xiii. administration
  - xiv. other business
  - xv. close and next meeting.
3. The minutes are to include the recording of decisions taken by the WACHS HREC in addition to a summary of relevant discussion. This includes reference to views expressed by absent members.
4. In relation to the review of new applications or amendments, the minutes are to record a summary of the main ethical issues considered, including any requests for additional information, clarification or modification of the project. Where possible, reference to the National Statement is to be made.
5. In recording a decision made by the WACHS HREC, any significant minority view (i.e. two or more members) is to be noted in the minutes.
6. To encourage free and open discussion and to emphasis the collegiate character of the WACHS HREC, particular views are not to be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.

7. Declarations of conflicts of interest by any member of the WACHS HREC and the absence of the member concerned during the WACHS HREC consideration of the relevant application are to be minuted (refer to P 5 regarding a member's declaration of a conflict of interest).
8. The minutes are to be produced as soon as practicable following the relevant meeting and should be verified by either the Chair and/or the Deputy Chair, for accuracy.
9. The minutes are to be circulated to all members of the WACHS HREC as an agenda item for the next meeting. All members will be given the opportunity to seek amendments to the minutes prior to their ratification. The minutes are to be formally ratified at the next WACHS HREC meeting.
10. The original copy of each meeting's minutes are to be retained in a confidential file with the WACHS TRIM recordkeeping system.
11. The ratified minutes of each WACHS HREC meeting are to be available to the CE.

## 7. Record Keeping

### Reference Number: P7

**Purpose:** To describe the procedure for the preparation and maintenance of records of the WACHS HREC's activities.

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1. The EQIC will utilise the Research Governance Service Information Technology system (RGS) to prepare and maintain written or electronic records of the WACHS HREC's activities, including agendas and minutes of all meetings of the WACHS HREC.
2. The RGS will also be used by the EQIC and members to review and maintain electronic records on projects through the life-cycle of each project. The EQIC is to prepare and maintain a confidential electronic record for each application received and reviewed and is to record the following information in a project registry:
  - Unique project identification number.
  - The Principal Investigator/s (PI(s)).
  - The name of the responsible institution or organisation.
  - Title of the project.
  - Ethical approval or non-approval with date.
  - Approval or non-approval of any changes to the project.
  - The terms and conditions, if any, of approval of the project.
  - Whether approval was by expedited review.
  - Action taken by the WACHS HREC to monitor the conduct of the research.
3. All relevant records of the WACHS HREC, including applications, membership, minutes and correspondence is to be kept as confidential files and in accordance with the [State Records Act \(2000\)](#) and any other applicable legislation.
4. To ensure confidentiality, all documents provided to WACHS HREC members, which are no longer required, are to be disposed of in a secure manner, such as shredding or placed in confidential bins. Members who do not have access to secure disposal are to leave their documents with the EQIC for disposal or if not located in Perth, are to return the documents to the closest WACHS site for secure disposal.
5. All relevant records pertaining to research projects are to be held for sufficient time to allow for future reference. Retention periods are to comply with the General Disposal Authority for Administrative Records issued by the State Records Office and the WACHS TRIM and recordkeeping system.

## 8. Submission Procedure for New Applications

### Reference Number: P8

**Purpose:** To describe the procedure for the submission of new applications.

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1. All applications for ethical review must be submitted via RGS to the EQIC/CRM of the WACHS HREC, by close of business on the relevant closing date. The closing date for receipt of new applications onto the next WACHS HREC agenda shall be readily available to prospective applicants on RGS.
2. The closing dates for applications should normally be no later than 22 days prior to each WACHS HREC meeting.
3. Applications must be submitted in the appropriate format as set out in RGS, and are to include all documentation as required by the WACHS HREC. The procedures for application to the WACHS HREC and the application format is readily available to applicants in RGS.
4. Guidelines are to be issued by WACHS to assist applicants in the preparation of their applications, including guidance on how to determine whether application to the WACHS HREC is necessary.
5. A fee is not to be charged for applications submitted for assessment by the WACHS HREC. However, an amount of \$3,500 is to be included in the budget for each application in RGS for the ethical approval process as a project specific in-kind support from WACHS Central Office.
6. Applications involving only WACHS sites or participants and no other WA Health sites (single centre projects) must submit their proposal for ethical review to the WACHS HREC. Applications involving WACHS sites or participants and other WA Health sites (multi-centre projects) only require ethical review by one WA Health Lead HREC under the [WA Health Single Ethical Review Standard Operating Procedures \(2013\)](#).
7. Notwithstanding paragraph 6, applications for review of research proposals that involve a clinical trial must be referred for ethical review and approval by a WA Health Lead HREC with clinical trials as a nominated category of expertise according to the [WA Health Single Ethical Review Standard Operating Procedures \(2013\)](#).

## 9. Processing of Applications for Review

### Reference Number: P9

**Purpose:** To describe the procedure for the processing of new applications

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1. Applications for ethical review must be submitted via the RGS on the relevant closing date and will be checked for their completeness by the EQIC/CRM prior to their acceptance onto the agenda. Incomplete applications are to be returned to the applicant.
2. Upon submitting an application via RGS, the RGS assigns a unique project identification number to the project (Refer to P7 for appropriate record keeping procedure). The project is to be added to the WACHS HREC's register of received and reviewed applications.
3. The EQIC/CRM is to acknowledge acceptance of the application for ethical review by issuing an acknowledgement notice to the project Coordinating Principal Investigator (CPI) or CPI Delegate within seven days of receipt of the application. The acknowledgement notice will be sent via RGS which will include the date of the meeting at which the application will be reviewed.
4. The application is to be included on the agenda for the next available WACHS HREC meeting, provided it is received by the relevant closing date and is complete.

## 10. Consideration of Applications for Ethical Review

### Reference Number: P10

**Purpose:** To describe the process of the WACHS HREC's consideration of applications for ethical assessment.

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1. The WACHS HREC is to consider a new application at its next available meeting provided that the application is received by the relevant closing date and is complete.
2. Each monthly agenda will accommodate a maximum of eight new applications or as determined at the Chair's discretion.
3. The application is to be reviewed by all members of the WACHS HREC present at the meeting or providing written comments in lieu of attendance.
4. The WACHS HREC is to ethically assess each application in accordance with:
  - the NHMRC National Statement
  - Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders
  - the Department of Health Research Governance Policies and Procedures
  - guidelines approved under the Commonwealth *Privacy Act 1988* and any other privacy legislation where applicable
  - any other applicable principles or guidelines required by the NHMRC or by legislation.
5. The WACHS HREC must ensure that it is sufficiently informed on all aspects of a research protocol, including its scientific validity, in order to make an ethical assessment.
6. The WACHS HREC is to consider whether an advocate for any participant or group of participants is to be invited to the WACHS HREC meeting to ensure informed decision making.
7. Where research involves the targeted recruitment of persons unfamiliar with the English language, the WACHS HREC is to ensure that the participant information sheet is translated into the participant's language.
8. The WACHS HREC, after consideration of an application at a meeting is to make one of the following decisions:
  - The project is approved as being ethically acceptable, with or without conditions.
  - The project is pending approval, subject to minor modifications or further information, which can be reviewed out of session.
  - The project is not approved in its current format and will require extensive modifications and re-submission to the HREC.
  - The project is not approved.

9. The WACHS HREC is to endeavour to reach a decision concerning the ethical acceptability of a project by unanimous agreement. Where a unanimous decision is not reached, the decision will be considered to be carried by a majority of two-thirds of members who examined the project provided that the majority includes at least one layperson. Any significant minority view (i.e. two or more members) is to be noted in the minutes.
10. Where there is less than full attendance of the minimum membership (as set out in SOP 4.9) then the Chair 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.
11. In order to facilitate consideration of an application, the WACHS HREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions.
12. For projects where the WACHS HREC has requested clarification, the provision of further information, or modification of the project, the WACHS HREC may choose to delegate the authority to review that information and approve the project between meetings to one of the following:
  - Chair alone; or
  - Chair, in oral or written consultation with one or more named members that were present at the meeting or who submitted written comments on the application (subcommittee).
13. In such circumstances, the WACHS HREC is to be informed at the next available meeting, of the final decision taken on its behalf, including the applicant's response and the reason for the decision taken.
14. Exceptionally, the WACHS HREC may decide that the information should be considered at a further meeting of the WACHS HREC. In this event, the members must retain their original application documents for the project in order to review against the further information that is provided by the researcher at the time of re-consideration.



## 11. Exemptions

### Reference Number: P11

**Purpose:** To describe projects that are exempt from review by the WACHS HREC.

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1. Projects are to be exempt from full ethical review by the WACHS HREC where they:
  - have undergone ethical review and been granted approval by another WA Health Lead HREC;
  - have undergone ethical review and been granted approval under the National Mutual Acceptance Scheme; or
  - involve only negligible risk (see National Statement 2.1.7) and involves the use of existing collections of data or records that contain only non-identifiable data about human beings (see National Statement 5.1.22).
2. Quality improvement projects (also known as quality assurance, audits or evaluation projects) are governed by the QI Ethical Assessment Panel Terms of Reference and Standard Operating Procedures.

## 12. Expedited Review

### Reference Number: P12

**Purpose:** To describe the procedure for the expedited review of research by the WACHS HREC.

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1. The WACHS HREC may establish a subcommittee, consisting of at least the Chair and the EQIC/CRM.
2. The subcommittee should undertake expedited review of:
  - minor amendments and extensions of approved protocols
  - reports such as safety / notification reports or annual progress reports
  - urgent amendments to approved protocols for safety reasons
  - other items as determined by the Chair.
3. The subcommittee may seek advice from other WACHS HREC members or suitably qualified experts, as appropriate, before reaching a decision. The subcommittee must table a report of the review outcome for noting at the next WACHS HREC meeting.
4. Expedited review of projects may be undertaken by the WACHS HREC by electronic means between scheduled meetings at the discretion of the Chair.
5. Where the Chair considers that research may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the relevant item as per paragraph 2, must be considered by the full WACHS HREC and cannot be dealt with by expedited review.

## 13. Notification of Decisions

### Reference Number: P13

**Purpose:** To describe the procedure for the notification of decisions of the WACHS HREC concerning the review of new applications.

1. The WACHS HREC is to report in writing via RGS to the CPI(s), advising whether the application has received ethical approval (including any conditions of approval), within seven working days of the meeting, unless otherwise notified.
2. If the WACHS HREC determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the CPI(s) is to clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information, clarification or modification are to refer to the National Statement or other relevant pieces of legislation.
3. If the requested information is not received from the applicant within three months or three meetings (whichever occurs sooner), the project may be dismissed with the applicant required to resubmit the project at a later date.
4. The WACHS HREC is to endeavour to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues. The WACHS HREC may nominate one of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant WACHS HREC meeting.
5. The WACHS HREC is to notify the applicant of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Notification of ethical approval is to be in writing in a standard format, and are to contain the following information:
  - Title of project
  - Name of the PI and other research personnel
  - Unique WACHS HREC project identification number
  - Date of WACHS HREC meeting at which the project was first considered
  - Date and duration of WACHS HREC approval
  - WA Health site(s) where the research will be conducted
  - A list of all approved application documentation with version numbers
  - Conditions of WACHS HREC approval, if any.
6. The WACHS HREC approval is normally granted for three years. The WACHS HREC has the capacity to set a shorter or longer approval period dependent upon the risk and complexity of the project.
7. If the WACHS HREC determines that a project is ethically unacceptable, the notification of the WACHS HREC's decision will include the grounds for rejecting the project with reference to the National Statement or other relevant pieces of legislation.
8. The status of the project shall be updated on the WACHS HREC register of received and reviewed applications.
9. A lay summary of the approved project will be made publically available on the WACHS HREC website.

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## 14. Amendments Requests

### Reference Number: P14

**Purpose:** To describe the procedure for the submission and WACHS HREC review of requests for amendments requests to approved protocols.

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1. Proposed changes to approved projects, project documentation, the research team, or WA Health sites involved in the study, or requests for extensions to the length of WACHS HREC approval are required to be reported by the CPI(s) to the WACHS HREC for review via RGS.
2. Requests are to outline the nature of the proposed changes and/or request for extension, reasons for the request, and an assessment of any ethical implications arising from the request on the conduct of the research using the Amendment Form within RGS. All amended documents must have the changes highlighted and contain revised version numbers and dates.
3. Expedited review of requests for minor amendments and extensions, and urgent amendments to approved protocols for safety reasons may be undertaken by the WACHS HREC subcommittee between scheduled meetings at the discretion of the Chair and in accordance with P12.
4. All other requests for amendments are to be reviewed by the WACHS HREC at its next available meeting, provided the request has been received by the EQIC/CRM by the agenda closing date.
5. The WACHS HREC is to report in writing via the RGS to the CPI(s), advising whether the proposed amendment and/or request for extension has been given ethical approval, within five working days of the meeting at which the request was considered (this may be the full WACHS HREC meeting or the sub-committee meeting).
6. If the WACHS HREC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the CPI(s) is to articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification is to refer to the National Statement or relevant pieces of legislation.

## 15. Monitoring of Approved Projects

### Reference Number: P15

**Purpose:** To describe the procedure for monitoring projects approved by the WACHS HREC to ensure compliance with ethical approval

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1. The WACHS HREC will monitor approved projects to ensure compliance with the approved protocol. In doing so it may request and discuss information on any relevant aspects of the project with the PI at any time. In particular, the WACHS HREC will require applicants to provide a report at least annually, and at completion of the study. Continuing approval of the research will be subject to the PI submitting an annual report within three months of the due date.
2. Annual Progress Reports or Final Reports must be submitted via RGS using the appropriate form within the system.
3. The submitted report is to include the following information:
  - Progress to date, publications or outcome in the case of completed research
  - Maintenance and security of records and data
  - Compliance with the approved protocol
  - Compliance with any conditions of approval
  - Changes to the protocol or conduct of the research
  - Changes to the personnel or contact details of the PI(s)
  - Adverse events or complaints relating to the project.
4. The WACHS HREC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary.
5. The WACHS HREC is to require, as a condition of approval of each project, that the PI immediately report anything which might warrant review of ethical approval of the protocol, including:
  - proposed changes in the protocol
  - any unforeseen events that might affect continued ethical acceptability of the project
  - new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the study.
6. The WACHS HREC is to require, as a condition of approval of each project that the CPI(s) inform the WACHS HREC, giving reasons, if the research project is discontinued before the expected date of completion, and that the investigators comply with the approved data retention and disposal plan.

7. Where the WACHS HREC is satisfied that circumstances have arisen where a research project is not being or cannot be conducted in accordance with the approved project, the WACHS HREC may withdraw approval. In such circumstances, the WACHS HREC is to inform the CPI(s) and all relevant sites of such withdrawal of approval in writing, and recommend the research project be discontinued, suspended, or that other necessary steps be taken.
8. In determining the frequency and type of monitoring required for approved projects, the WACHS HREC is to give consideration to the degree of risk to participants in the research project.

## 16. Researcher Safety Reporting

### Reference Number: P16

**Purpose:** To describe the process for reporting and handling of issues or adverse events that may affect the continued ethical responsibility of the project

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#### Reporting

1. The WACHS HREC is to require, as a condition of approval of each project, that researchers immediately report protocol deviations, violations or serious adverse events of the approved protocol to the WACHS HREC.
2. The EQIC/CRM is the person nominated to receive safety reports of an approved protocol. The report is to include information on the following matters:
  - a description of the event(s), deviation and/or violation
  - participants affected
  - actions recommended and/or implemented
  - the outcome
  - notification to other relevant parties
  - declaration by the CPI / PI.
3. Safety report must be submitted via RGS using the appropriate form within the system.
4. The EQIC/CRM is to notify the Chair of the WACHS HREC of the report as soon as possible.
5. The report is to be reviewed by the subcommittee via expedited review or by the WACHS HREC at the next available meeting where it is to be decided if the appropriate course of action has been completed.
6. The CPIs is to report all adverse events and/or protocol deviations/violations and the response to those events in the annual and final reports for the project.

## 17. HREC Reporting Requirements

### Reference Number: P17

**Purpose:** To describe the reporting requirements of the WACHS HREC.

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1. The WACHS HREC shall provide an annual report on its activity for the calendar year to the CE via the EDMS, including:
  - membership changes
  - number of meetings
  - number of meetings that achieved a quorum
  - member meeting attendance
  - number of projects reviewed, approved and requiring further information;
  - predominant themes, administering institutions / organisations and targeted WACHS locations of the research projects
  - monitoring procedures for ethical aspects of research in progress including amendment requests, safety reporting, annual progress reports and final reports
  - number of declarations of interest and the number of conflicts of interest declared by members
  - description of any complaints, breaches or concerns received and their outcome
  - general issues raised.
2. The WACHS HREC is to provide a quarterly report to the CE via the EDMS, on its key activity as determined by the EDMS or CE.
3. The WACHS HREC is to make available to the public, a condensed version of the annual report to the CE as well as quarterly reports of approved project's summaries via the WACHS HREC website.
4. The WACHS HREC is to provide compliance reports to the NHMRC and is to act in accordance with all statutory reporting requirements.
5. The WACHS HREC ToR, procedures and membership is to be available upon request to the general public, and is to be posted on the WACHS HREC website.



## 18. Breaches in the Conduct of a Project

### Reference Number: P18

**Purpose:** To describe the mechanism for receiving, handling and responding to reports of breaches of protocol in the conduct of projects approved by the WACHS HREC.

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#### Reporting

1. The WACHS HREC is to require, as a condition of approval of each project, that researchers immediately report breaches of the approved protocol to the WACHS HREC.
2. The CRM is the person nominated to receive reports of a breach of an approved protocol. The report is to include information on the following matters:
  - The nature of the breach
  - The steps taken to prevent any further injury, damage, or disclosure of confidential information
  - The sensitivity of any information concerned
  - Whether any breach was inadvertent, negligent or intentional
  - Proposed changes to the protocol as a result of the breach.
3. The CRM is to send an acknowledgment of the breach report within ten calendar days of receipt of the report.
4. The CRM is to notify the Chair of the WACHS HREC and any other institutional HRECs that have approved the project of the report as soon as possible.

#### Investigation

5. The Chair of the WACHS HREC is to examine the report within 30 calendar days of receipt of the initial breach report and determine whether the breach warrants further investigation. Where there is to be no further investigation, the Chair of the WACHS HREC is to inform the CPI(s).
6. Where the Chair determines that the breach warrants further investigation, the Chair is to notify the CE or delegate of the breach. The CE or delegate is to convene an Incident Review Committee to investigate the breach and determine the consequences.
7. The CE or delegate is to chair the Incident Review Committee. The membership of the committee is to include the Chair of the WACHS HREC, or delegate, the CRM, the EQIC, and other members with appropriate expertise as required.

8. The Incident Review Committee is to immediately instigate an investigation into the breach. The Incident Review Committee may co-operate with any other institution or HREC concerned with the project to investigate the incident and may conduct a joint investigation. The investigation is to take no longer than 60 calendar days from the time of notification of the incident from the Chair, unless exceptional circumstances exist.
9. The Incident Review Committee may require the suspension of the project during the course of the investigation. Where the Incident Review Committee requires such suspension of the project the Incident Review Committee is to notify the responsible institution and the PI that the project must be suspended.
10. Where the reported incident concerns the conduct of any person other than the CPI(s), the Incident Review Committee is to notify that person of the report and is to provide that person with an opportunity to make submissions.
11. The Incident Review Committee may seek any other information it requires and may access any documents relating to the project, interview other people, and seek internal and external expert advice, as it sees fit.

### **Consequences**

12. If the Incident Review Committee is satisfied that a breach has occurred it is to determine the consequences by considering the following matters:
  - The severity of the breach
  - The sensitivity of any information concerned
  - Whether any breach was inadvertent, negligent or intentional.
13. The possible consequences may include the following:
  - Notation on the file of the occurrence of the breach
  - Increased monitoring of the project
  - Amendments to the approved protocol
  - Suspension or cancellation of WACHS ethical approval of the project (with the immediate return or destruction of all data files)
  - Exclusion of particular individuals responsible for the breach from future access to WACHS sites and/or data
  - Reporting the individuals responsible for the breach to their employer, with a complaint of misconduct
  - Reporting the individual responsible for the breach to the funding agency that has supported the project, with a complaint of misconduct
  - Reporting the individual responsible for the breach to any external agency with jurisdiction (such as professional registration board or the Privacy and Information Commissioner), with a complaint of misconduct; and/or
  - Reporting allegations of criminal conduct to the police.
14. The Chair of the Incident Review Committee will notify the responsible institution, the CPI(s) and any other person for whom there are individual consequences of the outcome of the investigation and the consequences in writing.

15. The Chair of the Incident Review Committee is to notify the WACHS HREC and any other institutional HRECs concerned with the project of the outcome of the investigation and the consequences.
16. The Chair of the Incident Review Committee is to report to the CE on the outcome of the investigation and the consequences.
17. The WACHS HREC may review the ethical approval of any project in the light of the outcome of the investigation of the breach and will notify the responsible institution and the CPI(s) if ethical approval for the project is withdrawn.
18. If the CPI(s) or any other person for whom there is an individual consequence is not satisfied with the outcome of the investigation he/she may refer the matter to the CE.
19. The CE is to review the report of the Incident Review Committee and decide whether and what further action is required, and inform the CPI(s) or any other person affected as well as the Chair of the Incident Review Committee and the Chair of WACHS HREC of that decision. This review is to be conducted within 60 days of notification (paragraph 18).
20. If the CPI(s) or any other person affected is not satisfied with the decision of the CE, then depending on the nature of the breach and the decision, the matter can be referred for external review to the Ombudsman Western Australia. The Ombudsman may conduct a procedural review of the decision.
21. All relevant records pertaining to the breach and investigation are to be kept as confidential files and in accordance with the *State Records Act 2000* and any other applicable legislation.

## 19. Complaints about the Conduct of a Project

### Reference Number: P19

**Purpose:** To describe the mechanism for receiving, handling and responding to complaints about the conduct of a project approved by the WACHS HREC.

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#### Reporting

1. The WACHS HREC is to require, as a condition of approval of each project that the researchers immediately report to the CRM any complaints received. The Complaint must be submitted via RGS.
2. The CRM is the person nominated to receive complaints from participants in research or members of the public about the conduct of projects approved by the WACHS HREC. If the complaint is made to another person within WACHS, that person must refer the complaint to the CRM via RGS.
3. The CRM is responsible for obtaining, in writing, the grounds of the complaint. The CRM is to notify the Chair of the WACHS HREC of the report as soon as possible.
4. The CRM is to send an acknowledgment via RGS to the complainant within ten calendar days of receipt of the initial complaint with a description of the complaint, the desired outcome that the complainant seeks as a satisfactory resolution to the complaint as well as the complaints management process, expected timeframes for resolution of the complaint and the contact details of the CRM.
5. The CRM is to report the concern or complaint to any other institutional HRECs that have approved the project.

#### Investigation

6. The Chair of the WACHS HREC is to examine the complaint within 30 calendar days of receipt of the initial complaint and determine whether the complaint warrants a further investigation. Where there is to be no further investigation the Chair of the WACHS HREC is to inform the complainant.
7. Where the Chair determines that the complaint warrants a further investigation the Chair is to notify the CE delegate, the EDMS, of the complaint. The EDMS is to convene an Incident Review Committee to investigate and determine the consequences.
8. The EDMS is to chair the Incident Review Committee. The membership of the committee is also to include the Chair of the WACHS HREC or delegate, the CRM, the EQIC and other members with appropriate expertise as required.
9. The Incident Review Committee may co-operate with any other institution or HREC concerned with the project to investigate the complaint and may conduct a joint investigation.

10. The CRM is to send a letter of notification via RGS to the CPI(s) of any complaint about a project received by the WACHS HREC outlining the mechanism for investigating the complaint. Where the complaint concerns the conduct of the any other person the Incident Review Committee is to also notify that person.
11. The Incident Review Committee is to instigate an investigation into the complaint within ten working days of receipt of the WACHS HREC Chair's notification as per paragraph 6. The investigation is to take no longer than 60 calendar days from the time of notification of the complaint from the Chair, unless exceptional circumstances exist.
12. Notwithstanding paragraph 11, if there is a delay in conducting the investigation and/or resolving the complaint the complainant must be advised and updates on the progress of the investigation provided every 30 calendar days.
13. The Incident Review Committee may require the suspension of the project during the course of the investigation. Where the Incident Review Committee requires such suspension of the project the Incident Review Committee is to notify the responsible institution and the PI that the project must be suspended.
14. The Incident Review Committee is to give the complainant and the CPI(s) an opportunity to make submissions. Where the complaint concerns the conduct of any other person the Incident Review Committee is also to provide that person with an opportunity to make submissions.
15. The Incident Review Committee may seek any other information it requires and may access any documents relating to the project, interview other people, and seek internal and external expert advice, as it sees fit.

### **Consequences**

16. If the Incident Review Committee is satisfied that the complaint is justified it is to determine the consequences by considering the following matters:
  - The severity of the matter
  - The sensitivity of any information concerned including the amount and type of information and the level of identifiability
  - Whether any breach of the approved protocol, which may be established, was inadvertent, negligent or intentional.
17. The possible consequences include the following:
  - Notation on the file of the occurrence of the matter
  - Increased monitoring of the project
  - Amendments to the approved protocol
  - Suspension or cancellation of WACHS ethical approval of the project (with the immediate return or destruction of all data file)
  - Exclusion of particular individuals responsible for the breach from future access to WACHS sites and/or data

- Reporting the individuals responsible for any breach to their employer, with a complaint of misconduct in the conduct of the project
  - Reporting the individual responsible for any breach to the funding agency that has supported the project, with a complaint of misconduct
  - Reporting the individual responsible for any breach to any external agency with jurisdiction (such as professional registration board or the Privacy and Information Commissioner), with a complaint of misconduct; and/or
  - Reporting allegations of criminal conduct to the police.
18. The Chair of the Incident Review Committee is to notify the responsible institution, the PI and any other person for whom there is an individual consequence of the outcome of the investigation and the consequences in writing.
19. The Chair of the Incident Review Committee is to notify the WACHS HREC and any other institutional HRECs concerned with the project of the outcome of the investigation and the consequences.
20. The WACHS HREC may review the ethical approval of any project in the light of the outcome of the investigation of any complaint and is to notify the responsible institution and the CPI(s) if ethical approval for the project is withdrawn.
21. The Chair of the Incident Review Committee is to send a written report of the outcome of the investigation and the consequences to the complainant.
22. If the complainant is not satisfied with the outcome, he or she may refer the complaint to the CE.
23. The CE is to review the report of the Incident Review Committee and decide whether and what further action is required and inform the CPI(s) or any other person affected as well as the Chair of the Incident Review Committee and the Chair of WACHS HREC of that decision. This review is to be conducted within 60 days of notification (paragraph 22).
23. If the complainant is not satisfied with the decision of the CE, then depending on the nature of the concern or complaint, the matter may be referred for external review to the Ombudsman Western Australia, the Office of Health Review or the Federal Privacy Commissioner.
24. All relevant records pertaining to the complaint and investigation are to be kept as confidential files and in accordance with the *State Records Act 2000* and any other applicable legislation.

## 20. Complaints about the Review or Rejection of an Application

### Reference Number: P20

**Purpose:** To describe the mechanism for receiving, handling and responding to complaints about the review or rejection of an application by the WACHS HREC.

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#### Reporting

1. The CRM is the person nominated to receive any complaints or concerns about the WACHS HREC's review process or the rejection of an application. The Complaint must be submitted via the RGS.
2. The CRM is responsible for obtaining, in writing, the grounds of the concern or complaint and notifying the CE or delegate and the Chair of the WACHS HREC. If the complaint is made to another person within WACHS, that person must refer the complaint to the CRM.
3. The CRM is to send an acknowledgment via RGS to the complainant within ten calendar days of receipt of the initial complaint with a description of the complaint, the desired outcome that the complainant seeks as a satisfactory resolution to the complaint as well as the complaints management process, expected timeframes for resolution of the complaint and the contact details of the CRM.

#### Investigation

##### **Complaint about procedural or administrative aspects of having an application reviewed by the HREC.**

4. The Business Support Consultant is to instigate an investigation within ten working days of receipt of the initial complaint. This investigation is to take no longer than 30 calendar days from the time of notification of the complaint or concern, unless exceptional circumstances exist.
5. If the Business Support Consultant is satisfied that the complaint is justified he/she is to determine the consequences by considering the following matters:
  - The severity of the matter;
  - The sensitivity of any information concerned; or
  - The nature of the complaint.
6. Consequences may include:
  - Requesting the WACHS HREC to reconsider its decision at the next HREC meeting;
  - Reconfirming the WACHS HREC's original decision/s concerning the application; or



- Recommending changes to the administration and procedures for review of applications; or
- Recommending any other consequences as he/she determines appropriate.

### **Complaint about the HREC's review process or rejection of an application**

7. The Chair of the WACHS HREC is to instigate an investigation within ten working days of receipt of the initial complaint. This investigation is to take no longer than 30 calendar days from the time of notification of the complaint or concern, unless exceptional circumstances exist.
8. Upon the completion of the investigation, the Chair may:
  - Request the WACHS HREC to reconsider its decision at the next HREC meeting;
  - Reconfirm the WACHS HREC's original decision/s concerning the application;
  - Recommend any other consequence as he/she determines appropriate.
9. If the complainant is not satisfied with the outcome of the Business Support Consultant or Chair's (the applicable First Investigator)(whoever conducted the first investigation) investigation, he/she can refer the complaint to the CE delegate, the EDMS.
10. The applicable First Investigator is to provide the EDMS with all relevant information about the complaint including:
  - details of the concern or complaint
  - material reviewed in the investigation
  - the results of the investigation
  - the recommended course of action
  - any other relevant documentation.
11. The EDMS is to determine whether there is a further investigation of the concern or complaint. Where there is to be no further investigation the EDMS is to inform the complainant and the applicable First Investigator.
12. If there is to be a further investigation, the EDMS is to establish an Incident Review Committee to consider the complaint. The committee is to include, at least, the following members:
  - The EDMS as the convenor of the panel
  - Two nominees of the CE or delegate (who are not members of WACHS HREC)
  - A person experienced in the ethical review of research projects (who is not a member of the WACHS HREC).

Where the complaint concerns the rejection of an application, an expert in the discipline of research of the project under consideration.
13. The panel is to give the complainant and the applicable First Investigator the opportunity to make submissions. The panel may seek any other information it requires and may access any documents relating to the project, interview other people, and seek internal and external expert advice, as it sees fit.



14. The panel is to ascertain whether:
  - the WACHS HREC acted in accordance with its ToR, Procedures, and the National Statement and otherwise acted in a fair and unbiased manner; or
  - whether the Business Support Consultant or acted in a fair and unbiased manner and the determinations reached were reasonable.
15. The panel is to instigate an investigation into the concern or complaint within ten working days of receipt notification the complainant was dissatisfied with the outcome of the applicable First Investigator's review. The investigation is to take no longer than 60 calendar days from the time of notification from the applicable First Investigator, unless exceptional circumstances exist.
16. Notwithstanding paragraph 15, if there is a delay in conducting the investigation and/or resolving the complaint the complainant must be advised and updates on the progress of the investigation provided every 30 calendar days.
17. The EDMS will notify the complainant and the applicable First Investigator of the outcome of the investigation. The outcomes may include:
  - dismissing the complaint; or
  - referring the complaint back to the applicable First Investigator for reconsideration in light of the findings of the panel.
18. If the WACHS HREC is requested to review its decision, then the outcome of this review by the WACHS HREC will be final. The Incident Review Committee cannot substitute its approval for the approval of the WACHS HREC.
19. The panel may also make recommendations about:
  - the operation of the WACHS HREC including review of the TOR and/or Procedures, and of the committee membership; or
  - the administration and procedures for review of research applications.
20. If the complainant is not satisfied with the outcome of the panel's investigation, he/she can refer the complaint to the Ombudsman Western Australia. The Ombudsman may conduct a procedural review of the decision of the WACHS HREC and the review panel.
21. All relevant records pertaining to the complaint and investigation is to be kept as confidential files and in accordance with the *State Records Act 2000* and any other applicable legislation.

## 21. Review of HREC Procedures and Terms of Reference

### Reference Number: P21

**Purpose:** To describe the procedure for the approval of amendments to the WACHS HREC Procedures and Terms of Reference.

1. The Procedures and TOR are to be reviewed at least every two years and amended as necessary.
2. The Procedures and TOR may be amended by following the procedure below:
  - a. For those proposals made by a WACHS HREC member, the:
    - proposal must be in writing and circulated to all WACHS HREC members for their consideration
    - views of the members should be discussed at the next scheduled meeting of the WACHS HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register his or her views in writing
    - proposal is to be ratified if two thirds of the members agree to the amendment
    - Chair is to send the amendment to the CE or delegate for review and approval if appropriate.
  - b. For those proposals made by the CE or delegate:
    - the CE or delegate is to send the proposal to the WACHS HREC and seek the views of any relevant person.
3. The CE or delegate is to consider the views of the members of the WACHS HREC and other relevant persons and will determine whether the amendment is to be made.

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