Government of **Western Australia**
Department of **Health**

Department of Health Western Australia Human Research Ethics Committee

Standard Operating Procedures

July 2018

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Contents

Abbreviations	
CALD	Culturally and Linguistically Diverse
Department	The WA Department of Health
DG	Director General
DOH HREC	Department of Health Human Research Ethics Committee
DLB	Data Linkage Branch
EEO	Ethics Executive Officer of the DOH HREC
IRC	Incident Review Committee
IT	Information Technology
NHMRC	National Health Medical Research Council
RGO	Research Governance Officer
RGS	Research Governance Service
RGU	Research Governance Unit
SOP	Standard Operating Procedures
TOR	Terms of Reference

1. Appointment of Members

The procedure for the appointment of members to DOH HREC.

1. Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organisation, group or opinion.

2. Prospective members of the Department of Health Human Research Ethics Committee (DOH HREC) may be recruited by the OnBoardWA website, direct approach, nomination, or by advertisement for Expressions of Interest. Prospective members may be asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their names, professions and biographies being made available to the public, including being published on the DOH HREC website.

3. Members must have basic computer skills as well as access to the internet, a private email address and printing resources for the purpose of reviewing applications, project amendments and responding to out of session queries.

4. The Director General (DG) of Health or delegate may appoint a selection committee, which includes at least one representative of the DOH HREC who is not an institutional member to interview prospective applicants and make a recommendation to the DG. Prospective members may be invited to attend a meeting of the DOH HREC as an observer and will be subject to a duty of confidentiality in relation to the proceedings of that meeting.

5. The Chair, Deputy Chair and members are appointed by the DG in consultation with other senior officials within the Department, as deemed appropriate. New members will receive a formal notice of appointment after their appointments have been submitted to Cabinet for noting.

6. In the absence of the Chair, the Deputy Chair will perform the role and duties of the Chair.

7. Members will be provided with a letter of appointment, which will include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a DOH HREC member, the circumstances whereby membership may be terminated and the conditions of their appointment.

8. Members will be required to sign a confidentiality form upon appointment, stating that all matters of which they become aware during the course of their work on the DOH HREC will be kept confidential; that any conflicts of interest, which exist, are perceived, or may arise during their tenure on the DOH HREC will be declared; and that they have not been subject to any criminal conviction or disciplinary action, which may prejudice their standing as a member.

9. Upon appointment, members will be provided with the following documentation:
   - Terms of Reference (TOR)
   - Standard Operating Procedures (SOP)
   - up to date list of members' names and contact information including that of the Ethics Executive Officer (EEO)
   - National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (National Statement)
   - NHMRC Values and Ethics: Guidelines for Ethical conduct in Aboriginal and Torres Strait Islander Research
   - Guidelines approved under s95 and s95A of the *Privacy Act (Cwth) 1988*
   - the WA Department of Health Practice Code for the Use of Personal Health Information
   - the latest reports on the DOH HREC's activities
   - Research Governance Service (RGS) Training Manual
   - any other relevant information about the DOH HREC's processes, procedures and protocols.

10. The positions within the DOH HREC are fixed term, three year appointments. Recruitment is staggered to ensure continuity of expertise and knowledge.

11. Members are recruited and appointed to these fixed term positions as they become vacant. Members may serve one term only unless otherwise approved by the DG. The DG may approve further terms, as required.

12. Deputy members are appointed to the DOH HREC to provide category representation when the relevant member is unable to attend meeting(s). Deputy members are appointed to fixed term sitting deputy positions as they become vacant. Deputy members may only serve two consecutive terms unless otherwise approved by the DG.

13. Members will be remunerated in accordance with advice from the WA Department of Premier and Cabinet.

14. Members may seek a leave of absence from the DOH HREC for extended periods. Steps will be taken to fill the vacancy as required.

15. Membership will lapse if a member fails to attend three consecutive meetings without reasonable explanation, unless exceptional circumstances exist. The Chair will notify the member of such lapse of membership in writing. Steps will be taken to fill the vacancy, should the need arise.

16. Membership will lapse if a member fails to attend in full at least two thirds of all scheduled meetings in each year, barring exceptional circumstances and an approved leave of absence.

17. The DG may terminate the appointment of any member if the DG is of the opinion that:
    - it is necessary for the proper and effective functioning of the DOH HREC
    - the person is not a fit and proper person to serve on the DOH HREC
    - the person has failed to carry out their duties as a member of the DOH HREC.

18. Members will be expected to participate in relevant specialised working groups as required. The Chair will be expected to be available between meetings to participate in Executive meetings where required.

19. A member may resign at any time upon giving notice in writing to the Chair. Steps will be taken to fill the vacancy of the former member as soon as possible. Where a member resigns, the appointment of the new member will be for the remaining term of the fixed term position.

20. New DOH HREC members must be provided with adequate orientation.

21. New members are expected to attend training sessions as soon as practicable after their appointment. All members are expected to attend education and training sessions. Reasonable costs associated with attendance at training and education sessions will be met in accordance with the Public Sector Commission's remuneration of Government Boards and Committees.

22. Orientation of new members may involve:
    - introduction to other members prior to the DOH HREC meeting
    - informal meeting with Chair and EEO to explain the responsibilities as a DOH HREC member, including processes and procedure
    - an opportunity to sit in on meetings before their appointment takes effect
    - 'partnering' with another member in the same category
    - priority given to participate in training sessions.

2. Record Keeping

The procedure for the preparation and maintenance of records of the DOH HREC's activities.

1. The EEO will utilise the Research Governance Service (RGS), which is a web-based Information Technology (IT) system to prepare and maintain electronic records of the DOH HREC's activities, including agendas and minutes of all meetings.

2. The RGS will also be used by the EEO and members to review and maintain electronic records on projects throughout the life-cycle of each project.

3. Records pertaining to projects undertaken for quality assurance or evaluation purposes that are reviewed by DOH HREC will be maintained in a separate IT system from the RGS.

4. The EEO will prepare and maintain a confidential electronic and/or paper record for each application received and reviewed and will record the following information:
   - unique project identification number
   - the Principal Investigator(s) (PI(s)) and project investigators
   - the name of the responsible institution or organisation
   - title of the project
   - ethical approval or non-approval with date
   - Department approval for commencement of the project and/or release of personal information, including date of approval
   - 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 to monitor the conduct of the project.

5. The electronic and/or paper file will contain a copy of the application, including signatures, and any relevant correspondence including that between the applicant and the DOH HREC, all approved documents and other material used to inform potential participants.

6. Relevant records of the DOH HREC, including minutes and other meeting correspondence will be kept as confidential files and in accordance with the *State Records Act 2000* and any other applicable legislation.

7. To ensure confidentiality, all paper documents provided to or produced by 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 should leave their documents with the EEO for disposal.

8. Records pertaining to projects will be held for sufficient time to allow for future reference. Retention periods will comply with the General Disposal Authority for Administrative Records issued by the State Records Office and the WA Department of Health (the Department's) Records Retention and Disposal Schedule.

3. Preparation of Agenda

To describe the process and format of agenda for a DOH HREC meeting.

1. The EEO will prepare an agenda for each meeting in the RGS.

2. All completed applications and relevant documents received through the RGS will be included on the agenda for consideration at the next available meeting.

3. The meeting agenda and associated documents will be prepared by the EEO and made available to all members at least seven working 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 and/or EEO. New applications will not be tabled at the meeting unless there are exceptional circumstances or an expedited review has been approved.

5. Agenda items will include at least the following items:
    - apologies
    - confirmation of quorum
    - conflicts of interest
    - minutes of the previous meeting
    - business arising from the previous minutes
    - new applications
    - amendments to approved protocols
    - monitoring reports
    - other business
    - close and next meeting.

6. The agenda and all documentation will be made available on a need-to-know basis.

4. Conduct of Meetings

The format of meetings of the DOH HREC.

1. The DOH HREC will meet on a regular basis, which will normally be at monthly intervals. Meeting dates and agenda closing dates will be publicly available.

2. Members may attend meetings in person or via teleconference or video link.

3. The Chair may cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the DOH HREC will convene within five working days of the cancelled meeting to ensure all agenda items are considered.

4. Meetings will be scheduled for an allocated time. If the business has not been completed within the allocated time, then the DOH 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 should be held within five working days.

5. The DOH HREC meeting will be conducted in private, to ensure confidentiality and open discussion. Members will be advised of the meeting room details in the meeting agenda.

6. Notwithstanding paragraph 5, the DOH 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.

7. Members who are unable to attend a meeting may be asked to contribute prior to the meeting through written submissions to the EEO. 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 should record the submission of written comments.

8. A quorum must be present in order for the DOH HREC to reach a final decision on any agenda item. A quorum will exist when at least five members are present (either in person or via teleconference / videoconference), including one of each of the following categories: Chair/Deputy Chair, lay person, researcher familiar with the types of proposals that are normally reviewed by the DOH HREC, and at least one third of those present are from outside the WA health system.

9. Where there is less than full attendance at the meeting, the Chair must be satisfied, before a decision is reached, that the minimum membership listed in the National Statement have received all the papers and have had an opportunity to contribute their views in writing and that those views have been recorded.

10. If the meeting does not achieve quorum, the Chair may decide it can proceed only in exceptional circumstances. In such circumstances, decisions made by the DOH HREC must be ratified by at least one representative from those membership categories not present, within seven working days.

11. Where the EEO is concerned that a forthcoming meeting will not be attended by a quorum of members, the EEO will notify the Chair and the following options will be considered:
    i. postponing and re-arranging the meeting
    ii. cancelling the meeting.

12. Any member of the DOH HREC who has any interest, financial or otherwise, in a project or any other related matter(s) considered by the DOH HREC must declare such interest. This will be dealt with in accordance with SOP 5.

5. Managing of Conflicts Interest

The procedure for the managing of conflicts of interest of DOH HREC members.

1. A DOH HREC member must, as soon as practicable during the DOH HREC meeting, inform the Chair if they have an actual or perceived conflict of interest, whether financial or otherwise, in a project or any other matter(s) considered by the DOH HREC.

2. The DOH HREC will determine if this results in a conflict of interest for the member and if so, the member will withdraw from the meeting until the DOH HREC's consideration of the relevant matter has been completed. The member will not be permitted to adjudicate on the project. If the Chair has a conflict of interest, the Deputy Chair is to assume the role as Chair during this time. In the event the Deputy Chair is unavailable, the Chair is to nominate an Acting Chair.

3. All declarations of conflict of interest and the absence of the member concerned will be minuted.

4. Any breach of the above process and consequently, the WA Health Managing Conflicts of Interest Policy and Guidelines (2010) (3. Breaches of the Conflict of Interest Policy) is to be handled in accordance with the WA Health Misconduct Policy (2016) whereby a member may have their appointment to the DOH HREC terminated.

6. Preparation of Minutes

The process and format for minutes of a meeting of the DOH HREC.

1. The EEO will prepare and maintain minutes of all meetings of the DOH HREC meetings within RGS.

2. The format of the minutes will include at least the following items:
   - apologies
   - confirmation of quorum
   - attendance
   - minutes of the previous meeting
   - business arising from the previous minutes
   - conflicts of interest
   - new applications
   - amendments to approved projects
   - monitoring reports
   - other business
   - close and next meeting.

3. The minutes should include the recording of decisions taken by the DOH HREC as well as a summary of relevant discussion. This includes reference to any views expressed by absent members.

4. In relation to the review of new applications or amendments, the minutes will 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 should be made.

5. In recording a decision made by the DOH HREC, any significant minority view (i.e. two or more members) will be noted in the minutes.

6. To encourage free and open discussion and to emphasise the collegiate character of the DOH HREC, particular views should not be attributed to particular individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded.

7. Declarations of, and conflicts of interest by any member of the DOH HREC and the absence of the member concerned during the deliberation of the relevant matter will be minuted (refer to SOP 5 regarding a members' declaration of a conflict of interest).

8. The minutes will be produced as soon as practicable following the relevant meeting and should be reviewed by either the Chair and/or the Deputy Chair, for accuracy.

9. The minutes will be circulated to all members of the DOH 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 will be ratified at the next DOH HREC meeting.

10. The original copy of each meeting's minutes will be retained in the RGS.

7. Reporting Requirements

The reporting requirements of the DOH HREC.

1. The minutes of each meeting will be available to the DG following ratification.

2. The DOH HREC will provide an annual report on its progress for the calendar year to the DG, including:
   - membership/membership changes
   - number of meetings
   - number of projects reviewed, approved and rejected
   - monitoring procedures for ethical aspects of projects in progress and any issues encountered by the DOH HREC in undertaking its monitoring role
   - description of any complaints received and their outcome
   - description of any projects where ethical approval has been suspended or withdrawn and the reason(s) for suspension or withdrawal of approval
   - general issues raised.

3. The DOH HREC will provide reports to the Australian Health Ethics Committee in accordance with the requirements of the NHMRC and will comply with all statutory reporting requirements.

4. The DOH HREC TOR, SOP and membership details will be available upon request to the general public, and will be posted on the DOH HREC website.

8. Submission Procedure for New Applications

The procedure for the submission of new applications.

1. All applications for ethical review must be submitted via the RGS, by close of business on the relevant closing date. The closing date for receipt of new applications for the next DOH HREC meeting will be readily available to prospective applicants on the RGS.

2. The closing dates for applications should normally be no earlier than 21 calendar days and no later than 14 calendar days prior to each DOH HREC meeting.

3. Applications must be submitted in the appropriate format and include all documentation as determined by the DOH HREC. The procedures for application to the DOH HREC and the application format will be readily available to applicants on the DOH HREC website.

4. Applications for review of project proposals that involve a clinical trial or innovations in clinical practice must include evidence that the project has been granted ethical approval and institutional approval from the responsible institution(s). Information on requirements for site specific research governance review and approval processes can be obtained from the relevant site or health service provider.

5. RGS help pages are available to assist applicants in the preparation of their applications in RGS, including guidance on how to determine whether application to the DOH HREC is necessary.

6. A fee will not be charged for non-commercial applications submitted for assessment by the DOH HREC. Fees for reviewing commercial applications may apply.

9. Processing of Applications for Review

The procedure for the processing of new applications.

1. Applications will be checked for their completeness and validity by the EEO prior to their acceptance for DOH HREC review. Incomplete applications will be returned to the applicant.

2. The EEO will circulate the completed application and associated documents to all members at least seven calendar days prior to the meeting.

3. Once a completed application has been accepted for ethical review, the RGS will assign a unique project identification number to the project (Refer to SOP 2 for appropriate record keeping procedure). The project will be added to the DOH HREC's register of received and reviewed applications.

4. The EEO will acknowledge acceptance of the application for ethical review by issuing an acknowledgement notice by letter or email to the project contact person within seven calendar days of receipt of the application. The acknowledgement notice may include the date of the meeting at which the application will be reviewed, as well as the unique project identification number given by the RGS to the project.

5. The application will be included on the agenda for the next available meeting, provided it is received by the relevant closing date and is complete.

10. Research Governance and Information Governance

To describe the procedure for research governance and data governance for new applications.

Data Governance

1. Where the applicant is requesting data held or linked by the Department of Health, the DG or their delegate is responsible for granting approval for the use or disclosure of the data in accordance with relevant departmental policies.

2. The PI(s) will be required to contact the relevant Data Custodian(s) about their data requirements prior to submitting an application for ethical review.

3. The Data Custodian is responsible for conducting a data governance review of the draft application documents and providing advice to the person responsible for granting approval for the use or disclosure of the data.

4. Unlinked Data Projects
   - 4.1. If the project requires personal information from a data collection held by the Department, and does not require linkage, the PI(s) will be required to contact the relevant Data Custodian about the data application process prior to submitting an application for ethical review.
   - 4.2. The Data Custodian will notify the PI(s) when the draft application documents are approved for submission to the EEO of DOH HREC.
   - 4.3. The PI(s) must then submit the relevant ethics form and the final approved version of the application documents and all relevant documents via the RGS for ethical review.

5. Linked Data Projects

   5.1. If the project requires linked data from data collections held by the Department, the PI(s) will be required to contact the relevant Data Custodian(s) by submitting draft application documents to the WA Data Linkage Branch, Client Services prior to submitting an application for ethical review. Client Services will coordinate the review of the draft application documents between the relevant Data Custodians.

   5.2. The Data Custodian(s) will conduct a data governance review of the project, consult with the PI(s) as required and will advise Client Services of any concerns relating to data governance issues.

   5.3. Client Services will advise the PI(s) when consultation has been completed with all relevant Data Custodian(s) and advise of any proposed amendments to the draft application documents.

   5.4. The PI(s) are then required to submit a final copy of the draft application documents to Client Services in light of the feedback received from the consultation process.

   5.5. Client Services will notify the PI(s) in writing when all associated documentation is approved for submission to the EEO of DOH HREC.

   5.6. The PI(s) must then submit the relevant ethics form and the final approved version of the draft application documents and all relevant documents via the RGS for ethical review.

6. The EEO may forward a copy of the final draft application documents to the relevant Data Custodian(s) for additional comment.

7. The Data Custodian(s) may provide a written data governance report on the application on any of the following matters they consider relevant to the ethical review to the EEO of the DOH HREC:
   - the availability of the data
   - whether the identity of the individuals could reasonably be ascertained
   - whether the project minimises the impact on privacy
   - the Security and the Retention and Disposal Plans
   - whether the project requires review and approval by any other committee
   - whether the use of disclosure of the data is likely to be approved
   - any other matter relevant to the ethical review.

8. The EEO will provide the members of the DOH HREC with copies of the Data Custodians' data governance reports for consideration at the meeting at which the DOH HREC considers the application.

9. For linked data projects, the PI will notify Client Services of the outcome of the DOH HREC review and Client Services will prepare the data release papers for approval by the DG or delegate to approve the use of the data.

10. For unlinked data projects, the PI will notify the Data Custodian of the outcome of the DOH HREC review. The Data Custodian will prepare the data release papers for approval by the DG or delegate to approve the use of the data.

11. Refer to SOP 14 and 15 regarding the review of amendments, extensions and ongoing monitoring of approved projects.

Research Governance

12. The DOH HREC will be responsible for ethical review and oversight only. Matters of research governance are the responsibility of the individual institutions.

13. Research Governance includes, but is not limited to, responsibility for determining whether the resources, facilities and staff at the site of the research are available, contractual arrangements between the parties to the research, insurance and indemnity arrangements, regulatory and financial agreements and any other legal issues.

14. Applications for review of research proposals that are conducted within the Department or involve access to the Department's data collections must undergo a formal research governance review process. The Research Governance Officer (RGO) at the Department will provide further information about this process, which can be undertaken concurrently with the ethical review process (refer to the website: Department of Health Research Governance).

11. Consideration of Applications for Ethical Review

The process of the DOH HREC's consideration of applications for ethical assessment.

1. The DOH HREC will consider a new application at the next available meeting provided that the application is complete and received by the relevant closing date.

2. The application will be reviewed by all members present at the meeting or providing written comments in lieu of attendance.

3. The DOH HREC will ethically assess each application in accordance with:
   - the NHMRC National Statement
   - the NHMRC Values and Ethics Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research where applicable
   - the Department of Health Practice Code for the Use of Personal Health Information
   - guidelines approved under the Commonwealth *Privacy Act 1988* where applicable and guidelines approved under any other applicable privacy legislation
   - any other applicable principles or guidelines required by the NHMRC, legislation or industry standard.

4. The DOH HREC must ensure that it is sufficiently informed on all aspects of a project protocol, including its scientific validity, in order to make an ethical assessment.

5. Where the project involves an application for record level information from an information system held or linked by the Department, the DOH HREC will consider information governance reports provided by the relevant Custodian(s).

6. The DOH HREC requires evidence of ethical and institutional approval from the responsible institution for all projects involving clinical trials or innovations in clinical practice.

7. The DOH HREC will consider whether an advocate for any participant or group of participants should be invited to the committee meeting to ensure informed decision making.

8. Where the project involves the targeted recruitment of persons who require assistance with the English language (e.g. culturally and linguistically diverse and visual or hearing impaired patients), the DOH HREC will ensure that the participant information is made available in an accessible format.

9. The DOH HREC, after consideration of an application at a meeting will make one of the following decisions:
   - it will approve the project as being ethically acceptable, with or without conditions
   - it will defer making a decision on the project until the clarification of information or the provision of further information to the DOH HREC
   - it will request modification of the project
   - it will reject the application for ethical review.

10. The DOH HREC will 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) will be noted in the minutes.

11. In order to facilitate consideration of an application, the DOH HREC may invite the applicant to be present at the relevant meeting for discussion and to answer questions. Should the applicant attend the meeting, this will be minuted for the agenda item that they are present for.

12. For projects where the DOH HREC has requested clarification, the provision of further information, or modification of the project, the DOH 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.

13. In such circumstances, the DOH HREC will 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. The DOH HREC may decide that the information should be considered at a further committee meeting.

15. The DOH HREC may consult with any person(s) they consider to be qualified to provide advice and assistance in the review of any project proposal submitted to it, subject to that person(s) having no conflict of interest and providing an undertaking of confidentiality. Such person(s) may not be entitled to vote on any matter.

16. The DOH HREC may take into account the views or opinion of another HREC in relation to a project.

12. Exempt Projects and Expedited Review

Projects which are exempt from review and the procedure for the expedited review by the DOH HREC.

1. The DOH HREC may establish an Executive, consisting of at least the Chair and the EEO.

2. Projects will be exempt from ethical review where they:
   - involve only negligible risk (see National Statement 2.1.7), or
   - involve the use of existing information systems or records that contain only non-personal information about human beings.

3. The Executive may provide advice to a PI(s) or a Custodian as to whether a project is exempt from ethical review by the DOH HREC.

4. The Executive may undertake expedited review of:
   - project proposals involving low risk to participants
   - minor amendments, extensions of approval protocols and project reports
   - projects undertaken within the WA health system to prevent or lessen a serious and imminent threat to the life, health or safety of an individual or general public that requires the use or linkage of personal information from information systems held by the Department
   - urgent amendments to approved protocols for safety reasons
   - other items of business such as adverse events and the like.

5. The Executive may seek advice from other DOH HREC members or suitably qualified experts, as appropriate, before reaching a decision. The Executive must table a report on the decision of this review for noting at the next meeting.

6. Expedited review of projects may be undertaken by the DOH HREC by electronic means between scheduled meetings at the discretion of the Chair. A quorum must participate in the expedited review of the project but need not be physically present. The expedited review will be conducted in accordance with SOP 12, items 3-16.

7. The minutes of Executive meetings will be tabled for ratification at the next DOH HREC meeting.

8. Projects with the potential for physical or psychological harm should generally not be considered for expedited review. This includes clinical trials, research involving invasive physical procedures and projects exploring sensitive personal, social or cultural issues.

9. Where the Chair considers that a project may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol must be considered by the full DOH HREC and cannot be dealt with by expedited review.

13. Notification of Decisions

The procedure for the notification of decisions of the DOH HREC concerning the review of new applications.

1. The DOH HREC will advise PI(s) in writing whether the application has been granted ethical approval (including any conditions of approval), within five working days of the meeting, unless otherwise notified.

2. If the DOH HREC determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the PI(s) should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification should refer to the National Statement or relevant legislation.

3. If the requested information is not received from the applicant within three months or two meetings (whichever occurs sooner), the project may be dismissed and the applicant will be required to resubmit the project application in full at a later date.

4. The DOH HREC will endeavour to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues. The DOH HREC may nominate one of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant committee meeting.

5. The DOH HREC will endeavour to complete the ethical review within a 60 calendar day timeframe, which allows for a 'stop clock' capability when additional input is required from a sponsor or investigator before consideration can continue.

6. The DOH HREC will only notify the applicant of ethical approval of a project once all outstanding requests for additional information or modification have been resolved.

7. Notification of ethical approval will be in writing via the RGS, and will contain the following information:
   - title of project
   - name of the PI(s)
   - unique RGS project identification number
   - date of DOH HREC meeting at which the project was first considered
   - date and duration of DOH HREC approval, and
   - conditions of DOH HREC approval, if any.

8. The DOH HREC approval is granted for three years with option for five years if justified, except where action is taken to suspend or terminate the decision. The DOH HREC has the capacity to set a shorter approval period dependent upon the risk and complexity of the project.

9. If the DOH HREC determines that a project is ethically unacceptable, the notification of the Committee's decision will include the grounds for rejecting the project with reference to the National Statement or other relevant pieces of legislation, where applicable.

10. The status of the project will be updated on the DOH HREC's register of received and reviewed applications.

11. A lay summary of the approved project will be made publically available on the DOH HREC website, with the consent of the PI(s).

14. Submission of Amendments and Extensions

The procedure for the submission and DOH HREC review of requests for amendments and extensions to approved protocols.

1. Proposed changes to approved projects or requests for extensions to the duration of DOH HREC approval are required to be reported by the PI(s) to the DOH HREC for review.

2. Requests will 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 project. All amended documents must have the changes highlighted and contain revised version numbers and dates.

3. The Chair will nominate a delegate, such as the EEO, to review minor amendments to approved projects and Annual Progress Reports on behalf of the Chair.

4. The Custodians and DLB Client Services will review amendment requests, where applicable.

5. Approval for extension of a project is limited to a maximum period of three years. Any further request for an extension will be at the discretion of the Chair or the application may need to be resubmitted as a new application.

6. Expedited review of requests for minor amendments and extensions, and urgent amendments to approved protocols for safety reasons may be undertaken by the DOH HREC Executive, or EEO, between scheduled meetings at the discretion of the Chair and in accordance with SOP 12.

7. All other requests for amendments may be reviewed by the DOH HREC at its next available meeting, provided the request and necessary documentation has been received by the EEO by the agenda closing date.

8. The DOH HREC will advise the PI(s) in writing advising whether the proposed amendment and/or request for extension has been granted ethical approval, within five working days of the meeting at which the request was considered (this may be the full DOH HREC meeting or the Executive meeting).

9. Notification of the approval of amendments and extensions will be in writing.

10. If the DOH HREC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the PI(s) should clearly articulate the reasons for this determination, and clearly set out the information that is required. Where possible, requests for additional information/clarification/modification should refer to the National Statement or relevant legislation.

11. All received and approved requests for amendments and extensions will be recorded, and the status of the project will be updated on the project file and the DOH HREC project register.

15. Monitoring of Approved Projects

The procedure for monitoring projects approved by the DOH HREC to ensure compliance with ethical approval.

1. The DOH 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(s) at any time. In particular, the DOH HREC will require applicants to provide a report at least annually, and at completion of the study. Continuing approval of the project will be subject to the PI(s) submitting an annual report within three months of the due date.

2. The DOH HREC may require the following information in the annual report:
   - progress to date, publications or outcome in the case of completed project
   - maintenance and security of records and information
   - compliance with the approved protocol
   - compliance with any conditions of approval
   - changes to the protocol or conduct of the project
   - changes to the personnel or contact details of the PI(s)
   - adverse events or complaints relating to the project.

3. The DOH HREC may adopt any additional appropriate mechanism(s) for monitoring, as deemed necessary, such as:
   - random inspections of project sites, data and signed consent forms
   - interview, with their prior consent, of project participants.

4. The DOH HREC requires, as a condition of approval of each project, that PI(s) 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 upon the continued ethical acceptability of the project, or which may indicate the need for amendments to the project protocol.

5. The DOH HREC may require the DLB Client Services and/or Custodians to review any draft project outputs within 10 business days.

6. In determining the frequency and type of monitoring required for approved projects, the DOH HREC will give consideration to the degree of risk to participants in the project.

Suspension and Termination

7. When the project has not been completed or has been discontinued before the expected date, the DOH HREC requires, that PI(s) inform the Committee via a final report. After approval of the final report, the investigators must also enact and comply with the approved Retention and Disposal Plan.

8. The EEO will prepare a letter to the PI(s), contact person nominated for the project and the Head of Department / School / Research Organisation overseeing the project, outlining the following:
    - The project name and project identifier
    - The approved project commencement and completion dates
    - The nature of the concern/s of the DoH HREC
    - A requirement to address the concerns within 28 days
    - A statement informing the PI(s) that in line with the requirements of the National Statement, decision may be made to suspend ethical approval until the matter is resolved.

9. If the matter remains unresolved following 28 calendar days from date of the notification letter, a second letter will be sent from the DOH HREC Chair via the Director overseeing the DOH HREC. This letter will advise that the project's ethical approval has been suspended pending a decision.

10. If the project is suspended, PI(s) will be notified that no further activity can be conducted until the matter is resolved.

11. Whilst the project is suspended, the Department will take reasonable steps to determine whether the project may continue. This process will be conducted fairly and with respect to the investigators and others involved in the project. This process will be carried out between the EEO and a representative of the RGU.

12. Where a project is not being or cannot be conducted in accordance with the approved study protocol, or that remedial measures are insufficient to address the concerns raised by the DOH HREC, this must be reported to the DOH HREC Chair and RGU Manager. The DOH HREC Chair and RGU Manager may then determine whether the project's ethical and governance approvals will be terminated.

13. The PI(s), contact person and the Head of Department / School / Research Organisation overseeing the project will be informed of the decision in writing by DOH HREC Chair via the Director overseeing the DOH HREC. This letter will advise whether the project's ethical and governance approval has been terminated or suspension removed.

14. Where a project also holds ethical approval from another institution(s) or review bodies, the PI(s) must notify the institution(s) or review bodies that they have had their DOH HREC ethical approval suspended/terminated, in line with the requirements of the National Statement.

16. Complaints Regarding the Review or Rejection of an Application

The mechanism for receiving, handling and responding to complaints regarding the review or rejection of an application by the DOH HREC.

Reporting

1. The EEO is the person nominated to receive any complaints or concerns about the DOH HREC's review processes or the rejection of an application. The PI(s) must direct the complaint in writing to the attention of the Chair via the EEO, outlining the grounds of the complaint.

2. The EEO will send an acknowledgment to the PI within seven calendar days of receipt of the complaint. The EEO will notify the Chair and the Director overseeing the DOH HREC.

3. The Chair of the DOH HREC will investigate the complaint and its validity, and make a recommendation to the DOH HREC on the appropriate course of action. The investigation will be conducted as expeditiously as possible

4. If the complainant is not satisfied with the outcome of the Chair's investigation, they can refer the complaint to the DG, or their delegate, or request the Chair to do so.

5. The Chair will provide the DG or delegate with all relevant information about the complaint, including;
   - details of the complaint
   - material reviewed in the investigation
   - the results of the investigation
   - the recommended course of action
   - any other relevant documentation.

6. The DG or delegate will determine whether further investigation is warranted. Where no further investigation is required, the DG or delegate will inform the complainant and the Chair.

7. If there is to be a further investigation, then the DG or delegate will establish a panel (of non-current DOH HREC members) to consider the complaint. The Panel will include, at least, the following members:
   - the DG or the DG's nominee as the convenor of the Panel
   - a person experienced in the ethical review of projects (who is not a member of the DOH HREC)
   - an expert in the discipline of the project under consideration, and
   - additional members, as required by the DG.

8. 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.

9. The Panel will ascertain whether the DOH HREC acted in accordance with its TOR, SOP, the National Statement and otherwise acted in a fair and unbiased manner.

10. The DG or delegate will notify the complainant and the DOH HREC of the outcome of the investigation in writing. The outcomes may include:
    - dismissing the complaint, or
    - referring the complaint back to the DOH HREC for reconsideration in the light of findings of the Panel.

11. If the DOH HREC is requested to review its decision, then the outcome of this review by the DOH HREC will be final. The Panel or the DG or delegate cannot provide ethical approval.

12. The panel may also make recommendations about the operation of the DOH HREC including:
    - review of the TOR
    - review of SOPs
    - review of the committee membership.

13. If the complainant is not satisfied with the decision of the DG, then depending on the nature of the complaint the matter may be referred for external review to the Ombudsman Western Australia, the Health and Disability Services Complaints Office or the State or Federal Information Commissioner.

14. The outcome must be recorded in the RGS and it must include the date of review and by whom and any additional information that is required.

17. Complaints regarding the Conduct of a Project

The mechanism for receiving, handling and responding to complaints regarding the conduct of a project approved by the DOH HREC.

Reporting

1. The EEO is the person nominated to receive concerns and regarding the conduct of DOH HREC approved projects.

2. The DOH HREC requires PI(s) to immediately report any complaints received to the EEO of DOH HREC.

3. The EEO will notify the Chair and the Department's RGO of the complaint as soon as possible.

4. The EEO will send an acknowledgment to the complainant and PI(s), if applicable, outlining the mechanism for investigating the concern or complaint.

5. The EEO will liaise with the RGO to ensure the complaint is reported to any other institutional HRECs and their RGOs.

Investigation

6. The EEO and RGO will investigate the complaint and its validity, and make a recommendation to the Chair on the appropriate course of action.

7. The Chair will examine the concern or complaint, and the recommendation for course of action. The Chair will determine whether the complaint warrants a further investigation. Where there is to be no further investigation the Chair will inform the complainant in writing.

8. Where the Chair determines that the concern or complaint warrants further investigation the Chair will notify the Director overseeing the DOH HREC of the complaint. The Director will convene an IRC to investigate and determine the consequences.

9. The Director will chair the IRC. The membership of the committee will also include the Chair of the DOH HREC, RGO and other members with appropriate expertise as required.

10. The EEO will send a letter of notification to the PI(s) outlining the mechanism for investigating the concern or complaint. Where the complaint concerns the conduct of any other person the IRC will also notify that person.

11. The IRC will immediately initiate an investigation into the complaint. The IRC may co-operate with any other institution or HREC concerned with the project and may conduct a joint investigation. The investigation will be conducted as expeditiously as possible.

12. The IRC may require the suspension of the project during the course of the investigation. Where the IRC requires the project to be suspended the IRC will notify the PI(s), the responsible institution and the Chair of other HRECs, where necessary.

13. Where the reported incident concerns the conduct of any person the IRC will notify that person of the report and will provide that person with an opportunity to respond to concerns.

14. The IRC 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

15. If the IRC is satisfied that the complaint is justified it will 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 an individual(s) conduct, was inadvertent, negligent or intentional.

16. The possible consequences include the following:
    - notation on the project's file of the occurrence of the matter
    - increased monitoring of the project
    - counselling on security practices
    - amendments to the approved protocol
    - suspension or termination of ethical approval of the project (with the immediate return or destruction of all data files)
    - exclusion of particular individuals from future access to personal health information provided by the Department either for a period of time or indefinitely
    - reporting the individual(s) to their employer
    - reporting the individual(s) to the funding agency that has supported the project
    - reporting the individual(s) responsible to any external agency with jurisdiction (such as professional registration board or the Privacy and Information Commissioner), with a complaint of misconduct
    - reporting allegations of criminal conduct to the relevant authorities.

17. The Chair of the IRC will notify the following personnel in writing, of the outcome of the investigation
    - the DOH HREC
    - responsible institution
    - the PI(s)
    - any other person for whom there is an individual consequence
    - relevant institutional HRECs and RGOs
    - the complainant.

18. If the complainant is not satisfied with the outcome they may refer the complaint to the DG.

19. The DG or delegate will review the decision of the IRC and decide whether and what further action is required and inform the complainant and the Chair of the IRC or the DOH HREC of that decision.

20. If the PI(s) or any other person affected is not satisfied with the decision of the DG, depending upon the nature of the breach and the decision, the matter can be referred for external review by the Ombudsman Western Australia, the Health and Disability Services

Office or the State or Federal Information Commissioner. The Ombudsman may conduct a procedural review of the decision.

21. The outcome must be recorded in the RGS and within the project's file and must include the date of review and by whom and any additional information that is required.

18. Breaches in the Conduct of a Project

The mechanism for receiving, handling and responding to reports of breaches of protocol in the conduct of a project approved by the DOH HREC.

Reporting

1. The DOH HREC will require, as a condition of approval of each project, that PI(s) and project members immediately report breaches of the approved protocol to the DOH HREC.

2. The EEO is the person nominated to receive verbal or written reports of a breach of an approved protocol. The report should 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 including the amount and type of information and the level of identifiability
   - whether any breach was inadvertent, negligent or intentional, and
   - proposed changes to the protocol as a result of the breach.

3. The EEO will notify the Chair and the Department's RGO of the breach as soon as possible.

4. The EEO will liaise with the Department's RGO to ensure all other relevant approval bodies are aware of the breach.

Investigation

5. The EEO and RGO will liaise with each other to investigate the complaint and its validity, and to make a recommendation to the Chair on the appropriate course of action.

6. The Chair will examine the report of the breach, as well as the recommendation for course of action and determine whether the breach warrants a further investigation. Where there is to be no further investigation the Chair will inform the PI(s) and RGO of the resolution of the complaint.

7. Where the Chair determines that the breach warrants a further investigation the Chair will notify the Director overseeing the DOH HREC of the breach. The Director will convene an Incident Review Committee (IRC) to investigate the breach and determine the consequences.

8. The Director will chair the IRC. The membership of the committee will include the Chair of the DOH HREC, RGO, and other members with appropriate expertise as required.

9. The IRC will immediately initiate an investigation into the breach. The IRC 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 will be conducted as expeditiously as possible.

10. The IRC may require the suspension of the project during the course of the investigation. Where the IRC requires the project to be suspended the IRC will notify the PI(s), the responsible institution and the Chair of other HRECs where necessary.

11. Where the reported incident concerns the conduct of any person, the IRC will notify that person of the report and will provide that person with an opportunity to respond to concerns.

12. The IRC 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, in accordance with legislation.

Consequences

13. If the IRC is satisfied that a breach has occurred it will determine the consequences by considering the following matters:
    - the severity of the breach
    - the sensitivity of any information concerned including the amount and type of information and the level of identifiability
    - whether any breach was inadvertent, negligent or intentional.

14. The possible consequences may include the following:
    - notation on the project's file of the occurrence of the breach
    - increased monitoring of the project
    - counselling on security practices
    - amendments to the approved protocol
    - suspension or cancellation of ethical or governance 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 personal health information provided by the Department, either for a specified period of time or indefinitely
    - reporting the individuals responsible for the breach to their employer, with a complaint of misconduct in the conduct of the project
    - 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
    - reporting allegations of criminal conduct to the relevant authorities (per complaint SOP).

15. The Chair of the IRC will notify the following in writing, of the outcome of the investigation
    - the DOH HREC
    - responsible institution
    - the PI(s)
    - any other person for whom there is an individual consequence
    - relevant institutional HRECs and RGOs

16. The Chair of the IRC will report to the DG on the outcome of the investigation and the consequences.

17. The DG will review the report of the IRC and decide whether further action is required, and inform the PI(s) or any other person affected and the Chair of that decision.

18. The Chair of the IRC will notify the responsible institution, the PI(s) and any other person for whom there are individual consequences of the outcome of the investigation and the consequences in writing.

19. The Chair of the IRC will notify the DOH HREC and any other institutional HRECs and RGOs concerned with the project of the outcome of the investigation and the consequences.

20. The DOH HREC may review the ethical approval of the project in the light of the outcome of the investigation of the breach and the DOH HREC will notify the responsible institution and the PI(s) in writing if ethical approval for the project is withdrawn, and measures to be taken to conclude the project.

21. If the PI(s) or any other person for whom there is an individual consequence is not satisfied with the outcome of the investigation they may refer the matter to the DG or delegate who will review the decision.

22. If the PI(s) or any other person affected is not satisfied with the decision of the DG, depending upon the nature of the breach and the decision, the matter can be referred for external review by the Ombudsman Western Australia, the Health and Disability Services Complaints Office or the State or Federal Information Commissioner. The Ombudsman may conduct a procedural review of the decision.

23. The outcome must be recorded in the RGS and in the project's file and must include the date of review and by whom and any additional information that is required.

19. Reporting and Handling of Adverse Events

The process for reporting and handling of adverse events in clinical trials.

Introduction

An adverse event is defined in the National Statement and refers to undesirable clinical responses to an intervention including a treatment or diagnostic procedure.

Reporting of Adverse Events

1. PI(s) should immediately report all adverse events in clinical trials to the Ethics Committee(s) and RGOs of the institution(s) responsible for the conduct of the project.

2. The PI(s) must comply with all mandatory reporting obligations required by the ethics committee and governance review processes at the relevant site(s) (refer to the WA Health Research Governance Framework).

3. PI(s) should report upon all adverse events and the response to those events in the periodic and final reports for the project.

20. Review of Standard Operating Procedures and Terms of Reference

The procedure for review and approval of the DOH HREC Standard Operating Procedures and Terms of Reference.

1. The SOPs and TOR will be reviewed at least every three years and amended as necessary.

2. Minor amendments to the SOP and TOR can be actioned by the EEO. A minor amendment means a correction or change which is administrative in nature and does not significantly change the specific meaning, purpose or intent of the document.

3. The SOPs and TOR may be amended by following the procedure below:

   a. For major amendments, including changes in meaning, purpose or intent:
      - the proposal must be in writing and circulated to all DOH HREC members for their consideration
      - the views of the members should be discussed at the next scheduled meeting of the DOH HREC, and a vote taken at that meeting. Any member unable to attend such a meeting may register their views in writing
      - the proposal will be ratified if two thirds of the members agree to the amendment
      - the Chair will send the amendment to the DG for review and approval.

   b. For those proposals made by the DG or their delegate:
      - the DG or their delegate will send the proposal to the DOH HREC and seek the views of any relevant person.

4. The DG or their delegate will consider the views of the members of the DOH HREC and other relevant persons and will determine whether the amendment should be made.

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