



Government of Western Australia
Department of Health

Human Research Ethics Committee

Standard Operating Procedures

Version: 8 June 2011

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1. Appointment of Members

Reference Number: SOP1

Purpose: To describe the procedure for the appointment of members to the 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 Western Australia Human Research Ethics Committee (**the HREC**) may be recruited by direct approach, nomination or by advertisement. Prospective members shall be asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their names and professions being made available to the public, including being published on the Department of Health Western Australia (**DOHWA**) website.
3. The Director General (**DG**) of the DOHWA may appoint a selection committee, which includes at least one representative of the HREC who is not an institutional member to interview prospective applicants, consult with the HREC members and make a recommendation to the DG of the DOHWA. Prospective members may be invited to attend a meeting of the 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 by the DG of the DOHWA in consultation with the HREC and will receive a formal notice of appointment.
5. The Deputy Chair will be appointed by the DG of the DOHWA. In the absence of the Chair, the Deputy Chair will perform the role and duties of the Chair.
6. The letter of appointment shall 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 HREC member, the circumstances whereby membership may be terminated and the conditions of their appointment.
7. Members will be required to sign a confidentiality form undertaking upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.
8. Upon appointment, members shall be provided with the following documentation:
 - HREC Terms of Reference (**TOR**);
 - HREC Standard Operating Procedures (**SOP**);
 - Up to date list of members' names and contact information including that of the HREC Executive Officer (**EO**);
 - NHMRC National Statement on Ethical Conduct in Human Research;
 - 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;
 - DOHWA Practice Code for the Use of Personal Health Information;
 - Any previous reports on the HREC's activities; and
 - Any other relevant information about the HREC's processes, procedures and protocols.
9. The positions within the HREC are fixed term 3 year appointments. Recruitment into these positions are staggered to ensure continuity and expertise within the Committee.
 10. 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 of the DOHWA. The DG of the DOHWA may approve further terms, of varying duration, for members in order to ensure continuity and expertise of the HREC.
 11. Deputy members are appointed to the HREC to provide category representation when the relevant member is unable to attend meeting(s). Deputy members are appointed to fixed term deputy positions as they become vacant. Deputy members may only serve two consecutive terms unless otherwise approved by the DG of the DOHWA.
 12. 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 by the DOHWA.
 13. Member's shall be remunerated at the rate recommended by the Department of Premier and Cabinet for advisory committees.
 14. Members may seek a leave of absence from the HREC for extended periods. Steps shall be taken to fill the vacancy.
 15. Membership will lapse if a member fails to attend three consecutive meetings of the HREC without reasonable excuse or apology, unless exceptional circumstances exist. The Chair will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy, which may arise.
 16. Membership will lapse if a member fails to attend in full at least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.
 17. 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.
 18. A member may resign from the HREC at any time upon giving notice in writing to the Chair. Steps shall 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.

2. Orientation of New Members

Reference Number: SOP2

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

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

3. Preparation of Agenda

Reference Number: SOP3

Purpose: To describe the process and format of agenda for an HREC meeting

1. The EO will prepare an agenda for each HREC meeting.
2. All completed applications and relevant documents received by the EO will be included on the agenda for HREC consideration at its next available meeting.
3. The meeting agenda and associated documents will be prepared by the EO and circulated to all HREC members at least 7 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 shall new applications for research be tabled at the meeting.
5. Agenda items will include at least the following items:
 - i. apologies;
 - ii. confirmation of quorum;
 - iii. minutes of the previous meeting;
 - iv. business arising from the previous minutes;
 - v. conflicts of interest;
 - vi. new applications;
 - vii. amendments to approved protocols;
 - viii. monitoring reports;
 - ix. other business; and
 - x. close and next meeting.
6. The agenda and all documentation shall remain confidential.

4. Conduct of Meetings

Reference Number: SOP4

Purpose: To describe the format of meetings of the HREC

1. The HREC shall meet on a regular basis, which will normally be at monthly intervals. Meeting dates and agenda closing dates shall be publicly available.
2. Members may attend HREC meetings in person or via teleconference or video link.
3. The Chair shall cancel a scheduled meeting if a quorum cannot be achieved. Should this occur, the HREC will convene within 5 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 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 5 working days.
5. The 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 HREC may agree to the presence of visitors or observers to a meeting.
7. Members who are unable to attend a meeting should contribute prior to the meeting through written submissions to the EO. These should normally be received at least 3 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 HREC to reach a final decision on any agenda item. A quorum shall exist when at least 5 members are physically present, 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 HREC, and at least one third of these present are from outside the DOHWA.
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 on Ethical Conduct in Human Research* have received all the papers and have had an opportunity to contribute their views in writing and that those views have been recorded and considered at the meeting.
10. If the meeting does not achieve quorum, the Chair shall decide it can proceed only in exceptional circumstances. In such circumstances, decisions made by the HREC must be ratified by at least one representative from those membership categories not present.
11. Any member of the HREC who has any interest, financial or otherwise, in a project or other related matter(s) considered by the HREC should declare such interest. This will be dealt with in accordance with SOP 5.

5. Handling of Conflicts of Interest

Reference Number: SOP5

Purpose: To describe the procedure for the handling of conflicts of interest of HREC members

1. An HREC member shall, as soon as practicable during the HREC meeting, inform the Chair if he/she has a conflict of interest, financial or otherwise, in a project or other related matter(s) considered by the HREC.
2. The 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 HREC's consideration of the relevant matter has been completed. The member shall not be permitted to adjudicate on the research.
3. All declarations of conflict of interest and the absence of the member concerned will be minuted.

6. Preparation of Minutes

Reference Number: SOP6

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

1. The HREC EO will prepare and maintain minutes of all meetings of the HREC.
2. The format of the minutes will include at least the following items:
 - i. apologies;
 - ii. confirmation of quorum;
 - iii. attendance;
 - iv. minutes of the previous meeting;
 - v. business arising from the previous minutes;
 - vi. conflicts of interest;
 - vii. new applications;
 - viii. amendments to approved projects;
 - ix. monitoring reports;
 - x. other business; and
 - xi. close and next meeting.
3. The minutes should include the recording of decisions taken by the HREC as well as 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 shall record a summary of the main ethical issues considered, including any requests for additional information, clarification or modification of the project.
5. In recording a decision made by the HREC, any significant minority view (i.e 2 or more members) will be noted in the minutes.
6. To encourage free and open discussion and to emphasis the collegiate character of the HREC, particular views should not 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 HREC and the absence of the member concerned during the HREC consideration of the relevant application 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 checked by either the Chair and/or the Deputy Chair, for accuracy.

9. The minutes will be circulated to all members of the 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 formally ratified at the next HREC meeting.
10. The original copy of each meeting's minutes will be retained in a confidential 'Minutes' file.
11. The ratified minutes of each Committee meeting shall be available to the DG of the DOHWA.

7. Record Keeping

Reference Number: SOP7

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

1. The EO will prepare and maintain written records of the HREC's activities, including agendas and minutes of all meetings of the HREC.
2. The EO will prepare and maintain a confidential electronic and/or paper record for each application received and reviewed and shall record the following information:
 - 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;
 - DOHWA approval for commencement of research and/or release of personal information 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; and
 - action taken by the HREC to monitor the conduct of the research.
3. The paper file shall contain a hard copy of the application, including signatures, and any relevant correspondence including that between the applicant and the HREC, all approved documents and other material used to inform potential research participants.
4. All relevant records of the HREC, including applications, membership, minutes and correspondence will be kept as confidential files and in accordance with the *State Records Act 1998* and any other applicable legislation.
5. To ensure confidentiality, all documents provided to 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 should leave their documents with the EO for disposal.
6. All relevant records pertaining to research projects shall be held for sufficient time to allow for future reference. Retention periods shall comply with the General Disposal Authority for Administrative Records issue by the State Records Office and the DOHWA Records Retention and Disposal Schedule.

8. HREC Reporting Requirements

Reference Number: SOP8

Purpose: To describe the reporting requirements of the HREC

1. The minutes of each HREC meeting will be available to the DG of the DOHWA following confirmation.
2. The HREC shall provide an annual report on its progress for the calendar year to the DG of the DOHWA, including:
 - membership/membership changes;
 - number of meetings;
 - number of projects reviewed, approved and rejected;
 - monitoring procedures for ethical aspects of research in progress and any problems encountered by the HREC in undertaking its monitoring role;
 - description of any complaints received and their outcome;
 - description of any research where ethical approval has been withdrawn and the reasons for withdrawal of approval; and
 - general issues raised.
3. The HREC will provide reports to the Australian Health Ethics Committee (**AHEC**) in accordance with the requirement of the NHMRC and will comply with all statutory reporting requirements.
4. The HREC TOR, SOP and membership will be available upon request to the general public, and will be posted on the DOHWA website.

9. Submission Procedure for New Applications

Reference Number: SOP9

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

1. All applications for ethical review must be submitted to the EO of the HREC, by close of business on the relevant closing date. The closing date for receipt of new applications onto the next HREC agenda shall be readily available to prospective applicants.
2. The closing dates for applications should normally be no earlier than 21 days and no later than 14 days prior to each HREC meeting.
3. Applications must be submitted in the appropriate format as determined by the HREC, and shall include all documentation as required by the HREC. The procedures for application to the HREC and the application format shall be readily available to applicants.
4. Applications for review of research 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.
5. Guidelines shall be issued by the HREC to assist applicants in the preparation of their applications, including guidance on how to determine whether application to the HREC is necessary.
6. A fee will not be charged for applications submitted for assessment by the HREC.

10. Processing of Applications for Review

Reference Number: SOP10

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

1. Applications will be checked for their completeness by the EO prior to their acceptance onto the agenda. Incomplete applications will be returned to the applicant.
2. Once a completed application has been accepted for ethical review, the EO shall assign a unique project identification number to the project (Refer to SOP 7 for appropriate record keeping procedure). The project will be added to the HREC's register of received and reviewed applications.
3. The EO will acknowledge acceptance of the application for ethical review by issuing an acknowledgement notice by letter or email to the project contact person within 7 days of receipt of the application. The acknowledgement notice shall include the date of the meeting at which the application will be reviewed, as well as the unique project identification number given by the HREC to the project.
4. The application will be included on the agenda for the next available HREC meeting, provided it is received by the relevant closing date and is complete.

11. Research Governance and Data governance

Reference Number: SOP11

Purpose: To describe the procedure for research governance and data governance.

Research Governance

1. The HREC will be responsible for ethical review and oversight only. Matters of research governance are the responsibility of the individual institutions.
2. 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.
3. Applications for ethical review must contain an acknowledgement of institutional responsibility for research governance signed by a person at the relevant institution with authority to do so.

Data Governance

4. Where the applicant is requesting the use or disclosure of data owned or held by the DOH WA the DG of the DOHWA or a person authorised by statute, or delegate, is responsible for granting approval for the use or disclosure of the data.
5. The Data Manager is responsible for conducting a data governance review of the application for data and providing advice to the person responsible for granting approval for the use or disclosure of the data.
6. The PI(s) will be required to contact the relevant Data Manager/s by submitting an *Application for Data (Form DS001)* to the Data Services Officer (**DSO**) prior to submitting an application for ethical review.
7. The DSO will forward the *Application for Data* to all relevant Data Managers for consultation.
8. The Data Manager/s will conduct a data governance review of the project, consult with the PI(s) as required and will advise the DSO of any concerns relating to governance issues within 2 week of the receipt of the Application for Unit Record Data.
9. The DSO will advise the PI(s) when consultation has been completed with all relevant Data Managers.
10. The PI(s) may submit an *Application for Ethical Review (Form DS001 + HREC002)* to the EO on completion of the consultation period.
11. The EO will forward a copy of the Application for Data to the relevant Data manager/s.
12. The Data Manager/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 EO of the HREC within a specified timeframe:

- The availability of the data;
 - Whether the identity of the individuals could reasonable 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; and
 - Any other matter relevant to the ethical review.
13. The EO will provide the members of the HREC with copies of the Data Managers data governance reports for consideration at the meeting at which the HREC considers the application.
 14. A copy of the data governance report will be kept in the records relating to the application.
 15. The EO will notify the DSO of the outcome of the HREC review and the DSO will prepare the data release papers for approval by the DG of the DOHWA, or delegate, or a person authorised by statute to approve the use or disclosure of the data.

12. Consideration of Applications for Ethical Review

Reference Number: SOP12

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

1. The HREC will consider a new application at its next available meeting provided that the application is received by the relevant closing date and is complete.
2. The application will be reviewed by all members of the HREC present at the meeting or providing written comments in lieu of attendance.
3. The HREC will ethically assess each application in accordance with:
 - The NHMRC *National Statement on Ethical Conduct in Human Research*;
 - The NHMRC *Values and Ethics Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* where applicable;
 - The DOHWA *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; and
 - Any other applicable principles or guidelines required by the NHMRC or by legislation.
4. The 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.
5. Where the research involves an application for unit record data from a data collection held by the DOHWA the HREC will consider governance reports provided by the relevant data manager/s.
6. Where the research involves a clinical trial or innovations in clinical practice the HREC will satisfy itself that the project has been granted ethical approval and institutional approval from the responsible institution.
7. The HREC will consider whether an advocate for any participant or group of participants should be invited to the HREC meeting to ensure informed decision-making.
8. Where research involves the targeted recruitment of persons unfamiliar with the English language, the HREC will ensure that the participant information sheet is translated into the participant's language.
9. The 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 HREC.

- It will request modification of the project.
 - It will reject the project.
10. The 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. 2 or more members) shall be noted in the minutes.
 11. In order to facilitate consideration of an application, the HREC may invite the applicant to be present at the relevant meeting for its discussion and to answer questions.
 12. For projects where the HREC has requested clarification, the provision of further information, or modification of the project, the 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; or
 - A sub-committee of the HREC.
 13. In such circumstances, the HREC shall 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 HREC may decide that the information should be considered at a further meeting of the HREC.

13. Exempt Projects and Expedited Review

Reference Number: SOP13

Purpose: To describe projects that are exempt from review and the procedure for the expedited review of research by the HREC

1. The HREC may establish an Executive, consisting of at least the Chair and the EO.
2. Projects will be exempt from ethical review where they:
 - Involve only negligible risk (see *National Statement on Ethical Conduct in Human Research 2.1.7*); or
 - Involve the use of existing collections of data or records that contain only non-identifiable data about human beings.
3. The Executive may provide advice to a PI(s) or a data manager as to whether a project is exempt from ethical review by the HREC.
4. The Executive may undertake expedited review of:
 - Minor amendments and extensions of approval protocols; or
 - Urgent amendments to approved protocols for safety reasons.
5. Expedited review of research projects may be undertaken between scheduled meetings at the discretion of the Chair. The Executive may seek advice from other HREC members or suitably qualified experts, as appropriate, before reaching a decision. The decision of this review must be tabled for ratification at the next HREC meeting.
6. The Executive may consider other items of business that are considered to be of minimal risk to participants such as appropriate adverse events, project reports and the like.
7. The minutes of Executive meetings will be tabled for ratification at the next HREC meeting.
8. Research 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 research exploring sensitive personal or cultural issues.
9. Where the Chair considers that research may involve a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol must be considered by the full HREC and cannot be dealt with by expedited review.
10. The HREC will apply the provisions of this SOP to projects approved by the Confidentiality of Health Information Committee (CHIC).

14. Notification of Decisions of the HREC

Reference Number: SOP14

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

1. The HREC will report in writing to the PI(s), advising whether the application has received ethical approval (including any conditions of approval), within 5 working days of the meeting, unless otherwise notified.
2. If the 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 NHMRC *National Statement on Ethical Conduct in Human Research* or other relevant pieces of legislation.
3. If the requested information is not received from the applicant within 3 months or 2 meetings (whichever ever occurs sooner), the project may be dismissed and the applicant will be required to resubmit the project at a later date.
4. The HREC shall endeavour to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of projects relating to ethical issues. The HREC may nominate one of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant HREC meeting.
5. The HREC will 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 will be in writing in a standard format, and will contain the following information:
 - Title of project;
 - Name of the PI(s);
 - Unique HREC project identification number;
 - Date of HREC meeting at which the project was first considered;
 - Date of HREC approval;
 - Duration of HREC approval; and
 - Conditions of HREC approval, if any.
6. If the HREC determines that a project is ethically unacceptable, the notification of the HREC's decision will include the grounds for rejecting the project with reference to the *National Statement* or other relevant pieces of legislation.
7. The status of the project shall be updated on the HREC's register of received and reviewed applications.

15. Submission of Amendments and Extensions

Reference Number: SOP15

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

1. Proposed changes to approved projects or requests for extensions to the length of HREC approval are required to be reported by the PI(s) to the HREC for review.
2. Requests shall 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. 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 HREC Executive between scheduled meetings at the discretion of the Chair and in accordance with SOP 13 on the condition that it be ratified at the next HREC meeting.
4. All other requests for amendments shall be reviewed by the HREC at its next available meeting, provided the request has been received by the EO by the agenda closing date.
5. The HREC will report in writing to the PI(s), advising whether the proposed amendment and/or request for extension has been given ethical approval, within 5 working days of the meeting at which the request was considered (this may be the full HREC meeting or the Executive meeting).
6. Notification of the approval of amendments and extensions will be in writing in a standard format.
7. If the 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 pieces of legislation.
8. All received and approved requests for amendments and extensions shall be recorded, and the status of the project shall be updated on the HREC's register of received and reviewed applications.
9. The HREC will apply the provisions of this SOP to proposed amendments and requests for extensions to projects approved by the CHIC.

16. Monitoring of Approved Projects

Reference Number: SOP16

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

1. The 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 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(s) submitting an annual report within 3 months of the due date.
2. The HREC shall require the following information in the annual report:
 - 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); and
 - Adverse events or complaints relating to the project.
3. The HREC may adopt any additional appropriate mechanism/s for monitoring, as deemed necessary, such as:
 - random inspections of research sites, data and signed consent forms; and
 - interview, with their prior consent, of research participants.
4. The HREC shall require, 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; and
 - new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.
5. The HREC shall require, as a condition of approval of each project, that PI(s) inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion, and that the investigators comply with the approved Retention and Disposal Plan.

6. Where the HREC is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved project, the HREC may withdraw approval. In such circumstances, the HREC shall inform the PI(s) and the DOHWA of such withdrawal of approval in writing, and recommend to the DOHWA that the research project be discontinued, suspended, or that other necessary steps be taken.
7. In determining the frequency and type of monitoring required for approved projects, the HREC will give consideration to the degree of risk to participants in the research project.
8. The HREC will monitor projects approved by the CHIC and will apply the provisions of this SOP to those projects.
9. Where projects approved by CHIC have not been completed within two years of the cessation of the operation of the CHIC the HREC may require the PI(s) to submit a new application for review and approval by the HREC.

17. Reporting and Handling of Adverse Events

Reference Number: SOP17

Purpose: To describe the process for reporting and handling of adverse events in clinical trials

Introduction

An adverse event is defined in the National Statement on Ethical Conduct in Human Research 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 of the institution/s responsible for the conduct of the research in accordance with the reporting conditions required by that Ethics committee.
2. PI(s) should report all adverse events and the response to those events in the periodic and final reports for the project.

18. Breaches in the Conduct of a Project

Reference Number: SOP18

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

Reporting

1. The HREC will require, as a condition of approval of each project, that researchers immediately report breaches of the approved protocol to the HREC.
2. The EO of the HREC is the person nominated to receive 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 EO of the HREC will notify the Chair of the HREC of the report as soon as possible.
4. EO of HREC will notify any other institutional HRECs that have approved the project of the report as soon as possible.

Investigation

5. The Chair of the HREC will examine the report of a breach and determine whether the breach warrants a further investigation. Where there is to be no further investigation the Chair of the HREC will inform the PI(s).
6. Where the Chair determines that the breach warrants a further investigation the Chair will notify the Director of Performance DOHWA of the breach. The Director of Performance will convene an Incident Review Committee to investigate the breach and determine the consequences.
7. The Director of Performance DOHWA or the Director's delegate will chair the Incident Review Committee. The membership of the committee will include the Chair of the HREC or delegate, and other members with appropriate expertise as required.
8. The Incident Review Committee will 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 will take no longer than 2 weeks from the time of notification of the incident, 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 will notify the responsible institution and the PI(s) that the project must be suspended.
10. Where the reported incident concerns the conduct of the any person other than the PI(s) the Incident Review Committee will notify that person of the report and will 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 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; and
 - 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;
 - Counselling on security practices;
 - Amendments to the approved protocol;
 - Suspension or cancellation of DOHWA 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 DOHWA either for a 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; and
 - Reporting allegations of criminal conduct to the police.
14. The Chair of the Incident Review Committee 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.

15. The Chair of the Incident Review Committee will notify the 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 will report to the DG of the DOHWA on the outcome of the investigation and the consequences.
17. The 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 PI(s) if ethical approval for the project is withdrawn.
18. If the PI(s) or any other person for whom there is an individual consequence is not satisfied with the outcome of the investigation he or she may refer the matter to the DG of the DOHWA.
19. The DG of the DOHWA will review the report of the Incident Review Committee and decide whether and what further action is required and inform the PI(s) or any other person affected and the Chair of HREC of that decision.
20. If the PI(s) or any other person affected is not satisfied with the decision of the DG of the DOHWA, 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. The provisions of this SOP will apply to projects approved by the CHIC.

19. Concerns and Complaints about the Conduct of a Project

Reference Number: SOP19

Purpose: To describe the mechanism for receiving, handling and responding to concerns and complaints in the conduct of a project approved by the HREC

Reporting

1. The HREC will require, as a condition of approval of each project, that the researchers immediately report to the EO of HREC any concerns or complaints received.
2. The EO of HREC is the person nominated to receive concerns and complaints from participants in research or members of the public about the conduct of projects approved by the HREC.
3. The EO of HREC is responsible for obtaining, in writing, the grounds of the concern or complaint. The EO of the HREC will notify the Chair of the HREC of the report as soon as possible.
4. The EO of the HREC will send an acknowledgment to the complainant outlining the mechanism for investigating the concern or complaint.
5. The EO of the HREC will report the concern or complaint to any other institutional HREC that have approved the project.

Investigation

6. The Chair of the HREC will examine the concern or complaint and determine whether the concern or complaint warrants a further investigation. Where there is to be no further investigation the Chair of the HREC will inform the complainant.
7. Where the Chair determines that the concern or complaint warrants a further investigation the Chair will notify the Director of Performance DOHWA of the complaint. The Director of Performance DOHWA will convene an Incident Review Committee to investigate and determine the consequences.
8. The Director of Performance DOHWA or the Director's delegate will chair the Incident Review Committee. The membership of the committee will also include the Chair of the HREC or delegate, and other members with appropriate expertise as required.
9. The EO of the HREC will send a letter of notification to the PI(s) of any concern or complaint about a project received by the HREC outlining the mechanism for investigating the concern or complaint. Where the complaint concerns the conduct of the any other person the Incident Review Committee will also notify that person.
10. The Incident Review Committee will immediately instigate an investigation into the concern or complaint. The Incident Review Committee may co-operate with any other institution or HREC concerned with the project to investigate the breach and may conduct a joint investigation. The investigation will take no longer than 2 weeks from the time of notification for the concern or complaint, unless exceptional circumstances exist.

11. 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 will notify the responsible institution and the PI(s) that the project must be suspended.
12. The Incident Review Committee will give the complainant and the PI(s) an opportunity to make submissions. Where the complaint concerns the conduct of any other person the Incident Review Committee will also provide that person with an opportunity to make submissions.
13. 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

14. If the Incident Review Committee is satisfied that the concern or 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; and
 - Whether any breach of the approved protocol, which may be established, was inadvertent, negligent or intentional.
15. The possible consequences include the following:
 - Notation on the file of the occurrence of the matter;
 - Increased monitoring of the project;
 - Counselling on security practices;
 - Amendments to the approved protocol;
 - Suspension or cancellation of DOHWA approval of the project (with the immediate return or destruction of all data file);
 - Exclusion of particular individuals responsible for any breach of the approved protocol, which may be established, from future access to personal health information provided by the DOHWA either for a period of time or indefinitely;
 - 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
 - Reporting allegations of criminal conduct to the police.
16. The Chair of the Incident Review Committee will notify the responsible institution, the PI(s) and any other person for whom there is an individual consequence of the outcome of the investigation and the consequences in writing.

17. The Chair of the Incident Review Committee will notify the HREC and any other institutional HRECs concerned with the project of the outcome of the investigation and the consequences.
18. The HREC may review the ethical approval of any project in the light of the outcome of the investigation of any breach or complaint and will notify the responsible institution and the PI(s) if ethical approval for the project is withdrawn.
19. The Chair of the Incident Review Committee will send a written report of the outcome of the investigation and the consequences to the complainant.
20. If the complainant is not satisfied with the outcome he or she may refer the complaint to the DG of the DOHWA.
21. The DG of the DOHWA will review the decision of Director of Performance DOHWA and/or the report of the Incident Review Committee and decide whether and what further action is required and inform the complainant and the Chair of the HREC of that decision.
22. If the complainant is not satisfied with the decision of the DG of the DOHWA, 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.
23. The provisions of this SOP will apply to projects approved by the CHIC.

20. Complaints About the Review or Rejection of an Application

Reference Number: SOP20

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

Reporting

1. The EO of the HREC is the person nominated to receive any complaints or concerns about the HREC's review processes or the rejection of an application. The EO of the HREC is responsible for obtaining, in writing, the grounds of the concern or complaint and notifying the DG of the DOHWA and the Chair of the HREC.
2. The EO of the HREC will send an acknowledgment to the complainant outlining the mechanism for investigating the concern or complaint.
3. The Chair of the HREC will instigate an investigation of the complaint and its validity, and make a recommendation to the HREC on the appropriate course of action. This investigation shall take no longer than two weeks from the time of notification of the complaint or concern, unless exceptional circumstances exist.
4. If the complainant is not satisfied with the outcome of the Chair's investigation, then he/she can refer the complaint to the DG of the DOHWA, or his/her nominee, or request the Chair to do so.
5. The Chair will provide the DG of the DOHWA with all relevant information about the complaint or concern, including;
 - Details of the concern or complaint;
 - Material reviewed in the investigation;
 - The results of the investigation;
 - The recommended course of action; and
 - Any other relevant documentation.
6. The DG of the DOHWA will determine whether there is a further investigation of the concern or complaint. Where there is to be no further investigation the DG of the DOHWA will inform the complainant and the Chair of DOHWA HREC.
7. If there is to be a further investigation, then the DG of the DOHWA will establish a panel to consider the concern or complaint. The panel will include, at least, the following members:
 - The DG of the DOHWA or his or her nominee as the convenor of the panel;
 - Two nominees of the DG of the DOHWA (who are not members of DOHWA HREC);
 - A person experienced in the ethical review of research projects (who is not a member of the DOHWA HREC); and

- Where the complaint concerns the rejection of an application, an expert in the discipline of research of the project under consideration.
8. The panel will give the complainant and the Chair or nominee of the HREC 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.
 9. The panel will ascertain whether the HREC acted in accordance with its TOR, SOP, the *National Statement on Ethical Conduct in Human Research* and otherwise acted in a fair and unbiased manner.
 10. The DG of the DOHWA will notify the complainant and the HREC of the outcome of the investigation. The outcomes may include:
 - Dismissing the concern or complaint; or
 - Referring the concern or complaint back to the HREC for reconsideration in the light of the findings of the panel.
 11. If the HREC is requested to review its decision, then the outcome of this review by the HREC will be final. The panel or the DG of the DOHWA cannot substitute its approval for the approval of the HREC.
 12. The panel may also make recommendations about the operation of the HREC including:
 - Review of the TOR; and
 - Review of the committee membership.
 13. If the complainant is not satisfied with the outcome of the panel's investigation, then he/she can refer the complaint to the Ombudsman Western Australia. The Ombudsman may conduct a procedural review of the decision of the HREC and the review panel.

21. Review of Standard Operating Procedures and Terms of Reference

Reference Number: SOP21

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

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



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