Bayside Health

Alfred Hospital Ethics Committee

Standard Operating Procedures (SOPs)

Standard Operating Procedure	Bayside Health
Document Number: 1.3	
Title: Ethics Committee member - appointment process	
Author: Nicole Rosenow	**Creation Date:** November 2013

1. Purpose

To describe the procedures for appointing members to the Ethics Committee

2. Applicability

Alfred Hospital Ethics Committee, Bayside Health (Alfred Care Group) Director of Research, Bayside Health CEO, Office of Ethics and Research Governance (ERGO).

To be read in conjunction with the Terms of Reference (TOR).

3. Background

The National Statement[1] requires procedures be in place for the appointment of committee members. This procedure relates to the appointment process for new members and re-appointment process for existing members.

Renewal of appointment is:

- based on a member's ability to comply with the Ethics Committee's 'Obligations of Members' document (referred to as "Obligations")
- subject to a member submitting an expression of interest for renewal of appointment
- by recommendation of the Chair of the Ethics Committee (EC), Chair of the Research Review Sub-committee (RRC) and Chair of the Health & Social Sciences (HSS) Group
- at the discretion of the Bayside Health CEO.

4. Procedure

NEW MEMBER APPOINTMENT PROCESS

New members are sought when either a vacancy arises or there is a need to address imbalance in the Committee.

New members for the role of **lay member** or **lawyer** are typically recruited through external advertising. The Chair of the Ethics Committee may use their discretion to waive the advertising requirement (e.g. if a vacancy needs to be filled as a matter of urgency).

A position description and advertisement are forwarded to the Bayside Health (Alfred Care Group) Workforce Department. Consideration is given to the best placement of the advertisement. Queries relating to the advertised position are addressed by the ERGO Manager.

A short list is created from the applications by the ERGO Manager. Applicants not short-listed are advised by email. The applicant/s are required to attend an interview.

There are several avenues for the recruitment of **pastoral care** members. The pastoral care service at Bayside Health (Alfred Care Group) has a service coordinator and a function of the service coordinator's position is to be a member of the Ethics Committee. The service coordinator may suggest a replacement if they are not able to fulfill the role. Other avenues are through targeted advertising or expressions of interest and word of mouth. In these instances the applicant is required to provide a CV and attend an interview.

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New members for the roles of **knowledge and experience in professional care** and **current research experience relevant to research proposals** are recruited through expressions of interest and word of mouth. In this instance the applicant is required to provide a CV and attend an interview.

Interview
The interview panel is selected. The minimum requirement is one of the Chairs of the Ethics Committee and the ERGO Manager.

A date and venue for the interview are confirmed and the short listed applicants invited for interview.

A decision about the appointment is made. The Chair of the Ethics Committee is informed if they were not on the interview panel.

Interviewed applicants who are not successful are advised by phone or email.

Provisional membership
Provisional membership is offered to the successful applicant. Provisional membership is for three Ethics Committee meetings unless the Chair deems otherwise (i.e. three meetings must be attended, whether consecutive or not, before full membership can be determined).

A provisional member is provided with the following information:
-dates of the Ethics Committee meetings
-Obligations of members
-Terms of Reference (TOR)
-website address
-map of the Alfred Research Alliance precinct and instructions on parking
-links to the National Statement[1] and the Code[2]
-induction process
-information about MS Teams (for on-line meetings)

A provisional member is introduced to the Ethics Committee members at the first meeting they attend.

If a provisional member is unable to attend three meetings or it becomes apparent they will be unable to fulfil the obligations or do the tasks required, suitability to become a full member will discussed by the ERGO Manager.

After three meetings have been attended (generally at the third meeting) and if the provisional member still wants to be considered for full appointment, the Ethics Committee will be asked to vote on full membership. The provisional member, if in attendance, is requested to leave the room for the vote. The provisional member will be informally advised of the outcome.

Full membership

The ERGO Manager will provide the Bayside Health CEO with a recommendation on full membership and a signed Letter of Appointment is sent from the CEO's Office if the recommendation is accepted. The HREC Member Indemnity is also provided.
The letter of appointment states an expectation that the Obligations will be met and is accompanied by the indemnity statement.

RENEWAL OF APPOINTMENT PROCESS

At the end of each calendar year members are advised to submit an expression of interest if they wish to renew their appointment.
Members are sent an email, along with the Obligations.

Members who do not submit an expression of interest are sent a letter to confirm that they do not wish to seek reappointment and to thank the member for their time on the Ethics Committee.

Members who do submit an expression of interest must also indicate that they are able to comply with the Obligations.

Members who submit an expression of interest but are unable to attend Ethics Meetings may be considered for a Non-sitting Membership to assist the Ethics Committee meet the requirements of the National Statement[1], or membership of the Inducted Member Pool (as per National Statement, 5.1.34).

Members may request up to twelve months leave of absence.

A meeting of the Committee Chairs (Chair of the EC, Chair of the RRC, Chair of the HSS Committee and Secretary of the EC) is held to go through the expressions of interest. Each expression is looked at and a recommendation made. The Chairs consider attendance record, completion and quality of reviews, and perceived ability to comply with the Obligations. The Chairs aim for a balance in the composition that best serves the National Statement[1].

The recommendations are provided to the Bayside Health CEO.

Those whose expression of interest is not accepted (i.e. rejected) are sent a letter from the Bayside Health CEO advising they have not been appointed.

Those whose expression of interest is accepted are sent a signed Letter of Appointment by the Bayside Health CEO.
The Letter of Appointment is either:

- Member with full obligations*
- Non-sitting member with obligations except those pertaining to attendance at meetings*

- Inducted Member Pool member with obligations pertaining to the review of research, attendance at meetings if required, provision of expertise – as negotiated with the individual*
- Member granted leave of absence

*The HREC Member Indemnity is provided along with the letter.

Appointment of Chair

The Chair is appointed by the Bayside Health CEO.

Obligations

Once the letter of appointment is received, the Member must then log into the ERA system to complete a statement confirming compliance with the Obligations (retained in the ERA system) and access the current Declaration of Relevant Interests form to complete and provide to the Ethics Committee Secretary (filed with Membership records).

5. References

1. National Statement on Ethical Conduct in Human Research (2025)
2. Australian Code for the Responsible Conduct of Research (2018)

6. Key Documents

7. Terms of Reference
   Obligations of members
   Declaration of Relevant Interests
   Indemnity
   Letters of Appointment (Member, Non-sitting member, Inducted Member Pool, Leave of absence)

Creation Date	Nov 2013
Review Date	Dec 2015
Review Date	Mar 2021
Review Date	Feb 2024
Review Date	Aug 2025
Review Date	May 2026

Standard Operating Procedure	Bayside Health
Document Number: 1.6	
Title: Induction of Ethics Committee members	
Author: Emily Bingle and Nicole Rosenow	**Creation Date: Nov 2013**

1. Purpose

To explain the induction and orientation processes for new Alfred Hospital Ethics Committee members.

2. Scope

All provisional Ethics Committee members ("New Members").

3. Applicability

Ethics Committee (EC) and Office of Ethics and Research Governance staff (ERGO).

4. Background

The National Statement[1] requires procedures be in place for the induction and continuing education of new committee members. This procedure relates to the induction process.

5. Procedure

- After receiving provisional membership information, an appointment is made with the New Member for an induction meeting. The meeting is held with the ERGO Manager and/or Ethics Officer(s) and aims to explain the EC member responsibilities, the EC processes and procedures.
- In person: New Members are introduced to ERGO staff and may be taken on a brief tour of the hospital including car parking.
- Online: New Members may be introduced to ERGO staff at a Teams staff meeting.
- New Members are asked to complete a confidentiality agreement.
- The provisional membership period is for attendance at three EC meetings (usually a 3-month period).
- New Members are provided with an Ethics Research Administration (ERA) log in and password. If they already have an account as a researcher they will be given access as a 'Reviewer' and 'HREC member' (ERA business rules ensure that they only have access to 'researcher viewable' comments for projects on which they are a researcher).
- New Members are provided with the relevant documents (including a reviewer guide and review template options) and may access projects for review prior to the Ethics Committee meetings. Whilst they are not given specific projects to review in the provisional period, they are encouraged to read the project applications and may contribute comments.
- Following the 3-month provisional membership period, New Members are asked if they wish to be considered for appointment, and if they do, the EC decides on full membership. If full membership is granted New Members receive a letter of appointment.
- Inexperienced New Members begin to review specific projects assigned to them as a "primary reviewer" in tandem with an experienced EC member for approximately two months (two review cycles), after which they conduct reviews independently. In the first month they are usually only given one project to review.
- New Members may approach the ERGO with queries and are encouraged to reflect on their reviews and any training requirements they may have.
- New members are encouraged to undertake further training. This may be attending internal or external sessions or taking part in formal online education. New Members may be given preference to attend courses such as the Intensive Ethics courses offered by Monash University or undertake online training with Praxis Australia.

6. References

1. National Statement on Ethical Conduct in Research (2025)

Creation Date	Nov 2013
Review Date	Sept 2021
Review Date	May 2024
Review Date	Sept 2025
Review Date	June 2026

Standard Operating Procedure	Bayside Health
Document Number: 1.7	
Title: Recording attendance at Ethics Committee Meetings	
Author: Nicole Rosenow, Kordula Dunscombe	**Creation Date: Nov 2013**

1. **Purpose**
   To describe how attendance at Ethics Committee Meetings is recorded.

2. **Scope**
   Monthly Ethics Committee Meeting.

3. **Applicability**
   Office of Ethics and Research Governance (ERGO), Alfred Hospital Ethics Committee.

4. **Procedure**
   4.1 For in-person Ethics committee meetings, ERGO are responsible for printing a monthly attendance sheet that is taken to the Ethics Committee meeting.

   4.2 For in-person meetings, Ethics Committee Members are asked to 'sign-in' on the monthly attendance sheet. This requires stating time of arrival as well as providing a signature. Members who leave the meeting early are to state their departure time.

   4.3 When meetings are held via MS Teams the attendance sheet is completed by the secretary and is also captured by the meeting program.

   4.4 Attendance is recorded by the secretary as a Key Performance Indicator for the Ethics Committee.

   4.5 ERGO are responsible for providing attendance figures to the Chairs of the Ethics Committee, Research Review Committee, D&I and H&SS groups, and to the Director of Research for the calendar year.

   4.6 An EC member attendance list, "quorum list", is routinely provided for clinical trials. EC member attendance lists can be provided to researchers upon request.

   4.7 The attendance sheet is used for attendance payments to Ethics Committee Members.

   4.8 Attendance of observers is recorded on the attendance sheet and in the Minutes, including that the observer signed a confidentiality agreement.

5. **Key Documents**
   Attendance Record
   Committee KPI Spreadsheet
   Confidentiality Agreement for meeting observers

Creation Date	Nov 2013
Review Date	Dec 2015
Review Date	Aug 2020
Review Date	May 2024
Review Date	Oct 2025
Review Date	June 2026

Standard Operating Procedure	Bayside Health
Document Number: 1.7	
Title: Recording attendance at Ethics Committee Meetings	
Author: Nicole Rosenow, Kordula Dunscombe	**Creation Date: Nov 2013**

Standard Operating Procedure	Bayside Health
Document Number: 2.2	
Title: Recording Research Proposals	
Author: Nicole Rosenow	**Creation Date: Aug 2013**

1. Purpose

To describe the recording of research proposals received by the Ethics and Research Governance Office (ERGO) for Alfred Health authorisation as an accepting site project or for submission and review of applications made to the Alfred Hospital Ethics Committee (Ethics Committee).

2. Scope

All research proposals.

3. Applicability

Researchers, Ethics Committee members and ERGO

4. Background

The National Statement on Ethical Conduct in Human Research (Chapters 5.1 and 5.2)[1] states procedures should be in place for record keeping. Recording research proposals is part of the record keeping.

5. Procedure

<u>Application for ethics review (Low Risk and Standard HREC review)</u>

5.1 Once a research application is received by the Ethics and Research Governance Office the research application is entered into the EthicsResDB research database (the database) and a container is created in the Ethics and Research Administration (ERA) system.

5.2 A unique project number is given to the project in the database. The Alfred project number should be used by the researchers in all correspondence regarding that research project.

5.3 Database

Project details are entered into the database "projects" listing using the unique project number. The detailed information is added to the "project details" and other tabs including:

- Researchers
- Financial
- Legal Documents
- EC meetings
- Funding
- Sites
- Radiation
- Sponsor details

5.4 ERA

Project details are entered to create a container. These include:

- Title of the project
- Short title

- Protocol number
- Centralised ethics number
- Level of review, Ethics Committee sub-committee allocation and administrator
- Name of the Principal Researcher, co-researcher/contact person
- Lead and participating site/s
- Review type (corresponding to RRC meetings and Ethics Committee meetings)
- Review expiry date
- HREC approval date
- Site authorisation date
- Special conditions of approval

5.5 For projects reviewed by the Alfred Hospital Ethics Committee, reviewer details and the meeting date are added. The ERA system updates for Research Review Committee and Ethics Committee meeting dates, whereas the database only contains the Ethics Committee meeting date. Meeting dates may be altered for projects that are delayed or require re-submission.

5.6 The ethics application and all relevant documents are uploaded into the ERA system.

5.7 The ERA system is able to identify the status of the project at any given point during the review process. (e.g. Awaiting researcher response, Ready for HREC).

5.8 Applications that receive ethics approval have an approval date entered. The status on ERA is updated to reflect ethics approval. Applications that are withdrawn have a withdrawn status entered in the database and ERA. Applications that are not approved are labelled NOT APPROVED in the database and ERA.

5.9 The site authorisation date is entered into the database once site authorisation has been given. ERA status is updated to reflect project authorisation.

5.10 A full copy of the application, scientific, ethics and governance reviews, correspondence to researchers and researcher's responses, independent reviews (where applicable), legal reviews, radiation reports, re-submissions, approval certificate and authorisation letter (if applicable) are retained in the ERA system and may also be retained in sub-folders in the Bayside Health (Alfred Care Group) server under the unique project number.

5.11 All applications made prior to 2014 are stored in subfolders on the Bayside Health (Alfred Care Group) server under the local project number. When amendments are submitted for projects that pre-date 2014, the ERA project container is created and documents uploaded as required.

5.12 Approval certificates can be generated from the ERGO templates and ERA, and populated with the key document types to be listed for approval (e.g. Protocol,

Participant Information and Consent Forms, recruitment and advertising materials, questionnaires, scales, CRFs. etc.).

Application for exempt for review

5.13 A copy of the request and correspondence to the researcher is retained in a sub-folder within the Projects/exemptions folder under the year the application is made. A unique project number is not allocated.

Endorsement to become or continue as an authorised prescriber

5.14 A copy of the application, reviews and correspondence to the researcher including endorsement letter where made, is retained in a sub-folder within the Authorised Prescriber folder under the year the application is made. A unique project number is not allocated.

Discarded tissue applications (pre-2014)

5.15 A copy of the application, reviews and correspondence to the researcher including approval letters, has been retained in a sub-folder within the Tissue folder under the year the application was made. A unique project number was allocated and information recorded in the research database (Project title, source of tissue, names of the Principal Researchers, co-researchers, research coordinators/assistants and research students.)

6. References

1. National Statement on Ethical Conduct in Research (2025)

Creation Date	Aug 2013
Review Date	Dec 2015
Review Date	Aug 2020
Review Date	Mar 2025
Review Date	June 2026

Standard Operating Procedure	Bayside Health
Document Number: 2.5	
Title: Standard HREC review and approval	
Author: Nicole Rosenow, Kordula Dunscombe	**Creation Date: August 2013**

1. **Purpose**
   To describe the procedure for review and approval of standard HREC research proposals.

2. **Scope**
   All research proposals.

3. **Applicability**
   Researchers, Ethics Committee Members and Office of Ethics and Research Governance staff (ERGO).

4. **Procedure**

4.1 Project registration

To register an application a researcher needs to submit the application by the project registration date. Electronic signatures are not necessary at this stage. Forms (e.g. HREA, VSM) completed online need to be provided as a document, rather than using the online submission process. Documents required for governance review are not required for registration but may be included. Missing documentation (for HREC review) should be stated.

The application will be checked for completeness by the ERGO and any omissions or changes requested will be conveyed to the researcher. The researcher will also receive detailed submission instructions including a unique project number and the date for full project submission.

4.2 Project submission

The full application including signatures, radiation assessments and changes requested during the registration screening must be uploaded into ERA by the project full submission date. Researchers are encouraged to submit governance documentation for site assessment at the same time as ethics documentation for concurrent review.

4.3 Review

Ethics applications are made available for review by the Ethics Committee (EC) and the Research Review Committee (RRC) members on the ERA system at least one week before the RRC meeting. When assigning projects to EC and RRC reviewers, the ERGO will refer to the Declarations of Relevant Interests Spreadsheet to ensure that members are not assigned projects in which they might have a competing interest.

The reviewers are added to ERA and the status of the project is changed to 'project awaiting review'.

The ERA system then sends an automatic email alert to the reviewers to let them know there is an application review which includes the due date.

4.4 Review of Drugs & Interventions (D&I) applications

RRC members receive only drugs and interventions applications, e.g. drug and device trials (including CTN) and more invasive interventional studies.

Members may review all project applications, but each project in this category is assigned to two` members for review.

The ERGO prepares the list of projects and allocates reviewers. This list is sent to the HREC Chair for final review. They may ask for changes. The RRC Allocation Lists are stored in EthicsRes/Ethics/Research Review Committee/Allocations/Year.

One "primary" reviewer and one "secondary" reviewer is assigned from the RRC to undertake the detailed scientific review. One secondary reviewer is assigned to comment on the acceptability of assigned projects.

Each project is assigned a 'lay' reviewer (member with a community perspective, pastoral care or lawyer). Comments by Ethics Committee members who are not members of the RRC are considered by the RRC members at the RRC meeting.

An independent expert review may be required for studies that involve unknown or very high risk to participants, such as new procedures, devices or drugs with known safety issues or an unknown safety profile, as in first-in-human studies.

The reviews are made available to the researchers via ERA and responses requiring further examination are dealt with by the reviewers in the week leading up to the main Ethics Committee meeting.

Prior to the meeting, the ERGO allocates a spokesperson for each project. This is usually either the primary or secondary reviewer. The list is sent to the HREC Chair for final review. The reviewers are notified via email which includes the list of projects and the allocated spokesperson for each project.

4.5 Review of Health & Social Science (H&SS) applications (including multi-site Low Risk applications)

Each project in these categories are usually assigned to two members to conduct a detailed review. If review of the project requires particular expertise, opinion may be sought from outside experts.

The ERGO prepares the list of reviewers. This is saved in the CD folder on the H drive.
The designated reviewers provide feedback via ERA two weeks before the Ethics Committee meeting. The reviews are made available to the researchers via ERA. The researcher's responses are then submitted in ERA and considered by the reviewers in the week leading up to the main Ethics Committee meeting.

Interviews may be requested for any project.

Approximately one week before the meeting, the H&SS Chair prepares a summary of the new applications that will be reviewed at the meeting (the 'Chair's Summary). This is included as an attachment to the agenda. The summary provides an overview of each application including the questions from the primary reviewers, responses from the researchers and flags

any outstanding ethical concerns or questions. The H&SS group can review the summary in preparation for the meeting. The Chair's summary includes the name of the reviewer who is nominated as the spokesperson for each project.

4.6 Main Ethics Committee meeting

Before the main meeting, all Ethics Committee members are sent an alert advising the agenda, agenda items and updated applications are available through ERA.

Projects for interview are usually considered by all Ethics Committee members.

After general business, the Ethics Committee splits into two groups, one to discuss the D&I applications and the other H&SS applications. Each sub-committee is fully constituted according to the National Statement on Ethical Conduct in Human Research (2025)[1].

Primary reviewers will have had the opportunity to review and comment on the researchers' responses and any issues they may have are presented at the meeting for discussion.

For each D&I project the spokesperson will raise any outstanding issues from the RRC review and provide the RRC recommendation on the project. The lay member will also be asked if the issues they had raised had been satisfactorily addressed.

For each H&SS project, the H&SS Chair will nominate a reviewer as spokesperson to provide an overview of the research, summarise issues raised by the reviewers and the researchers' responses, and identify any outstanding issues.

For all applications, comments from other members are called for and absentee comments are taken into account.

4.7 Project outcomes (compliance NS 5.2.11 -5.2.14)

Following the Main Ethics Committee Meeting researchers are notified of the outcome of the ethics review which may be to:

i) approve the application with or without special conditions; or
ii) approve the application subject to conditions and/or modification that need to be met before approval can be granted; or
iii) defer the application for further consideration following receipt of additional information
iv) not approve the application.

Projects approved 'subject to' may be reviewed post Ethics Committee Meeting by the relevant EC group or reviewers from within the group or by the Office of Ethics and Research Governance staff. Responses to significant issues will be referred to the Chair of the relevant group or the primary reviewers for their review and recommendation for final approval.

Where a project has been deferred for further consideration, the Ethics Committee may choose to delegate the authority to review that information and approve the project between meetings. Delegation may be to:

- Chair or Deputy Chair
- Chair or Deputy Chair with one or more named members (present at the Meeting or who provided documented comments on the application)
- Special sub-group of nominated members of the Ethics Committee

In such circumstances the Ethics Committee is informed of the final decision at the next meeting where approval, if granted, will be ratified.

4.8 Project approval

An ethics approval certificate will be issued once there are no further issues.
The approval date is recorded on ERA and in the research database, and the status on ERA will display ethics approval
Approval is ongoing, but will lapse if a progress report is not received by the anniversary of the approval date, or is not deemed satisfactory by the Ethics Committee.
Projects are subject to audit as part of monitoring requirements.

5. References

1. National Statement on Ethical Conduct in Research (2025)

Creation Date	August 2013
Review Date	Dec 2015
Review Date	Aug 2020
Review Date	Nov 2020
Review Date	May 2025
Review Date	June 2026

Standard Operating Procedure	Bayside Health
Document Number: 2.12	
Title: Format of Ethics Committee Meetings	
Author: Nicole Rosenow, Kordula Dunscombe	**Creation Date: August 2013**

1. Purpose

To describe the format of the Ethics Committee (EC) Meeting.

2. Applicability

Ethics Committee Members and Office of Ethics and Research Governance staff (ERGO)

3. Background

The Ethics Committee considers the ethical implications of all proposed research projects involving human participants and determines whether or not they are acceptable on ethical grounds. The Ethics Committee reviews research applications in accordance with the NHMRC National Statement on Ethical Conduct in Human Research. The Ethics Committee comprises two groups; the Drugs and Interventions group and the Health and Social Science group. Each group has the minimum membership required by the National Statement.

4. Procedure

4.1 The EC meets on a regular basis, which is normally at monthly intervals (usually the fourth Thursday each month). The Committee will meet at least 11 times each year. Meeting dates are available on the website.

4.2 Members attend the EC Meetings via MS Teams or in person (when face-to-face meetings are scheduled).

4.3 The meeting invitations are usually sent one week before the schedule meeting.

4.4 Meetings are scheduled to commence at a specific time and continue until all agenda items have been considered. The meeting time and location are stated on the agenda.

4.5 The EC Meeting is conducted in private to ensure confidentiality and open discussion. The meetings are not recorded.

4.6 Requests to be a visitor or observer are considered by the Chair of the EC prior to the EC Meeting. The requestor is required to provide their CV to assist in assessing whether or not their attendance is appropriate.

4.7 Visitors or observers are required to maintain confidentiality and sign a confidentiality agreement. By invitation of the Chair, others may attend as a resource or in an advisory capacity. In the event an expert is required to attend a meeting, the expert will be required to maintain confidentiality and sign a confidentiality agreement.

4.8 The EC Meeting is conducted in two parts:

- The first part is conducted with all EC members and covers the agenda items of attendance, apologies, minutes, matters arising from minutes, business, other business and the next meeting.
- The second part splits the full EC into its two groups to cover business arising, project applications and other business. The D&I group also consider the notes

from the RRC meeting. One group leaves the main meeting and re-convenes in a separate Teams meeting or meeting room when the full EC splits.

4.9 The EC may invite researchers to attend an interview to discuss their proposed research. Interviews are scheduled for a specific time and researchers attending for interview are advised of the time and Meeting format. Researchers must join the Teams Meeting at the agreed time or wait until invited to enter the meeting room. Interviews may involve the full EC or be conducted by one of the two groups.

4.10 The ERGO tries to ensure at least one member in each category intends to attend the EC Meeting for each group:

- a Chairperson
- at least two members who bring a broader community or consumer perspective, who have no paid affiliation with Bayside Health and are not currently involved in medical, or legal work
- two members with current research experience, that is relevant to the type of research to be considered at the meetings
- a member with knowledge of, and current experience in, the professional care, counselling or treatment of people, a nurse or allied health professional
- a member who performs a pastoral care role in a community
- a lawyer

4.11 Members who are unable to attend a meeting are required to contribute prior to the meeting with reviews posted on ERA. Absentee comments are encouraged and may be provided via email, phone or ERA. Reviews and absentee comments must be received prior to the meeting so they may be discussed by the members present. Views of those absent are considered at the EC Meeting.

4.12 Members have access to ERA throughout the meeting.

4.13 The proceedings are recorded by Ethics Officers from the ERGO. Decisions on project applications are made by consensus, or by majority vote if a consensus cannot be reached.

4.14 EC member attendance is recorded in the minutes for each EC Meeting and overall attendance for the calendar year is reported to the institution on an annual basis. An EC member attendance list, “quorum list”, is routinely provided to researchers with projects reviewed by the D&I group. EC member attendance lists can be provided to researchers upon request.

4.15 Catering and parking is arranged by the Office of Ethics and Research Governance.

5. References

1. National Statement on Ethical Conduct in Research (2025)

Standard Operating Procedure	Bayside Health
Document Number: 2.12	
Title: Format of Ethics Committee Meetings	
Author: Nicole Rosenow, Kordula Dunscombe	**Creation Date: August 2013**

Review Date	Dec 2015
Review Date	Aug 2020
Review Date	June 2026

Standard Operating Procedure	Bayside Health
Document Number: 2.13	
Title: Preparation of EC Agenda	
Author: Nicole Rosenow, Kordula Dunscombe	**Creation Date: August 2013**

1. Purpose

To describe the process and format of the Ethics Committee (EC) Meeting agenda.

2. Applicability

Ethics Committee Members and Office of Ethics and Research Governance staff (ERGO).

3. Background

The Ethics Committee considers the ethical implications of all proposed research projects involving human participants and determines whether or not they are acceptable on ethical grounds. The Ethics Committee reviews research applications in accordance with the NHMRC National Statement on Ethical Conduct in Human Research. The Ethics Committee comprises two groups; the Drugs and Interventions group and the Health and Social Science group.

4. Procedure

4.1 The ERGO is responsible for preparing an agenda for each EC Meeting.

4.2 The meeting agenda and associated documents are prepared by the ERGO and made available to members via ERA approximately one week prior to the EC meeting.

4.3 All complete applications submitted by the project submission date are included on the agenda for EC consideration at its next meeting.

4.4 Documentation received after the closing date and essential to project review will be made available/circulated to members. Non-essential documentation may be tabled at the meeting at the discretion of the EC Chair, RRC Chair or H&SS Chairs.

4.5 Agenda Items include:

- Members
- Apologies
- Training and/or presentations
- Minutes
- Business from previous applications
- Business
    - Declaration of conflicts of interest (including a list of the local and international commercial sponsors of projects under consideration)
    - Approved amendments (for ratification of approval)
    - Approved low risk applications (for ratification of approval)
    - Low Risk applications for which a waiver of the requirement for consent was approved (for ratification of the consent waiver)
    - Report or Notes of Research Ethical Issues Sub-Committee Meeting
    - Interviews (if relevant for full EC)
    - Items of general business
- Other Business
- Next Meeting
- Split List Activities

  - H&SS list activities
  - D&I list activities
- Health & Social Sciences list activities
  - Business Arising
  - Projects for consideration (H&SS projects and Low Risk Multi-site projects being submitted via the NMA single ethical review scheme)
  - Ratification of approval of applications requiring expedited ethical review outside of the usual review cycle in special circumstances
  - Other Business
- Drugs & Interventions list activities
  - Notes of Research Review Committee Meeting
  - Business Arising
  - Drugs & interventions applications for approval
  - Ratification of approval of applications requiring expedited ethical review outside of the usual review cycle in special circumstances
  - Other Business

4.6 The agenda is stored electronically by month in the year subfolder of the EC folder and is also on ERA in the meetings section. The ERA agenda includes a 'live' list of projects that is current at the time of the meeting, but subject to change after the meeting as projects move through the review and status cycle. The Secretary saves a pdf copy of the 'live' agenda on the day of the meeting.

4.7 All documents relating to projects under consideration are stored on ERA in the individual project containers, and can be accessed via the Meeting tab.

4.8 Documents relevant to specific agenda items are uploaded into the 'Details' tab of the meeting on ERA.

4.9 All documentation is confidential.

5. Key Documents

Agenda template

Agenda creation instructions (see Ethics Committee/Agenda/Agenda SOP folder in H Drive)

Creation Date	August 2013
Review Date	Dec 2015
Review Date	Aug 2020
Review Date	May 2025
Review Date	June 2026

Standard Operating Procedure	Bayside Health
Document Number: 2.14	
Title: Preparation of EC Minutes	
Author: Nicole Rosenow, Kordula Dunscombe	**Creation Date: August 2013**

1. Purpose

To describe the process and format of the Ethics Committee (EC) Meeting minutes.

2. Applicability

Ethics Committee Members and Office of Ethics and Research Governance staff (ERGO).

3. Background

The Ethics Committee considers the ethical implications of all proposed research projects involving human participants and determines whether or not they are acceptable on ethical grounds. The Ethics Committee reviews research applications in accordance with the NHMRC National Statement on Ethical Conduct in Human Research. The Ethics Committee comprises two groups; the Drugs and Interventions group and the Health and Social Science group.

4. Procedure

4.1 The ERGO is responsible for preparing minutes of each EC Meeting. Each ERGO staff member is responsible for recording minutes related to agenda items and projects that they are responsible for.

4.2 The minutes include:

- Members present
- Apologies
- Members on 'Leave of Absence'
- Observers
- New members (see 4.3)
- Training and presentation outline (if relevant)
- Minutes, approval of previous EC meeting minutes
- Business arising from previous minutes
- Business
    - Conflicts of Interest (record of interests declared)
    - Approved amendments (ratification of approval)
    - Approved low risk applications (ratification of approval)
    - Approved Low Risk applications with consent waiver (ratification of waiver)
    - Notes of Research Ethical Issues Sub-Committee (endorsement of Notes and recommendations)
    - Interview (if relevant)
- Other Business
- Next Meeting
- Split List Activities
    - HSS
        - Business Arising
        - Project Applications
        - Ratification of approval of applications requiring expedited ethical review outside of the usual review cycle in special circumstances
        - Other Business
    - D&I

- Acceptance of Research Review Committee Meeting Notes for that month
- Business Arising
- Project Applications
- Ratification of approval of applications requiring expedited ethical review outside of the usual review cycle in special circumstances
- Other Business

4.3 The minutes record when new members commence their probationary period and the outcomes of a vote at the end of the probationary period to determine full membership. The minutes also record member resignations.

4.4 The minutes record observers and the requirement to sign confidentiality agreements.

4.5 The minutes record ratification of approved amendments and low risk applications.

4.6 The minutes record endorsement where the Ethics Committee has decided to accept the review of another Ethics Committee or performed limited review based on prior approval having been granted by another Ethics Committee.

4.7 For each project application, the minutes record that a summary of the project was provided, relevant discussion, and reference views expressed by absent members. The minutes record ethical issues and in particular decisions made about substitute consent processes (e.g. by Medical Treatment Decision Maker) and requests for waivers of the requirement for consent.

4.8 For each application, a decision is recorded. Decisions are either “approved”, “approved subject to corrections”, “deferred” or “rejected”. The minutes record requests for additional information, clarification and modification of the project.

4.9 Particular views are not to be attributed to particular individuals, except where a member wishes to have their opinion recorded.

4.10 Declaration of conflict of interests (potential or actual) and management of conflict of interests (including leaving the room) are recorded at the beginning of the meeting, for particular business items and/or against relevant project applications.

4.11 Record meeting closure time for each group

4.12 The minutes are stored electronically by month in the year subfolder of the EC folder, and also with the meeting documents on ERA.

4.13 The minutes are reviewed by the Manager of the ERGO for accuracy prior to being circulated to Ethics Members as an agenda item for approval at the subsequent Ethics Committee Meeting.

5. References

1. National Statement on Ethical Conduct in Research (2025)

Creation Date	August 2013
Review Date	Dec 2015
Review Date	Aug 2020
Review Date	May 2025
Review Date	June 2026

Standard Operating Procedure	Bayside Health
Document Number: 2.15	
Title: Communicating with researchers during review of new applications	
Author: Nicole Rosenow, Kordula Dunscombe	**Creation Date: Sept 2013**

1. Purpose

To describe the procedure for communicating with researchers throughout the review process of new applications.

To describe the procedure for notifying decisions of the ethics committee concerning review of new applications.

2. Scope

All research undergoing standard review by HREC.

3. Applicability

Ethics Committee members, RRC members, Office of Ethics and Research Governance staff (ERGO), researchers

4. Background

The Ethics Committee considers the ethical implications of all proposed research projects involving human participants and determines whether or not they are acceptable on ethical grounds. The Ethics Committee reviews research applications in accordance with the NHMRC National Statement on Ethical Conduct in Human Research. The National Statement requires procedures be in place for communicating with researchers. This procedure is in relation to review of new applications.

5. Procedure

5.1 Researchers receive communication about their new applications at the following time points:

a. Screening. In the week of project registration, the ERGO provides researchers with feedback about the completeness of their application and any inconsistencies, and advises of the requirements for full submission. Communication is timely to enable researchers to address the points by full submission date.

b. Following review by the RRC and the pre-meeting review by EC primary and secondary reviewers, the ERGO conveys comments and requests for changes or clarifications to the researchers. Communication is within one day of the RRC Meeting/due date for Ethics Committee reviews to allow researchers time to address the points by 'submission for inclusion in the EC Meeting agenda' date.

c. Following the EC Meeting. The ERGO communicates the outcome of the Ethics Committee discussion, and any remaining matters to be addressed, to the researchers within 5 working days of the meeting unless otherwise notified.

5.2 Communication is sent to the Principal Investigator (PI) and the contact person for the ethics application (if not the PI) via the 'Comments' on ERA, and in some cases via email. Email communication should be copied into the ERA comments for the relevant project.

5.3 If the Ethics Committee determines that further information, clarification or modification is required the correspondence articulates the reason/s for the determination and outlines what is required. Where possible, reference will be made to the National Statement or relevant legislation.

5.4 If the researchers fail to provide any response at point (a) there will be no full submission and the project application cannot be reviewed. Failure to submit the full application will result in the project being moved to the next month and the researchers are advised of the new submission dates. Failure to provide a full submission within 6 months may result in a record made in the database of 'withdrawn' and the status on ERA changed to withdrawn.

5.5 If the researchers fail to provide any response at point (b) the project will be moved to the next month and the researchers are advised of the new submission dates. Failure to respond within 3 months (unless extenuating circumstances exist) will result in the application being withdrawn and a record made in the database of 'withdrawn' prior to EC meeting but after partial review, and the status on ERA changed to withdrawn. If researchers wish for their application to be reviewed it would need to be resubmitted at a later date.

5.6 If the researchers fail to provide any response at time point (c) within 3 months the project will be withdrawn (unless extenuating circumstances exist) and a record made in the database of 'withdrawn' after review/ prior to approval and the status on ERA changed to withdrawn. If researchers wish for their application to be reviewed it will need to be resubmitted at a later date.

5.7 The Ethics Committee endeavours to openly communicate with researchers to resolve outstanding requests relating to ethical issues. The Ethics Committee may communicate directly with the researchers by inviting the researcher to attend an Ethics Committee Meeting or, if following an Ethics Committee Meeting, a special sub-committee meeting outside of the review cycle. Researchers cannot request the identity of the primary or secondary reviewers with the purpose of contacting them directly. Researchers cannot demand a meeting with the Ethics Committee or demand to present for interview.

5.8 ERGO will notify researchers when an application is granted ethics approval (once any outstanding requests have been satisfactorily resolved). An ethics approval certificate is provided to document approval.

5.9 Certificate templates have been developed for either single site (non-NMA approval) and multi-site NMA approval. The certificates include project details and the option to add approved documents, documents that are acknowledged and the participating sites, etc. The certificates also include all possible options for conditions of approval and special conditions, depending on the project requirements.

5.10 All projects involving Bayside Health (Alfred Care Group) site(s) undergo Site Specific Assessment (governance review), even those that are single site applications. The governance review may be completed in tandem with the ethical review however the authorisation letter is issued as a separate document.

5.11 If the Ethics Committee determines that a project is to be rejected the researcher is notified in writing of the reasons and includes reasons linked to the National Statement.

6. References

1. National Statement on Ethical Conduct in Research (2025)

Creation Date	Sept 2013
Review Date	Dec 2015
Review Date	Aug 2020
Review Date	May 2025
Review Date	June 2026

Standard Operating Procedure	Bayside Health
Document Number: 2.17	
Title: Conflict of Interests – recording and reporting	
Author: Nicole Rosenow, Kordula Dunscombe	**Creation Date: Nov 2013**

1. **Purpose**
   To describe the recording processes for Conflict of Interests declarations.

2. **Scope**
   Declarations made by researchers, Alfred Hospital Ethics Committee members and advisors to the Ethics Committee (Research Review Committee Members).

3. **Applicability**
   Office of Ethics and Research Governance (ERGO).

4. **Background**
   The National Statement (Chapter 5.2.24 and 5.6) requires procedures be in place for the identification and management of conflict of interests. Separate guidelines exist for researcher declarations (including institutional conflict) and ethics committee member declarations. This procedure relates to the recording of declarations and supports the guidelines.

5. **Procedure**

   5.1 <u>Declaration at Time of Appointment – Ethics Committee and Research Review Committee Members</u>
   The Declaration of Relevant Interests form is provided to Members at the time the appointment letter is provided. Members must complete and return this is to the Ethics Committee Secretary.

   The declaration is stored on computer in a secure and confidential file. Interests declared are recorded in a password-protected spreadsheet, accessible to ERGO staff. The purpose of this spreadsheet is a reference when assigning applications to reviewers, to help ensure that reviewers do not receive an application for review in which they might have a competing interest.

   5.2 <u>Change to Declaration During Appointment – Ethics Committee and Research Review Committee Members</u>
   The change should be notified to the Ethics Committee Secretary within one month by way of an updated Declaration of Relevant Interests form or via email.

   The declaration or email is stored on computer in a secure and confidential file and recorded in the password-protected spreadsheet.

   5.3 <u>Declaration During Ethics Committee Meeting – Ethics Committee Members</u>
   Members are asked to declare competing interests as an item of EC business. A list of the commercial sponsors (international and local) of projects for discussion at the meeting is included on the agenda. The Ethics Officers minute any declaration and the management strategy.

   Members may also declare competing interests as projects or matters arise. The Ethics Officers minute the declaration and the management strategy.

Declarations and management strategy are recorded in the EthicsRes DB Database.

5.4 <u>Declaration during Research Review Committee Meeting – Research Review Committee Members</u>

Members are asked to declare competing interests as projects are presented for discussion. The Ethics Officers note the declaration and the management strategy.

Declarations and management strategy are recorded in the EthicsRes DB Database.

5.5 <u>Declarations – Researchers and Institutions</u>

Conflict of interests may be reported at the time of the ethics submission or SSA submission and during the review cycle or reported as a change to the project if already approved/authorised. Declarations and correspondence are stored with the project documentation. The ERGO records the conflict and the management strategy in the Database.

The process for recording the management of researcher and institution conflicts of interests is set out in Research Governance SOP 3.6: 'Conflicts of interest – recording management'.

6. Management strategy

Management strategies are set out in the Bayside Health (Alfred Care Group) 'Conflicts of Interest in Research' Guideline, which is applicable to Bayside Health (Alfred Care Group) employees (full time, part time, casual, agency, honorary and contract) conducting research. Management of non-Bayside Health (Alfred Care Group) researcher and institutional competing interests (for projects reviewed by the Alfred Hospital Ethics Committee) follows the same strategies.

7. References

1. National Statement on Ethical Conduct in Research (2025)

8. Key Documents

Declaration of Relevant Interests Form
Obligations of Members
Bayside Health (Alfred Care Group) 'Conflicts of Interests in Research' Guideline
Research Governance Standard Operating Procedure 3.6: Conflicts of interest – recording management

Creation Date	Nov 2013
Review Date	Dec 2015
Review Date	Aug 2020
Review Date	May 2025
Review Date	June 2026

Standard Operating Procedure	Bayside Health
Document Number: 2.21	
Title: Appeals process	
Author: Emily Bingle	**Creation Date: January 2014**

1. Purpose

To describe the process by which appeals from researchers about Alfred Hospital Ethics Committee (EC) decisions are managed.

2. Scope

Decisions made by the Research Review Committee (RRC) and the EC about new project applications or amendment applications.

3. Applicability

Researchers, Office of Ethics and Research Governance staff (ERGO), Director of Research, Chairs of the RRC and EC.

4. Background

The National Statement does not provide guidelines for an appeals process about an Ethics Committee's final decision to reject a proposal. 'Appeals' about decisions made by EC reviewers during the review process should be managed with good open communication with the intention to resolve issues about research proposals before a final decision by the EC.

The following procedure is specifically for appeals from researchers about a decision to recommend rejection of an application or amendment from the RRC or rejection of an application or amendment made by the EC. The procedure may also apply to any conditions of approval issued by the EC.

5. Procedure

5.1 The request for an appeal is to be emailed to the manager of ERGO by the Principal Investigator. The email should include an outline of the reason for the appeal and why it is justified. In the case of an amendment, the researcher should outline how the Ethics Committee's decision impacts on the approved study. Where a project is sponsored, evidence of correspondence/discussion with the sponsor should also be provided.

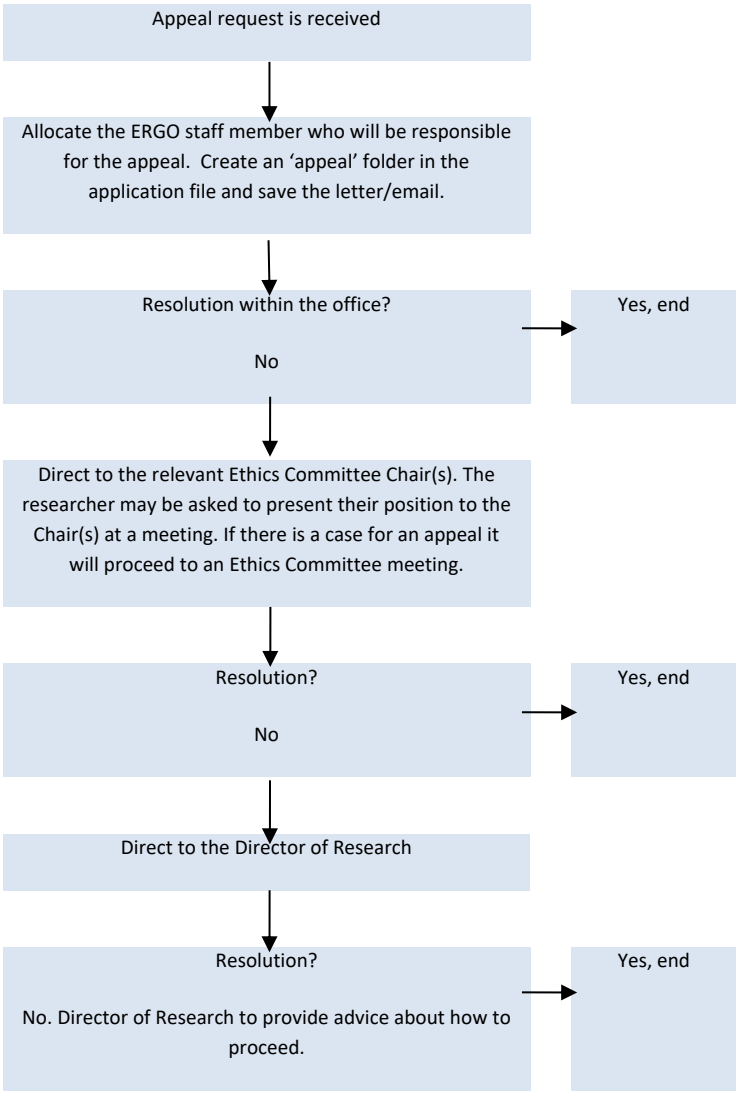
5.2 The ERGO manager may delegate the appeal to an Ethics Officer and/or Research Governance Officer.

5.3 ERGO staff member to assess the scope of the appeal and take the action outlined in the flow chart. An interview/meeting may be arranged with the researchers and the Chair(s).

5.4 All processes and decisions are to be documented and saved in the relevant folder as outlined in the flow chart.

5.5 Every effort should be made to resolve appeals within a reasonable timeframe as circumstances dictate.

Standard Operating Procedure	Bayside Health
Document Number: 2.21	
Title: Appeals process	
Author: Emily Bingle	**Creation Date: January 2014**



Appeals Process Flowchart

Creation Date	Jan 2014
Review Date	Dec 2015
Review Date	Apr 2024
Review Date	July 2026
Review Date	

Standard Operating Procedure	Bayside Health
Document Number: 2.26	
Title: Ethics review for external researchers	
Author: J McNeil, K Dunscombe, ERGO	**Creation Date: Feb 2023**

1. Purpose

To set out the process for dealing with requests for the Alfred Hospital Ethics Committee to undertake an ethics review of research being conducted by external researchers.

2. Scope

Requests from researchers with no affiliation with Bayside Health ('external researchers') and where

- there is no formal Agreement in place for the Alfred Hospital Ethics Committee to undertake a review (e.g. under NMA, Alfred Research Alliance, Monash Partners).
- The site is a private site which is not covered under NMA.

3. Applicability

Office of Ethics & Research Governance

4. Background

From time to time ERGO is approached by researchers who do not have access to an ethics committee asking whether the Alfred Hospital Ethics Committee (EC) could conduct the ethics review of their research project. These requests require careful consideration: such reviews potentially involve additional risks for the EC because of the 'unknown' nature of the researchers, site/s, research governance arrangements, etc.

The Ethics Committee has developed a position statement on such requests – 'Ethics review of research projects from other organisations' – which is accessible to potential applicants on the Ethics & Research Governance website
https://www.alfredhealth.org.au/research/ethics-research-governance/ethics-applications

5. Procedure

1. If initial enquiry received by phone:
   Applicants should be asked to email a 'request for ethics review of an external research project' to research@alfred.org.au and include brief information about themselves, their organisation and a summary of their research project, including:
   - the nature of risks arising from the project
   - the suitability of the site to be undertaking the project
   - the suitability, qualifications and experience of the principal investigator
   - the nature of the sponsorship arrangements (e.g. investigator initiated or commercially sponsored)
   - whether the site has a process for administrative oversight of research
   - the transparency of the funding arrangements (e.g. payments will not be directly made to individual researchers)
   - a Protocol/Research Proposal may be requested at the ERGO staff member's discretion. Note that there may be commercial in-confidence issues.

2. If initial enquiry received by email:
   One of the ERGO staff members to acknowledge the request and (if not included already) ask for information as per (1) above.
3. Email with the required information to be forwarded by the ERGO staff member to a Chair of the relevant EC group (D&I. H&SS, Low Risk). The ERGO Manager is also to be copied in.
4. Review fee will be as per Fees Schedule.
5. The ERGO staff member to contact researchers for more information if required for the Chair to make a decision about accepting the project.
6. Final decision to be communicated to the applicant by the ERGO staff member.
7. Information and correspondence relating to the initial enquiry, including decision to review or decline, to be saved on the H drive in EthicsRes/Ethics/Private sites reviewed by Alfred EC/Initial enquiries from external applicants/[in a sub-folder labelled with organisation and date received].
8. Requests will be considered on a project by project basis. If an external researcher submits (or intends to submit) further requests, a formal Agreement/MOU for HREC review may be required (to be discussed with Manager and the Bayside Health Legal Office if this situation arises).

If accepted for review:

9. Details to be added to the Excel spreadsheet **Private Sites included in Applications Reviewed by the Alfred Hospital Ethics Committee** on the H drive in EthicsRes/Ethics/Private sites reviewed by Alfred EC.
10. Application documents to be submitted as per the standard requirements for that type of application. In addition, if the principal researcher is acting in a private capacity, they must provide written confirmation that their insurance covers them for research.
11. Reviewers and EC to be advised that the application is from an external researcher when the project is reviewed and discussed.
12. Low Risk applications to go to H&SS group for discussion as for a full application.

6. References

1. National Statement on Ethical Conduct in Research (2025)

Creation Date	Feb 2023
Review Date	June 2026
Review Date	
Review Date	
Review Date	

Standard Operating Procedure	Bayside Health
Document Number: 3.3	
Title: Safety Monitoring and Reporting	
Author: Nicole Rosenow	**Creation Date: Oct 2013**

1. **Purpose**

To describe the procedures adopted by the Alfred Hospital Ethics Committee and Research Review Sub-committee (RRC), collectively 'the HREC', supporting the National Health and Medical Research Council's Safety monitoring and reporting in clinical trials involving therapeutic goods (2016). Supplementary guidance on related aspects of safety monitoring are also available.

Whilst the guidance document specifically refers to clinical trials involving therapeutic goods, the guidance has been adopted for all interventional studies submitted to the HREC for review.

Whilst it is the responsibility of the Principal Investigator to capture, assess and report all adverse events to the Sponsor and the Institution in accordance with the Protocol and local requirements, it is the Sponsor who has the primary responsibility of evaluating the safety information obtained from investigators and other sources and to communicate this information and its impact on patient safety, trial conduct or trial documentation to investigators, HRECs and the TGA as required.

The sponsor is responsible for communicating safety information to the reviewing Ethics Committee and the Co-ordinating or Site Principal Investigator.

The Co-ordinating or Site Principal Investigator is responsible for reporting to the institution.

2. **Scope**

Research reviewed by the Alfred Hospital Ethics Committee.

3. **Applicability**

Office of Ethics and Research Governance staff (ERGO).

4. **Procedure**

The role of the HREC is to assess the adequacy of the Sponsor's safety monitoring arrangements with respect to the risk, size and complexity of the trial and to evaluate these in light of new information about the risks and benefits.

The HREC fulfils this obligation through its review of the following:

a. **The safety monitoring plan:**

All applications submitted to the Ethics Committee are required to include in the protocol a safety monitoring plan which clearly describes:

- The assessment and management of risk
- Safety reporting definitions, procedures, responsibilities and reporting timelines, including where relevant, notifying the TGA
- Any serious adverse events that do not require immediate reporting

- The composition, roles and responsibilities of oversight committees set out in a committee charter
- Plans for ongoing safety monitoring

b. Reports from Data Safety Monitoring Boards (DSMBs) and/or Safety Monitors

The HREC considers reports from data and safety monitoring boards or other safety monitors. The timing of these reports should be in accordance with any monitoring and reporting arrangements requested/approved by the Committee for that project.

The reports are to be submitted to ERGO via ERA or email.

If a review is required, the reports are reviewed by a member of the RRC as per delegation from the Ethics Committee. This is usually the Chair of the HREC and/or primary reviewers of the project.

Any recommendations from the review of the event are to be forwarded to the researchers.

The details of the reports and reviews are recorded in the ERGO SQL database and acknowledged accordingly.

c. Updated Investigator's Brochures (IBs), Product Information (PI) and Executive Summaries of the Development Safety Update Reports (DSURs)

Updated IBs or Product Information (where applicable), or the executive summary of DSURs are to be submitted to the HREC along with an impact statement from the Co-ordinating or Site Principal Investigator advising whether or not, the changes may have an impact on study participants.

Sponsors are required to update IBs at least annually and when new and relevant information becomes available. Product Information and the executive summary of the DSUR should also be updated as required.

Updated IBs, PIs and DSUR Executive Summary are to be submitted with the Amendment Request Form to ERGO via ERA and are reviewed by a member of the RRC as per delegation from the Ethics Committee. This is usually the Chair of the HREC and/or primary reviewers of the project.

Any recommendations from the review of the event are to be forwarded to the researchers via ERA. The event may trigger the need for an amendment, particularly if further information should be included in the PICF or protocol.

Researchers and ERGO staff should retain the documents, approvals/acknowledgements and correspondence. ERGO retain information in ERA along with the details entered into the amendments section of the SQL database.

An approval/acknowledgement is to be provided to the researchers using the appropriate template. Approvals/acknowledgements are uploaded into ERA.

d. Annual Safety Reports

The annual safety report which includes a clear summary of the evolving safety profile of the trial should be accompanied by a statement from the Principal Investigator advising whether, or not, there may be any impact on study participants. The annual safety report is to be submitted once the Sponsor makes it available to the researchers.

The Alfred Hospital Ethics Committee has the discretion to request more frequent reporting for specific trials.

The Annual Safety Report form is available on the ERGO website. The DSUR Executive Summary is not considered appropriate as it does not meet the requirement of providing a clear summary of the evolving safety profile of the trial.

The Annual Safety Report form is to be submitted to ERGO via email or uploaded to ERA. If required, the report is reviewed by a member of the RRC as per delegation from the Ethics Committee. This is usually the Chair of the HREC and/or primary reviewers of the project.

Any recommendations from the review of the event are to be forwarded to the researchers via ERA.

Researchers and ERGO staff should retain the documents, acknowledgements and correspondence. ERGO retain information in ERA along with the details entered into the SQL database.

An acknowledgement is to be provided to the researchers using the appropriate template. Approvals/acknowledgements are uploaded into ERA.

e. Significant Safety Issues (SSIs) and Urgent Safety Measures (USMs)

A Significant Safety Issue (SSI) is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. An Urgent Safety Measure (USM) is a measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety; is a type of SSI.

Urgent safety measures (USMs) must be reported to the HREC within 72 hours of knowledge of the event. Other significant safety issues (SSIs) must be reported to the HREC within 15 calendar days of the sponsor instigating or being made aware of the issue.

Researchers are responsible for notifying the HREC of an SSI and/or USM by completing an Safety Report Form and submitting to ERGO either via email or uploaded into ERA. The form should be completed with sufficient information and context and signed by the Co-ordinating or Site Principal Investigator.

Identifiable participant information should not be included in the report or supporting information, and sponsor's reports are not required in the first instance, unless the information is essential to understanding the event.

Researchers should ensure adequate information is provided to assist the review of the safety report. Information includes how many participants are impacted by the safety issue, whether participants have been informed or are to be informed and the plan for informing them, and what action needs to be taken.

Urgent safety measures may be implemented without prior ethics or site review. Participants may be given safety information verbally prior to the provision of any written information. Researchers who provide urgent safety information verbally must document the discussion in the patient's medical record.

All SSIs and USMs are reviewed by a member of the RRC as per delegation from the Ethics Committee. This is usually the Chair of the HREC and/or primary reviewers of the project.

If the significant safety issues or urgent safety measures has occurred in a study conducted at the Bayside Health (Alfred Care Group), the report may also be sent to the Director of Research for review and assessment of continuance of the project.

An SSI occurring at Bayside Health (Alfred Care Group), may need reporting in the incident management system, Riskman. Researchers should refer to Prompt for the current guideline and reporting requirements.

Researchers may be required to provide further information and are provided with an acknowledgement of receipt of the report.

Researchers and ERGO staff should retain reports, acknowledgements and correspondence. ERGO retain information in the monitoring section of the project file along with the details entered into the safety event section of the SQL database. If the report has been submitted in ERA, the documents and correspondence are retained in the system.

An acknowledgement of receipt is to be provided to the researchers using the appropriate acknowledgement template if emailed to ERGO. The acknowledgement templates also allow for requests for additional information, clarification, action or follow-up reports. Acknowledgements are sent or uploaded into ERA as a pdf.

Any recommendations from the review of the event are to be forwarded to the researchers. The event may be presented to the Ethics Committee at the next meeting and any discussion recorded in the meeting minutes.

The event may trigger the need for an amendment, particularly if further information should be included in the PICF or protocol.

f. SUSARs and USADEs:

A Suspected Unexpected Serious Adverse Reaction (SUSAR) is an adverse reaction that is both serious and unexpected with a possible relationship to the study drug. The event should be considered unexpected or unanticipated if the nature, severity or frequency of that event is not consistent with the information on the Investigator's Brochure, device information or in the current Australian Product Information.

An Unanticipated Serious Adverse Device Effect (USADE) is a serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

A SUSAR or USADE may also be submitted to the HREC for review. Researchers are responsible for notifying the HREC of an SSI and/or USM by completing an Safety Report Form and submitting to ERGO either via email or uploaded into ERA. The form should be completed with sufficient information and context and signed by the Co-ordinating or Site Principal Investigator. Researchers should ensure adequate information is provided to assist the review of the safety report

Identifiable participant information should not be included in the report or supporting information, and sponsor's reports are not required in the first instance, unless the information is essential to understanding the event.

All SUSARs/USADEs are reviewed by a member of the RRC as per delegation from the Ethics Committee. This is usually the Chair of the HREC and/or primary reviewers of the project. The event may be presented to the Ethics Committee at the next meeting and any discussion recorded in the meeting minutes.

Researchers may be required to provide further information and are provided with an acknowledgement of receipt of the report.

Any recommendations from the review of the event are to be forwarded to the researchers. The event may be presented to the Ethics Committee at the next meeting and any discussion recorded in the meeting minutes.

The event may trigger the need for an amendment, particularly if further information should be included in the PICF or protocol.

If the SUSAR/USADE has occurred in a study conducted at the Bayside Health (Alfred Care Group), the report may also be sent to the Director of Research for review and assessment of continuance of the project.

A SUSAR/USADE occurring at Bayside Health (Alfred Care Group) may need reporting in the incident management system, (Riskman). Researchers should see Prompt for the current guideline and reporting requirements.

Researchers and ERGO staff should retain reports, acknowledgements and correspondence. ERGO retain information in the monitoring section of the project file along with the details entered into the safety event section of the SQL database. If the report has been submitted in ERA, the documents and correspondence are retained in the system. An acknowledgement of receipt is to be provided to the researchers using the appropriate acknowledgement template.

Local SUSARs/USADEs occurring in studies conducted at Bayside Health (Alfred Care Group) must be reported to Bayside Health (Alfred Care Group) Legal Counsel and the VMIA. Occasionally a project may present with an SAE not attributed to a drug or device but to a study related procedure and may constitute a potential legal/compensation risk. VMIA may need to be consulted to check whether they wish to receive information on the event.

g. Suspension or 'hold'

The Co-ordinating or Principal Investigator is responsible for informing the HREC if the research project is to be formally suspended e.g. FDA hold. This may be a result of safety issues.

Researchers should provide information on the nature of the hold (stopping further recruitment, no further enrolment/randomisation, no further dosing or dose escalation), the number of participants impacted and plans for those participants.

Researchers may be required to provide further information and are provided with an acknowledgement of receipt of the correspondence.

Suspension or a hold of a study conducted at Bayside Health (Alfred Care Group) will be notified to the Director of Research.

Any recommendations from the review of the event are to be forwarded to the researchers. The event may be presented to the Ethics Committee at the next meeting and any discussion recorded in the meeting minutes.

The event may trigger the need for an amendment, particularly if further information should be included in the PICF or protocol.

The suspension or hold is recorded in the SQL database.

h. Serious Breaches

A Serious Breach is a breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree:

a) The safety or rights of a trial participant, or
b) The reliability and robustness of the data generated in the clinical trial.

A Suspected Breach is a report that is judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor.

The role of an HREC in reviewing serious breaches is to evaluate the impact of the serious breach on the continued ethical acceptability of the study and to satisfy itself that the serious breach is managed appropriately. An amendment may be required.

Serious breaches may raise issues on which ethical advice is required such as if participants should be reconsented if a report of a serious breach has identified inadequacies in the consent process. HRECs may also assess whether any corrective and/or preventative actions implemented or planned are appropriate and have adequately addressed the underlying issue.

For trials conducted under the CTX/CTN Scheme, the HREC should inform the TGA and the sponsor if the notification of a serious breach leads to the suspension or withdrawal of the ethics approval for the trial.

Researchers are responsible for notifying the HREC of a serious breach within 7 calendar days by completing a Serious Breach Form and submitting to ERGO either via email or uploaded into ERA. Serious breaches occurring at Bayside Health (Alfred Care Group) should be reported within 72 hours.

The form should be completed with sufficient information and context and signed by the Co-ordinating or Site Principal Investigator. Researchers should ensure adequate information is provided to assist the review of the safety report

Identifiable participant information should not be included in the report or supporting information, and sponsor's reports are not required in the first instance, unless the information is essential to understanding the event.

All serious breaches are reviewed by a member of the RRC as per delegation from the Ethics Committee. This is usually the Chair of the HREC and/or primary reviewers of the project. The event may be presented to the Ethics Committee at the next meeting and any discussion recorded in the meeting minutes.

Researchers may be required to provide further information and are provided with an acknowledgement of receipt of the report.

Any recommendations from the review of the event are to be forwarded to the researchers. The event may be presented to the Ethics Committee at the next meeting and any discussion recorded in the meeting minutes.

Researchers and ERGO staff should retain reports, acknowledgements and correspondence. ERGO retain information in the monitoring section of the project file along with the details entered into the breaches section of the SQL database. If the report has been submitted in ERA, the documents and correspondence are retained in the system. An acknowledgement

of receipt is to be provided to the researchers using the appropriate acknowledgement template.

If the serious breach has occurred in a study conducted at the Bayside Health (Alfred Care Group), the report may also be sent to the Director of Research for review and assessment of continuance of the project.

All serious breaches occurring at Bayside Health (Alfred Care Group) may need reporting in the incident management system, Riskman. Researchers should see Prompt for the current guideline and reporting requirements.

The HREC may also consider non-serious and/or suspected breaches. In the event that a serious breach has occurred and the sponsor of the research does not agree or is unwilling to report the breach to the Ethics Committee, a suspected breach report form can be completed. Non-serious breaches are to be reported on the non-serious breach report form.

i. Other Adverse Events or Incidents

These are reported by the researcher to ERGO and are reviewed by a member of the Ethics Committee. This is usually the Chair of the HREC and/or primary reviewers of the project. The event may be presented to the Ethics Committee at the next meeting and any discussion recorded in the meeting minutes.

The researchers may be asked for further information or plans of action. Any recommendations from the review of the event are to be forwarded to the researchers. Event details are recorded in the project file and SQL database.

5. References

- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (2016).
- NHMRC Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (2018)
- Alfred Hospital Ethics Committee Safety monitoring and reporting requirements document (2017)
- NHMRC National Statement on Ethical Conduct in Human Research (2025)

6. Key Documents

Safety Report Form
Annual Safety Report Form
Amendment Request Form
Serious Breach form
Suspected Breach Form
Non-serious Breach Form

Standard Operating Procedure	Bayside Health
Document Number: 3.3	
Title: Safety Monitoring and Reporting	
Author: Nicole Rosenow	**Creation Date: Oct 2013**

Creation Date	Oct 2013
Review Date	Jan 2016
Review Date	July 2026
Review Date	
Review Date	

Standard Operating Procedure	Bayside Health
Document Number: 3.7	
Title: Monitoring of approved research by the Alfred Hospital Ethics Committee	
Author: Angela Henjak	**Creation Date: July 2026**

1. **Purpose**
   To describe the monitoring processes for studies approved by the Alfred Hospital Ethics Committee.

2. **Scope**
   Research reviewed by the Alfred Hospital Ethics Committee.

3. **Applicability**
   Alfred Hospital Ethics Committee, Ethics Officers, Director of Research

4. **Background**
   Chapter 5.4 of the NHMRC National Statement on Ethical Conduct in Human Research 2025 specifies that each institution has ultimate responsibility for ensuring, via its research governance arrangements, that all its approved research is monitored. The facets of monitoring include:
   - The review of annual progress reports
   - the review of safety events (please refer to SOP 3.3)
   - amendment applications
   - reports from bodies such as data and safety monitoring boards (please refer to SOP 3.3)
   - internal audits;
   - audits of research documentation by the institution or HREC;
   - interviews with researchers (please refer to SOP 2.12)
   - random or targeted inspections by sponsors or regulators;
   - feedback from participants
   - final reports

5. In addition to the requisite reporting of safety information, the National Statement also states that the granting of ethical approval for a research project must be on the condition that the researchers provide reports of the progress of the trial in accordance with the manner and form specified by the Reviewing HREC.

   This SOP deals with annual progress reporting; interviews with researchers; random or targeted inspections by sponsors or regulators and; final reports.

   Due to current limitations with resources, internal audits are not being conducted.

a. **Annual Progress Reports and Final Reports**
   Annual progress reporting is required for each research project reviewed by the Alfred Hospital Ethics Committee, regardless of level of risk, project progress or whether the project has commenced. The progress report should be submitted by the anniversary of HREC approval and completed to a satisfactory standard.

The Co-ordinating Site Principal or Site Principal Investigator is to submit the Annual Progress Report – Project Form in ERA. The system sends a reminder to the Principal Investigator and the contact person at the following times:

- 14 days prior to the anniversary of ethics approval
- 28 days after the anniversary of ethics approval
- 35 days after the anniversary of ethics approval
- 56 days after the anniversary of ethics approval

Current templates:

- Progress report – project form (HREC report form to cover all sites under the HREC's oversight)
- Ethical Review Manager (ERM) project progress report VIC (HREC report form to cover all sites under the HREC's oversight)

If a Bayside Health (Alfred Care Group) Sites are involved in the study, the following templates can also be used

- Progress report – site form (form to cover activities at one site)
- ERM site progress report (form to cover activities at one site)

The progress reporting scenarios table, available from the Bayside Health (Alfred Care Group) website, describes the various site and HREC combinations and the progress report templates required for each scenario.

Single site Alfred projects approved by the Committee may report using the HREC progress report form or the site progress report form.

Safety reports and safety committee/data safety committee (DMC/SMC/DSMB) reports are not substitutes for progress reports.

Tele-trial sites subcontracted under Bayside Health (Alfred Care Group) and approved by the Alfred Hospital Ethics Committee are required to report at the same time as the Bayside Health (Alfred Care Group) report. Figures for tele-trial sites need to be separate to figures for the main Alfred Health site. The same report form or separate report forms are acceptable.

Final reports are due at project completion, site closure or research discontinuation. Final reports may be submitted earlier than the anniversary date.

The Project Final Report and Site Closure Report make provision for publications, seminars and conferences at which the study findings were published or presented.

Self Audit Tool

A self-audit tool has been designed to help research personnel reflect on their research conduct and comply with guidelines for responsible research conduct. It is not mandatory, but recommended to be completed annually and retained in the researcher's study files.

There is no requirement for researchers to submit the self-audit tool to ERGO as self-reflection is individual. The self-audit tool is available from the AH website.

6. Procedure

Progress Reports

The Co-ordinating Principal Investigator or Site Principal Investigator (for single site applications) is responsible for reporting the progress of their research and for ensuring a progress report has been submitted to the Alfred Hospital Ethics Committee.

Templates are available for download from the Bayside Health (Alfred Care Group) website or from the ERM system.

Progress reports are submitted in the ERA system using the Progress Reports tab. Progress reports can be submitted in the ERM system.

If the project has insurance, a current insurance certificate should be included as part of the submission. In ERA, this needs to be uploaded as an amendment.

Final Reports

Final reports are due on the completion of a project, site closure in a multi-site streamlined review project or if the research is discontinued before the expected date of completion.

The project final report-site closure template should be completed and submitted. The form is available from the Bayside Health (Alfred Care Group) website or the ERM system. The form has options of selecting a single site closing or all sites closing.

Final reports are submitted in the ERA system using the Progress Reports tab. Final reports can be submitted in the ERM system.

Review, acknowledgement and record retention

All reports are reviewed by the ERGO for completeness, consistency with project details and signatures. A report without the CPI/PI/Sponsor signature cannot be accepted.

In ERA, reports are reviewed and queries arising from the review of a report are sent to the researcher using the comments feature.

Reports may be sent to the HREC for review if the report contains information which may be of relevance to the Committee. Publications may also be shared with the HREC.

All satisfactory reports are acknowledged. The acknowledgement template covers review by the Alfred Hospital Ethics Committee.

The template is stored internally and available through the certificate function in ERA. Reports in ERA will be acknowledged in ERA.

Reports in ERM will be acknowledged in ERM.

Researchers and the ERGO should retain reports, acknowledgements and correspondence. ERGO retains information in ERA. If the report has been processed in ERM, the documentation can be reproduced in ERA by downloading the reports from ERM and adding a submission to the ERA progress reporting section.

The ERGO administrator records details of the progress report in the SQL database.

Additional actions for final reports
In ERA, final site reports for external sites are processed in the amendments section. Only final reports for all sites under the Alfred Hospital Ethics Committee or the final site report for Bayside Health (Alfred Care Group) as a participating site are located in the final reports section.

Final reports can also be submitted in ERM.

For final reports for First-in-Human projects with an independent expert review, the date concluded should be added to the independent review register located on the internal system.

6. Key Documents

Progress and final report forms
Progress report acknowledgement template

b. Random or targeted inspections by sponsors or regulators

The institution, Bayside Health (Alfred Care Group), has a guideline on Sponsor and Regulatory Reports which outlines the process for the consideration of targeted inspections by sponsors and regulators.

The research team is responsible for forwarding a final audit report to ERGO for inclusion at the next meeting of the institution's research governance committee, the Research Leadership and Governance Committee meeting. The Committee will use the audit reports to monitor clinical trial performance and provide feedback to the clinical trial community. The Committee will use the findings as a quality improvement opportunity to build and promote learning and training activities, review resources, develop guidelines to support compliance with trial protocols, SOPs, GCP, and regulatory requirements.

If the clinical trial was reviewed by the Alfred Hospital Ethics Committee, the audit report will also be shared with the Chairs of the Alfred Hospital Ethics Committee.

6. Key Documents

- NHMRC National Statement on National Statement on Ethical Conduct in Human Research (2025)

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Review Date	
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