



1 PURPOSE & SCOPE

The purpose of this SOP is to outline the administrative steps involved in the ethical review of research projects and related items submitted to the Peter MacCallum Cancer Centre (Peter Mac) Ethics Committee.

This SOP applies to administrative duties related to the ethical review process. This SOP satisfies the requirements set out in the *National Statement on Ethical Conduct in Human Research (2007 and as amended)* (The National Statement).

This SOP applies to single site submissions for review by the Ethics Committee and multisite submissions where Peter Mac is the reviewing Ethics Committee.

For administration steps related to governance submissions refer to **Guideline001: Peter Mac Governance Review Requirements for Human Research**.

2 TARGET AUDIENCE

The target audience is Sponsors, Contract Research Organisations, Investigators, participating Institutions and their delegates, of research projects that will be reviewed or were approved by the Peter Mac Ethics Committee.

3 RELATED POLICY

POLICY 21.1.1 Responsible Conduct of Research

SOP001 Ethics Committee

SOP004 Monitoring of Ongoing Research

SOP006 Safety Reporting

4 DEFINITIONS

None.

5 RESPONSIBILITIES

The Ethics Committee Secretariat has delegation from the Ethics Committee to communicate decisions to researchers, on behalf of the Ethics Committee and its sub-committees and panels. It is the responsibility of the Ethics Committee Secretariat staff to ensure that all communication, review administration, decision recording, record keeping and archiving are confidential and performed in accordance with this SOP.

It is the responsibility of the Ethics Committee Secretariat to keep records securely and provide copies of records in response to requests, where appropriate.

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6 PROCEDURE

The following procedures describe the administrative steps for both single site and multisite ethical review of research. For multisite ethical review projects additional administrative steps may be required.

6.1 Receipt of Ethics Submissions

6.1.1 Receipt and Review of Research Projects

The due date for new project submissions is 14 calendar days prior to the Ethics Committee meeting.

Research projects are allocated to the appropriate level of review. Projects are allocated based on the type of research. Reference should be made to **Guideline002: Ethical Review Pathways and Submission Requirements** or the Ethics Committee Secretariat website <http://www.petermac.org/research> for further information.

Upon receipt of the project, pertinent project details must be entered into the relevant database/s for the purpose of data recording and tracking. A unique project number will be generated and an electronic project folder created for each proposal.

Once all queries/issues have been addressed to the satisfaction of the Ethics Committee the project may be approved. Refer to section 6.4.1.

6.1.2 Receipt and Review of Substantive Amendments/Urgent Amendments/Administrative Amendments

The due date for substantive amendment submissions is 7 calendar days prior to the review meeting.

Urgent amendments can be submitted at any time.

Administrative amendments can be submitted at any time.

Before an amendment can begin the review process it must first be allocated to the appropriate level of review. This is determined by the Ethics Committee Secretariat. Reference should be made to **SOP004 Monitoring of Ongoing Research** or the Ethics Committee Secretariat website <http://www.petermac.org/research> for further information.

Upon receipt of the amendment/urgent amendment/administrative amendment, pertinent details must be entered into the relevant database/s for the purpose of data recording and tracking.

Once all queries/issues have been addressed to the satisfaction of the Ethics Committee the amendment/urgent amendment/administrative amendment may be approved. Refer to section 6.4.2.

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6.1.3 Receipt and Review of Reply to Queries and Resubmissions

Reply to queries for new projects and amendments to approved projects that were provisionally approved subject to changes can be submitted at any time. The reply will be reviewed within 5 business days of receipt.

The due date for resubmission of not approved new projects and amendments to approved projects is 7 calendar days prior to the relevant review meeting.

The Ethics Committee Secretariat will receive all replies to queries and resubmissions submitted by the Coordinating Principal Investigator or Principal Investigator in response to Committee queries regarding the ethical review of a new project or an amendment. Reply to queries and resubmissions can be reviewed by the Ethics Committee Secretariat, Ethics Committee or sub-committee or panel members or at an Ethics Committee or sub-committee or panel meeting, as appropriate. Once all queries/issues have been addressed to the satisfaction of the Ethics Committee the project/amendment may be approved. Refer to section 6.4.1 and 6.4.2.

6.1.4 Receipt and Review of Progress Reports and Notification Items

The due date for progress reports and notification items is 7 calendar days prior to the Ethics Committee meeting.

Project progress reports, e.g. annual progress reports and final reports, and notification items, e.g. serious breach reports, project status/information updates, are received and handled in accordance with **SOP004 Monitoring of Ongoing Research**. Refer to SOP004 or the Ethics Committee Secretariat website <http://www.petermac.org/research> for further information.

6.1.5 Receipt and Review of Safety Related Reports

The due date for progress reports and notification items is 14 calendar days prior to the Ethics Committee meeting.

Significant Safety Issues, Annual Safety Reports, Investigator Brochures, Product Information, and other safety related reports are received and handled in accordance with **SOP006 Safety Reporting**. This may include review by the Ethics Committee and/or sub-committee as necessary. Refer to SOP006 or the Ethics Committee Secretariat website <http://www.petermac.org/research> for further information.

6.1.6 Receipt and Review of Other Correspondence

The due date for other correspondence is 14 calendar days prior to the Ethics Committee meeting.

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Each correspondence item is dealt with by the Ethics Committee Secretariat as appropriate. These items will be placed on the next Ethics Committee and/or sub-committee meeting agendas as necessary.

6.2 Creation and Distribution of Agendas

After the submission deadline for a given meeting, the Ethics Committee Secretariat will not accept further submissions for that meeting. Refer to the Ethics Committee website <http://www.petermac.org/research> for submission deadline dates. The Ethics Committee Secretariat is responsible for creating agendas for the Committee meetings according to agreed agenda templates.

Meeting agendas are prepared and distributed, along with all associated project documentation, to each member of the relevant committee no less than 4 clear calendar days prior to the meeting.

6.3 Creation of Meeting Minutes

Upon completion of each review meeting of the Ethics Committee, Clinical Research Committee, Tissue Research Management Committee and Low and Negligible Risk Research Ethical Review Committee minutes must be created according to an agreed template, outlining the decisions and outcomes of the meeting. Minutes are tabled at the next corresponding committee meeting.

6.4 Communication of Committee Decisions

6.4.1 New Projects

Decisions on new projects are communicated to researchers within 3 business days after the review date.

There are three possible outcomes that could arise from an ethical/scientific review of a new project. These three possibilities are:

Project is Approved

In the case where a project has been approved, an approval certificate must be created and sent to the Coordinating Principal Investigator (multisite submission) or Principal Investigator (single site submission).

Refer to Section 6.5.

Project is Approved, Subject to Changes

In the case where a project has been approved subject to changes, a memo detailing comments/queries/changes required must be sent to



the Coordinating Principal Investigator (multisite submission) or Principal Investigator (single site submission).

The Memo links the changes required to the relevant section of the National Statement.

Project is Not Approved/Resubmission Required

In the case where a project has not been approved, a memo detailing comments/queries/changes required must be sent to the Coordinating Principal Investigator (multisite submission) or Principal Investigator (single site submission).

The Memo links the changes required to the relevant section of the National Statement.

6.4.2 Amendments/Urgent Amendments/Administrative Amendments

6.4.2.1 Amendments

Decisions are communicated within 3 business days after the review date.

There are three possible outcomes that could arise from an ethical/scientific review of an amendment. These three possibilities are:

Amendment is Approved

In the case where an amendment has been approved, an approval memo must be created and sent to the Coordinating Principal Investigator (multisite submission) or Principal Investigator (single site submission).

Amendment is Approved, Subject to Changes

In the case where an amendment has been approved subject to changes, a memo detailing comments/queries/changes required must be sent to the Coordinating Principal Investigator (multisite submission) or Principal Investigator (single site submission).

The Memo links the changes required to the relevant section of the National Statement.

Amendment is Not Approved/Resubmission Required

In the case where an amendment has not been approved, a memo detailing comments/changes required must be sent to the



Coordinating Principal Investigator (multisite submission) or Principal Investigator (single site submission).

The Memo links the changes required to the relevant section of the National Statement.

6.4.2.2 Urgent Amendments

Urgent amendments are approved upon receipt by the Ethics Committee Secretariat.

An interim approval may be provided for an Urgent Amendment. A memo is sent out to the Coordinating Principal Investigator (multisite submission) or Principal Investigator (single site submission) stating that interim approval has been provided. After the provision of Interim Approval, the item is ratified by the Ethics Committee at the next Ethics Meeting. Following this, a ratification memo must be sent to the Coordinating Principal Investigator (multisite submission) or Principal Investigator (single site submission).

6.4.2.3

Administrative amendments are reviewed by the Ethics Committee Secretariat. Once any queries are resolved the amendment can be approved.

6.4.3 Progress Reports and Notification Items

Decisions are communicated within 10 business days after the review date.

After review project progress reports, e.g. annual progress reports and final reports, and notification items, e.g. serious breach reports, project status/information updates, are noted/acknowledged and filed or filed only in accordance with SOP004 – Monitoring of Ongoing Research.

6.4.4 Safety Reports

Decisions are communicated within 10 business days after the review date.

After review Significant Safety Issues, Annual Safety Reports, Investigator Brochures, Product Information, and other safety related reports are acknowledged in accordance with SOP006 Safety Reporting.

Queries will be sent to the Coordinating Principal Investigator (multisite submission) or Principal Investigator (single site submission).

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6.4.5 Other Correspondence

Decisions are communicated within 10 business days after the review date.

Any outcome regarding other correspondence will be communicated to the relevant parties as appropriate, via a formal memo.

4.5 Provision of Approval Certificates

Approvals are communicated within 3 business days after completion of all requirements.

Upon ethical approval, an approval will be created by the Ethics Committee Secretariat and sent to the Coordinating Principal Investigator (multisite submission) or Principal Investigator (single site submission). The approval contains details such as:

- Project name and number
- Approval date
- Participating sites (if applicable)
- A list of approved documents
- Conditions of ethical approval
- Reporting requirements

Where the Peter Mac Ethics Committee is acting as the ethical review committee for a multisite ethical review project, an Ethical Approval Certificate will be issued to the Coordinating Principal Investigator.

Please note that in order to commence a new research project at Peter Mac a Project Authorisation Certificate is required. Refer to **Guideline001: Peter Mac Governance Review Requirements for Human Research** for more information.

- For approved multisite ethical review projects a **Multisite Ethical Approval Certificate** is issued.
- For approved single site ethical review projects a **Single Site Project Authorisation Certificate** is issued.
- For approved multisite ethical review amendments a **Multisite Ethical Amendment Approval Memo** is issued.
- For approved single site ethical review amendments a **Single Site Amendment Approval Memo** is issued.

Note: Where a single site Project Authorisation Certificate or Amendment Approval Memo is issued for a new project, all relevant research governance

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requirements must also have been satisfied, according to **Guideline001: Peter Mac Governance Review Requirements for Human Research** before the Authorisation/Amendment Approval will be issued.

4.6 Record Keeping

A record of all research proposals received and reviewed at Peter Mac must be maintained, as outlined in the National Statement.

4.6.1 Soft Copy Records

A soft copy of all research proposals received and reviewed by Peter Mac must be kept. These soft copies are stored in designated Project folders within the S/ drive. Each folder should contain the following, where applicable:

- The approved project documentation
- Current and superseded versions of the PICF and Protocol
- Decisions made by the committees
- Approval Certificate/s
- Correspondence between the committees, sponsors and researcher/s
- Project Invoices, if any
- All governance documentation
- Post approval amendments

4.6.2 Databases

Pertinent information about each research proposal must be stored in an appropriate database. This provides an efficient way to assign project identification numbers, to track the progress of a project through the review process, allows for greater accessibility to pertinent project details and provides a means by which to generate meaningful reports.

The database contains information about all projects. Information may include, but is not limited to:

- Project Number and Title
- Researcher details
- Department
- Submission Date
- New project review timeline
- Project type
- Sponsors
- Funding Information
- Status
- Date of Ethics Approval

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4.7 Archiving

Once a research project has been completed, it is no longer necessary to store any hard copy project folders within the Ethics Committee Secretariat office. Any hard copy project folder may be sent for archiving in a secure facility. Soft copy records do not require archiving. At any point after archiving, a project may be retrieved for reference.

The Ethics Committee Secretariat maintains a log of materials in the archives with records placed in boxes, fully labelled to indicate the contents. Ethics Committee Secretariat staff are the only people that can put records into, retrieve or return records to the archive. Any movement of records to/from the archive is logged.

4.8 Record Retention

Records are retained in accordance with Public Record Office Victoria PROS 11/01 Storage Standard.

7 KEY PERFORMANCE INDICATORS

- Compliance with stated timelines of at least 90%.
- Compliance with record keeping requirements of at least 95%.

8 RELATED MATERIALS

Consult the Peter MacCallum Cancer Centre website for advice and any forms required for submissions: <https://www.petermac.org/research/doing-research-us/ethics-governance>

9 REFERENCES

INTERNAL DOCUMENTS

- POLICY 21.1.1: Responsible Conduct of Research
- Ethics Committee SOP001: Ethics Committee
- Ethics Committee SOP 004: Monitoring of Ongoing Research
- Ethics Committee SOP006: Safety Reporting

EXTERNAL DOCUMENTS

- National Statement on Ethical Conduct in Human Research (2007, and updates)
- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (November 2016 and updates)

10 FURTHER INFORMATION

For enquiries related to this Procedure please email ethics@petermac.org

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11 VERSION AND APPROVAL HISTORY

Date	Version #	Author; Owner and Authoriser Changes
August 2011	1.0	Initial document Author: Dianne Snowden, Ethics Coordinator; Owner: Ethics Committee; Authorised by: Chair, Clinical Research Governance Committee Stakeholders involved in the review process: Clinical Research Governance Committee; Ethics Committee.
August 2014	2.0	Author: Dianne Snowden, Ethics Coordinator; Owner: Ethics Committee; Authorised by: Chair, Research Governance Committee Summary of Changes: Include cross referencing to relevant SOPs and Guidelines. Include specific instructions regarding multisite ethical review. Amend record keeping instructions due to move to electronic files. Amend database instructions due to move to a single database system.
July 2015	2.1	Author: Dianne Snowden, Manager Human Research Ethics; Owner: Ethics Committee; Authorised by: Chair, Research Governance Committee Summary of Changes: Transfer of agenda preparation for Tissue Research Management Committee from Research Division to Ethics Committee Secretariat. Correct typographical errors.
October 2017	3	Author: Dianne Snowden, Manager Human Research Ethics; Owner: Ethics Committee; Authorised by: Associate Director, Clinical Research Summary of Changes: Insert timelines for review and communications of decisions. Update safety advice based on revised SOP006 Safety Reporting and NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (November 2016). Transfer to revised SOP template.

END OF DOCUMENT

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