STANDARD OPERATING PROCEDURE

HUMAN RESEARCH ETHICS & GOVERNANCE OFFICE (HREG)

SOP003 CLINICAL RESEARCH PROJECT QUERIES/COMPLAINTS

TARGET AUDIENCE

The target audience is research participants or prospective participants, or their representatives, such as a family member or carer; sponsors; contract research organisations; investigators; participating institutions; and their delegates; and third parties, who wish to communicate a query or complaint in relation to a human research project that was provided ethical approval by the Peter MacCallum Cancer Centre Ethics Committee, or that is or was previously conducted at the Peter MacCallum Cancer Centre.

RELATED PETER MAC POLICIES, PROCEDURES OR GUIDELINES

POLICY Responsible Conduct of Research

PURPOSE

This document sets out the procedure for handling queries or complaints that may arise from the conduct of human research projects that were provided ethical approval by the Peter MacCallum Cancer Centre Ethics Committee, or that are or were previously conducted at the Peter MacCallum Cancer Centre.

It is intended to complement the organisational complaints and feedback procedure (Policy 2.1.1.1) that applies to a broad spectrum of activities of Peter Mac employees and adopts the relevant definitions, principles, policy statements and procedures described in that policy.

This procedure satisfies the requirements set out in the *National Statement on Ethical Conduct in Human Research (2023 and as amended)* and the *Australian Code for the Responsible Conduct of Research (2018 and as amended)*.

PROCEDURE

A complaint is an expression of dissatisfaction or concern regarding the provision of a service, decision or action by Peter Mac or an engaged service provider, which has personally affected an individual and which requires a response in order to promote resolution between the parties concerned.

1.1 COMPLAINT DETAILS

Gather and record the following details from the complainant or Peter Mac records:

- their preferred contact details (only if they wish to provide these details) to allow further correspondence regarding the query/complaint;
- the nature of the query/complaint; and
- the treating hospital, research project title, reference number, Principal Investigator (or any project details that can be provided).

1.2 QUERY/COMPLAINT FOLLOW-UP

Determine the appropriate person to follow up the query/complaint from the table below.

Nature of query/complaint	Person responsible for following up
Logistic or management issue specific to individual participant's management (e.g. do I fulfil eligibility requirements; is study drug compatible with other medications; when is my scan scheduled, etc.)	Principal Investigator (or delegate) and/or Study Team at participant's treating hospital and, if applicable, the Coordinating Principal Investigator (or delegate) of the research project.
Overall scientific design or structure or drug therapy of a research project, but NOT related to the participant's or prospective participant's own individual care (e.g. is it appropriate that there is a randomisation against placebo; is the comparator arm inappropriate, etc.)	In the first instance, Principal Investigator (or delegate) at participant's treating hospital. If unresolved, the Chair (or delegate) of the reviewing Ethics Committee in consultation with relevant members. If still unresolved, Consumer Liaison Office at participant's treating hospital.
Ethical elements of the research project or its conduct (e.g. distressed by wording in consent form; questioning if it is appropriate that their relative was enrolled without their next-of-kin being present; distressed by approach to participate in research, etc.)	In the first instance, Principal Investigator (or delegate) at participants treating hospital. If unresolved, the Chair (or delegate) of the reviewing Ethics Committee in consultation with relevant members. If still unresolved, Consumer Liaison Office at participant's treating hospital.
Complaint regarding quality of care or outcome or process involved in research project participation	Consumer Liaison Office at participant's treating hospital.
Allegations of research misconduct	Designated Person at the relevant organisation

Send a summary of the complaint/query to the person responsible for follow up. Request that the issue is dealt with promptly and the outcome communicated to the complainant in accordance with the contact details provided and also communicated to the Peter MacCallum Cancer Centre Human Research Ethics & Governance office.

If the issue is unable to be resolved by the person responsible for follow up, refer the matter as outlined in the table above. When referring, provide full details of actions taken in attempting to resolve the complaint/query to that point. Advise that the Peter MacCallum Cancer Centre Human Research Ethics & Governance office must be kept informed.

Consistent with the Peter Mac's organisational complaints procedure, queries/complaints must be dealt with promptly. As a guide the following timelines should be met:

acknowledge receipt of query complaint/query	within 48 business hours of receipt
resolution	within 30 days of receipt

Depending on the context of the complaint/query more rapid resolution may be necessary.

1.3 RESEARCH MISCONDUCT

If a complainant alleges research misconduct:

- Inform the Designated Person at the relevant institution(s).
- Any research participant safety concerns must be addressed as an absolute priority.
- Inform the Chair of the relevant Ethics Committee.

At Peter MacCallum Cancer Centre, Research Integrity will manage follow up of allegations of research misconduct by the Designated Person in accordance with the Peter MacCallum Cancer Centre research misconduct procedure.
About research integrity - Peter MacCallum Cancer Centre

Peter MacCallum Cancer Centre Human Research Ethics & Governance office must be kept informed.

1.4 QUALITY IMPROVEMENT

Complaints should be summarised for the Ethics Committee's and Human Research Ethics & Governance office review and to ensure improvements to processes and prevention of recurrences.

LEGISLATION/REFERENCES/SUPPORTING DOCUMENTS

National Statement on Ethical Conduct in Human Research (2023 and as amended)

Australian Code for the Responsible Conduct of Research (2018 and as amended)

AUTHORISED BY

Dianne Snowden, Manager Human Research Ethics & Governance

AUTHOR/CONTRIBUTORS

Dianne Snowden, Manager Human Research Ethics & Governance October 2024