1 PURPOSE

This document sets out the procedure for handling participant or prospective participant queries or complaints that may arise from the conduct of clinical research being conducted at the Peter MacCallum Cancer Centre (Peter Mac) or projects that received ethics approval from the Peter Mac, Human Research Ethics Committee, as part of the harmonised multisite ethics review system.

It is intended to complement the organisational complaints and feedback procedure (Refer 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 SOP satisfies the requirements set out in the *National Statement on Ethical Conduct in Human Research (2007 and as amended)* and the *Australian Code for the Responsible Conduct of Research (2007 and as amended)*.

2 *SCOPE*

This SOP applies to queries and complaints received from participants or prospective participants, or their representatives, such as a family member or carer, in research projects conducted at Peter Mac.

This SOP also applies to queries and complaints received from participants or prospective participants, or their representatives, in multi centre research projects for which the Peter MacCallum Cancer Centre Ethics Committee is the reviewing HREC.

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.

In this SOP, the term complainant refers to a research participant, prospective research participant or their representative such as a family member or carer.

3 RESPONSIBILITY

It is the responsibility of researchers and all other staff involved in research at Peter Mac, all Ethics Committee and sub-committee members and all Ethics Committee Secretariat staff to follow and comply with the information set out in this SOP.

4 PROCEDURE

When receiving a query or complaint regarding a research project, the Ethics Committee Secretariat staff, or any other staff member, must ensure that the query or complaint is dealt with promptly.

4.1 Recording details of query or complaint

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

- the participant or prospective participant's 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 participant's treating hospital, project title, project number, Principal Investigator (or any project details that are able to be provided) of the research project that the complainant wants to discuss.

4.2 Determine the person responsible for 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 and/or Study Coordinator at participant's treating hospital and, if applicable, the Coordinating Principal Investigator of the research project (or their delegate(s))
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 at participant's treating hospital. If unresolved, forward to the Chair of the Clinical Research Committee (in consultation with Chair, Tissue Research Management Committee if matter relates to human tissue use) Peter MacCallum Cancer Centre (or their delegate(s)). 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 at participants treating hospital (or their delegate). If unresolved, forward to the Chair of the reviewing Ethics Committee, this may be an ethics committee external to Peter Mac (or their delegate). If still unresolved, Consumer Liaison Office at participant's treating hospital.

Nature of query/complaint	Person responsible for following up
Complaint regarding quality of care or outcome or process involved in research project participation	Consumer Liaison Office, at participant's treating hospital.

4.3 Contact the person responsible for follow up

Send a summary of the complaint/query to the person responsible for follow up via e-mail and 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 Ethics Committee Secretariat at Peter Mac.

4.4 Resolution of the query/complaint

If the query/complaint 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 action taken in attempting to resolve the compliant/query to that point. The Peter Mac Ethics Committee Secretariat must be kept informed.

4.5 Timeliness

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

4.6 When a complaint raises the possibility of research misconduct

If a complainant alleges research misconduct, the Chair of the Ethics Committee must be advised and any research participant safety concerns must be addressed as an absolute priority.

The Executive Director, Cancer Research (EDCR) is the nominated 'Designated Person' at Peter Mac to receive and follow up on breaches or allegations of research misconduct. Any allegation of research misconduct must be forwarded to the EDCR for investigation in accordance with the Peter Mac research misconduct procedure available on the Peter Mac intranet research portal.

4.7 Quality Improvement

Queries/complaints should be summarised for the Ethics Committee's review and to ensure improvements to processes and prevention of recurrences.

5 RELEVANT DOCUMENTS

POLICY 21.1.1 Responsible Conduct of Research

PROCEDURE 2.1.1.1 Management of Complaints and Feedback

PROCEDURE 21.1.1 Management of Breaches and Allegations of Research Misconduct

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