

TITLE	Research Participant Complaints and Compliments Procedure
SETTING	Principal Investigators, Trial Coordinators, Quality Systems Team, Clinical Research Governance Office (CRGO)
	All Cabrini sites engaged in research or research support

PURPOSE

To outline the roles and responsibilities of research staff and associated staff in the management of feedback provided by research participants and their families/carers in relation to research undertaken at Cabrini sites, clinical trials and other clinical studies.

To ensure streamlined feedback management in line with a patient and family - centred culture that is consistent with the Cabrini's mission and values and supports the [Australian Charter of Healthcare Rights](#) so that consumers are empowered to take an active role in research participation.

PROCEDURE

The following procedure is an extension of the existing Cabrini [Patient, Resident and Family Feedback, Complaints and Compliments Management](#) policy. Please refer to a summary of the following procedure by referring to the flow chart under Appendix 1.

Complaints

- Complaints may be received either in writing or verbally by any Cabrini Research staff member or Cabrini Customer Relations staff member.
- Complaints that are investigated and/or resolved under this procedure must be related to research undertaken at Cabrini sites, clinical trials and other clinical studies.
- Verbal complaints must be noted by the staff member receiving the complaint and include:
 - Date of receipt
 - Complainant's contact information
 - The title of the research study and/or Cabrini Project Number the complaint relates to and name of the Principal Investigator
 - Detailed description of the issue/s including any relevant dates, any staff members' details that the complaint relates to
 - Clarify any desired resolutions the complainant may have
 - Permission to share the information to achieve the desired resolution
- All matters concerning complaints and grievances will be kept confidential except to the extent that the disclosure is necessary for the purpose of addressing the complaint or grievance. Anonymous complaints are permitted but may make subsequent review more challenging.
- If a complainant identifies themselves as an Aboriginal and/or Torres Strait Islander person and wishes for additional support, they can be referred to the expertise of external Aboriginal Liaison officer.
- Complaints and all noted details are to be sent to Customer Relations within one working day of receipt.
- All complaints will be logged into the RiskMan® Feedback Module by the Customer Relations Manager (CRM).
- Complaints are to be acknowledged within two working days of receipt of the complaint. This acknowledgement should follow as:

Dear [Complainants name],
We have received your complaint, and we are sorry to hear [enter summary of complaint/s here]. We will contact the relevant department/s and respond to you as soon as we can.
- Summaries of ongoing correspondence relating to the complaint to be sent to the CRM, including any full correspondence (emails, letters, documented phone calls) as necessary for complaint status tracking.

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- The complexity and severity of the complaint will be assessed according to Riskman Feedback® module matrix as outlined in the [Patient, Resident and Family Feedback, Complaints and Compliments Management Policy](#).
- Any complaints which indicate a possible breach of the [Australian Code for the Responsible Conduct of Research](#) will be redirected and managed according to the [Research Integrity and Misconduct](#).
- Complaints are to be investigated and/or resolved by relevant research team or research department in consultation with the CRGO and the Director of Research Operations. Please also notify relevant manager/s.
- Complaint resolution should be promptly resolved, within a maximum of 35 working days for complex cases. Possible resolutions may include:
 - **Meeting** with the research participant and/or their family. This should be discussed with the relevant Manager, in consultation with, CRGO and the Director of Research Operations the Department or Service Manager. The Customer Relations Manager can assist in facilitating a meeting with relevant Cabrini staff. Meeting discussion and outcome to be documented.
 - **Correspondence** using the complainant's preferred method of communication.
 - **Explanation** or provision of factual information to the complainant, consistent with Open Disclosure principles (see [Open Disclosure Policy](#) and [Patient, Resident and Family Feedback, Complaints and Compliments Management Policy](#)).
 - **An apology** is not the same as an admission of liability, and it can have a positive impact with regards to complaint resolution.
 - **Corrective and preventative action plan** development using the [Corrective and Preventative Action \(CAPA\) Plan](#) -to document the issue, root cause analysis, corrective action and resolution related to serious breaches or clinical incidents that occur during the conduct of research.
 - **An undertaking** to review policy and processes with a view to improving outcomes.
 - **Staff training** using de-identified learnings for education purposes to avoid similar complaints in the future.

Reporting back to the research participant any improvements the organisation has made as a result of their complaint.
- Customer Relations Manager to step in for complaint resolution, where required as per [Patient, Resident and Family Feedback, Complaints and Compliments Management](#) policy.
- Resolutions/Outcomes must be sent to Customer Relations to log into the RiskMan® Feedback Module. CRGO also to be notified of resolution.
- Delayed resolutions are to be communicated with the complainant, CRM, CRGO and the Director of Research Operations.
- All documentation relating to the complaint will be stored securely and confidentiality with the CRGO/ Research Operations.
- A summary of de-identified research participant complaints will be reported monthly to CRGC and tri-annually to the Cabrini Research Committee (CRC), Patient Quality and Safety meetings and consumer representatives.
- Information from the RiskMan® report will be sent to the Board via the Patient Experience and Clinical Governance Committee (PECG) and specific research complaints will be sent by the Cabrini Research Committee (CRC).
- Feedback will be actioned into quality improvement initiatives.
- Research participant rights to privacy and confidentiality will be adhered to according to the Policy and [Patient Rights and Responsibilities](#) policy.

Compliments

- Compliments may be documented by any research or customer relations staff and sent to the CRGO to be filed centrally by Research in a secure and confidential manner.
- Compliments received via the Research Participant Perception Survey will be tabulated by the CRGO for reporting.

- Compliments will be collated and reported monthly to the Cabrini Research Governance Committee and Cabrini Research Committee (CRC) and biannually to Cabrini Research Community Consumer Involvement Committee (CRCCIC), Customer Relations, Patient Experience and Clinical Governance Committee and Patient Quality and Safety meetings.
- Exemplary compliments to be sent to CRM for bulletin reporting.
- All research participant and family compliments will be communicated by the relevant manager directly to staff once received.
- Research participant rights to privacy and confidentiality will be adhered to according to the [Privacy Policy](#) and [Patient Rights and Responsibilities](#) policy.

BREACH

Breaches of the above procedures will be dealt with through Cabrini's relevant incident and/or risk management procedures.

EVALUATION

The evaluation of the following procedure is in alignment with the Cabrini [Patient, Resident and Family Feedback, Complaints and Compliments Management](#) policy.

- *Written and significant complaints received by Cabrini Health should be forwarded within one working day to the Customer Relations Manager.*
- *Complaints received in writing are to be acknowledged within 2 working days.*
- *Complaints are to be resolved within 35 working days.*
- *Letters of complaint, replies or minutes of meetings relating to complaints are retained in the Research Governance Office for a period of 7 years.*

REVIEW

The procedure is to be reviewed every two years, or more frequently, as required following significant incidents. Where possible, feedback received from consumers and other community members will be considered as part of the review process.

REFERENCES and ASSOCIATED DOCUMENTS

Cabrini Policies Procedures and Protocols

[Patient, Resident and Family Feedback, Complaints and Compliments Management Policy \(Policy no. 6420\)](#)
[Open Disclosure Policy](#)
[Customer, Patient, Resident and Family Engagement Framework](#)
[Cabrini Research Governance Framework](#)
[Corrective and Preventative Action \(CAPA\) Plan](#)
[Patient Rights and Responsibilities](#)
[Privacy Policy](#)
[Research Integrity and Misconduct](#)

Key Legislation and Standards

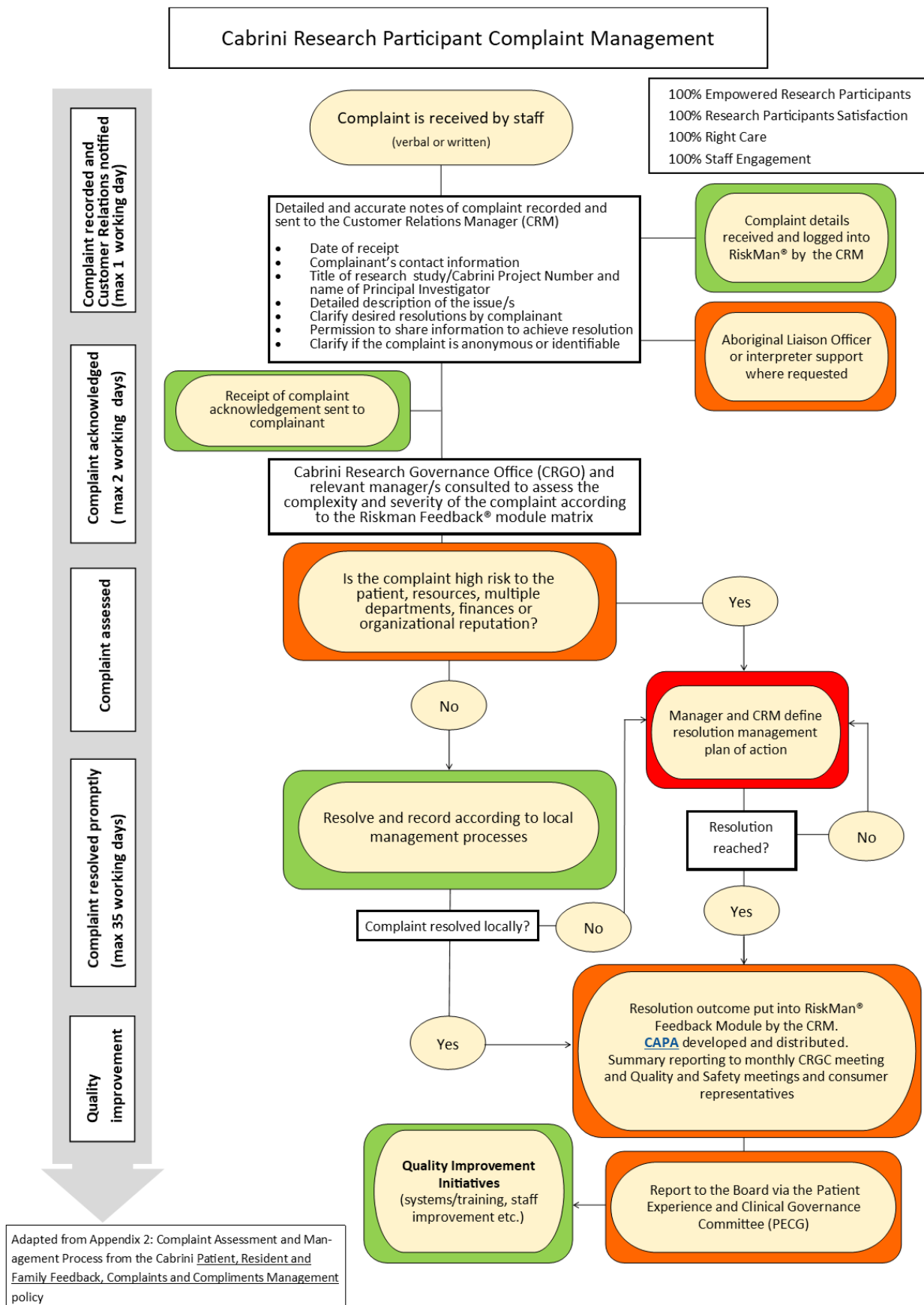
[National Clinical Trials Governance Framework Standards \(Action 1.7\)](#)
[Patient Rights and Responsibilities](#)
[Australian Commission on Safety and Quality in Health Care: Australian Charter of Healthcare Rights 2nd edition 2019](#)
[Australian Code for the Responsible Conduct of Research 2018](#)

Acknowledgements

Cabrini Research Consumer and Community Involvement Committee (CRCCIC)

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Appendix 1: Research Participant Complaint Management Process



Executive Sponsor	Group Director Cabrini Research	
Approved By:	Cabrini Research Governance Committee	Date: 5 October 2023
Authorised By:	S1 & S2 Governance and Consumer Partnerships Committee	Date: 20 March 2024