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Trial close out: Guidance for anaesthesia research teams

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Purpose of document:

This document provides anaesthesia, perioperative, and pain medicine researchers in Aotearoa New Zealand with practical guidance on navigating the national funding landscape. It outlines key funding bodies, equity-focused priorities, systemic challenges, and strategies for securing support through culturally responsive and collaborative research.

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The development of the Anaesthesia Research Coordinator Network (ARCN) and ANZCA CTN toolkit is being led by the CTN office team, in collaboration with the ARCN Sub-committee and the CTN executive. We gratefully acknowledge the contributions of the ANZCA CTN members, CTN office, ARCN sub-committee, and CTN executive in the creation, preparation, development, and review of this document.

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Trial close out: Guidance for anaesthesia research teams

This guide provides anaesthesia research teams with practical, step-by-step guidance for the close-out phase of a clinical trial. It covers both planned completion and premature termination, with a focus on ensuring regulatory compliance, data integrity, appropriate documentation, and clear communication with stakeholders.

1. Premature termination or suspension of trial

- Document the reason for early termination/suspension. This needs to be accurate and justified. The reason for termination may be described in the final manuscript and affect trial analysis.
- Notify the sponsor, Human Research Ethics Committee (HREC), and Research Governance Office (RGO) immediately.
- Cease all recruitment and participant procedures.
- Depending on the reason for termination, existing consented patients who have not entered a treatment arm should not proceed.
- Secure and review all data collected up to the point of termination.
- Conduct a debrief meeting with site staff and relevant departments.
- Ensure adequate follow up of existing participants, including appropriate medical care and counselling, if required.

2. Data and documentation

- Ensure all case report forms (CRFs) and source data are complete and up to date.
- Resolve all queries and ensure all data is accurate and complete before locking the database.
- Accurately record participant data in the Electronic Medical Record (EMR) and CRFs.
- Finalise and report all deviations, adverse events, and protocol violations.
- Submit a trial close-out report to HREC and RGO, summarising study outcomes and compliance.

3. Study files

- Update and organise the Investigator Site File (ISF), including all required documents, study logs, approvals and correspondence.
- Cross-check site files with the Trial Master File (TMF) to confirm completeness.
- Cross-check with site file checklists.
- Remove outdated drafts and duplicate documents.
- Prepare files for archiving per institutional and sponsor requirements.

4. Drug accountability

- Perform final drug accountability reconciliation.
- Confirm return or destruction of Investigational Product (IP) with records.
- Ensure all accountability logs are signed and included in archived documents.

5. Equipment accountability

- Ensure all study equipment is accounted for and removal and storage logs are maintained.
- Return or dispose of trial-specific equipment as per guidelines.
- Verify that all equipment maintenance and calibration logs are completed and stored appropriately.
- Coordinate decontamination or re-certification where needed.

6. Discussions and decisions

- Conduct a close-out meeting with all involved departments.
- Document reflections, recruitment metrics, and key challenges.
- Notify all departments of study completion and any implications.

7. Signatures

- Collect final signatures on delegation logs, monitoring reports, and financial records.
- Ensure all logs are dated and complete.

8. Clean house

- Return or dispose of study-related materials (e.g. labels, packaging).
- Remove signage and folders from clinical areas.
- Destroy outdated or duplicate working documents.
- Reset storage and equipment areas.

9. Formal close-out notifications

- Submit close-out letters to HREC and RGO.
- Include final participant numbers, major events, and confirmation of data completeness.
- File copies in the ISF.

10. Financial review

- Finalise reconciliation of budget and confirm payments.
- Invoice sponsor for final milestones.
- Retain financial records securely.

11. Archiving

- Prepare and archive essential documents (e.g. ISF, logs, correspondence).
- Ensure no further data queries/review of CRF's required before documents are archived
- Confirm archiving location and timeline.
- Record archiving details in the close-out checklist.

12. Data custodianship

- Confirm data access and long-term storage responsibilities.
- Ensure policies comply with privacy regulations and sponsor agreements.

13. Participant/consumer feedback on trial results

- Coordinate lay summaries or thank-you letters where applicable.
- Document feedback process and completion.

14. Final close-out

- Complete site close-out checklist and file in ISF.
- Conduct debriefs or handover with research office or CTN.
- Reflect on lessons learned.
- Celebrate team contributions!