

Appendix

Appendix Table 1: Standard operating procedures (SOP) and purposes.

SOP number and name	Purpose of SOP
SOP-01 Decentralised cancer trial processes	To describe the variations to normal clinical trial procedures when undertaking a decentralised clinical trial in New Zealand.
SOP-02 Informed consent	To describe the procedure for obtaining informed consent of participants for enrolment in a clinical trial.
SOP-03 Clinical trial training	To describe the procedure for documenting training that has been undertaken by members of the study teams.
SOP-04 Delegation of duties	To describe the procedure for delegating clinical trial-related duties undertaken by members of the study teams.
SOP-05 Handling investigational products	To describe the procedure for the management of all aspects of the investigational product (IP), either medicinal product or device.
SOP-06 Management of safety information	To describe the procedure related to the management of safety information.
SOP-07 Handling and shipping of biological samples	To describe the procedure for handling and shipping biological samples.
SOP-08 Hosting a regulatory inspection sponsor or other audit	To describe the procedure and activities for facilitating a regulatory inspection, either by the sponsor or an initiated audit by the Health and Disability Ethics Committee (HDEC).
SOP-09 Archiving	To describe the procedure for archiving essential documents for clinical trials for primary site (PS) and satellite site (SS).
SOP-10 Document management version	To describe the procedure for the creation and implementation of standard operating procedures (SOP) documents used for Decentralised Clinical Trials NZ, including version control and tracking amendments.
SOP-11 Essential document management	To describe the procedures relevant to the collection and maintenance of essential documents for clinical trials at the primary site (PS) and satellite site (SS).
SOP-12 Ethics and governance	To describe the procedure for obtaining ethical and governance approval for new and existing decentralised clinical trials.