

GenesisCare Research Information Pack



GenesisCare Site Research Network Capabilities

Our research network spans across **50 sites** throughout Australia. We undertake clinical trials across **all phases** including clinical quality registries and real-world data projects. Our specialty therapeutic areas include **medical oncology, radiation oncology, haematology, theranostics and precision medicine.**

➤ Feasibility

GenesisCare Research has a centralised approach in managing feasibilities for new studies across our network. All feasibilities can be emailed to our central feasibility mailbox: research.feasibilities@genesiscare.com

➤ Regulatory

GenesisCare has a centralised regulatory team who manage all HREC submissions and governance reviews. We accept ethical review from any NHMRC accredited HREC within Australia and are happy to be Lead site. GenesisCare generally uses Bellberry HREC. Please note, it is GenesisCare Research policy not to include sponsor logos on any patient facing documents as this can be interpreted as a form of advertising.

➤ Budgets and Contracts

One contract, budget and indemnity will be used for trials being conducted at multiple GenesisCare sites. GenesisCare Research will only accept Medicines Australia Clinical Trial Research Agreements and offer of Indemnity.

We work with multiple external vendors, including hospitals, imaging and pharmacy to conduct clinical trials. Vendor indemnification must be supplied by the sponsor.

Cancer Care Research Pty Ltd (CCR) is an indirect wholly owned subsidiary of the GenesisCare group. Its ultimate holding company is GenesisCare Pty Limited. All subsidiary companies in our group trade under GenesisCare and all share the same ultimate holding company – GenesisCare Pty Ltd.

Please see contract, bank and CTN details below.

GenesisCare entity contracting details:

Entity Name	Cancer Care Research PTY LTD (trading as GenesisCare Pty Ltd)
ABN	46 098 514 688
ACN	098 514 688
Address	Building 7C & D, Level 1, 41-43 Bourke Road, Alexandria NSW 2015
Signatory	Sonya McColl – Head of Research

Banking details:

Bank Name	ANZ
Account Name	Radiation Oncology Australia
Account Number	837560077
Account BSB	012-003
SWIFT Code	ANZBAU3M
Contact for Invoices	Research.Finance@genesiscare.com

CTN details:

Name of Approving Authority	Cancer Care Research Pty Ltd
Approving Authority Contact Officer	Julie Rowe
Position	Research Ethics and Governance Manager
Contact Phone	+61 498 477 691
Contact Email	contracts.budgets@genesiscare.com

➤ **Standard Fee Schedule**

Please see Appendix A.

➤ **Research Operations Team**

Each study is assigned a Research Operations Lead (project manager) from the national Research Operations Team. Their role is to oversee the study across all the GenesisCare sites participating in the study from start up through to close out. The main aims of the project manager are to ensure project oversight, consistency across sites, centralised communication pathway and efficient & successful study conduct.

➤ **Investigator Site Systems**

GenesisCare Research operates as a network with standardised systems and processes across all sites nationally. This includes having one EMR (Mosaiq) across all sites and standardised ISF/eISF filing systems and source data locations.

A copy of the below documents will be provided to Sponsors prior to Site Initiation and will be applicable to all GenesisCare sites:

- Investigator Site eSource-Readiness Assessment (eSRA) Handbook & Questionnaire
- Source Data Identification and Location Log
- eClinical Forum eISF Assessment Form

GenesisCare uses SiteDocs Portal (SDP) as our electronic Investigator Site File (eISF), electronic delegation log and training for all studies. SDP is a validated, FDA CFR 21 Part 11 compliant system and provides enhanced collaboration and communication between Sponsors and Sites. CRA access will be provided during study start-up and remain through the duration of the trial. To ensure we provide a high-quality clinical trials service to our patients, clinicians, partners and sponsors, the use of SiteDocs and the electronic delegation and training logs are mandatory for all studies being conducted at GenesisCare.

➤ **Participant Reimbursement**

Manually managing participant reimbursement is a highly administrative and time-consuming process and creates delays in reimbursing participants. For these reasons, it is our preference that Sponsors utilise third party vendor reimbursement systems such as Greenphire or Scout. If this is not possible then reimbursement should be included in the per visit payments and not be invoiced separately.

➤ **Archiving**

GenesisCare Research has a national agreement with Iron Mountain Australia Group Pty Ltd to archive paper records. Electronic records will be archived in the SiteDocs Portal.

For additional information and site-specific capabilities, please visit our website:
<https://www.genescare.com/au/clinical-trials>.

We look forward to working with you to provide patients across the GenesisCare network access to new therapies and treatments.

Sincerely,

Sonya McColl

Sonya McColl
Head of Research