

# GenesisCare External Researcher Information Pack

## Who is an External Researcher?

An external researcher is defined as a person who is not an employee or contractor supplying services to GenesisCare and who would like to work in partnership with GenesisCare on a research project.

Examples of an external researcher include:

- A PhD student or Research Fellow from a university or public hospital.
- A doctor or clinician from another institution/workplace.

For any queries, please contact the Research Development Team - [research.submissions@genesiscare.com](mailto:research.submissions@genesiscare.com).

## How do I submit a Research Proposal?

1. Obtain HREC approval for your research project
2. Complete Research Submission Checklist and draft documents as per instructions listed in Appendix A.
3. Complete the Principal Investigator Confirming of External Research Letter as listed within Appendix B
4. Complete the Research Submission Form <https://forms.office.com/r/2dfcund5EJ>
5. Ensure all study documents as per Appendix A and Appendix B are included as attachments to the research submission form.
6. Where your employer is sponsoring the research project, please liaise with your Research Office / Contract's Office regarding the drafting of contracts after submitting the Research Submission Form.

## What happens next?

1. Your proposal will be reviewed by the GenesisCare Research Development Team
2. The Research Development Team will contact you within 1 week of submission to discuss your project.
3. Once the project has been discussed and all documents are provided, the Research Governance team will then review the project.
4. Research Governance Authorisation will be provided once the review is complete and all GenesisCare requirements are met.

Sincerely,

*Sonya McColl*

Sonya McColl  
Head of Research

## Appendix A

### External Researcher Submission Checklist

Document Required for Submission	Version & Date	Included in Submission (Yes or NA)	Guidance
Investigator CVs			<ul style="list-style-type: none"> <li>To be signed and dated within the last 2 years</li> </ul>
Investigator GCP Certificates			<ul style="list-style-type: none"> <li>To have been completed within the last 3 years</li> </ul>
HREC Approvals			<ul style="list-style-type: none"> <li>Provide all HREC approval letters for the lifetime of the study, including HREC queries and responses</li> <li>For studies with research activity happening within GenesisCare, GenesisCare must be listed as a site (please discuss correct site name with Research Ethics and Governance Specialist)</li> </ul>
HREC Submission Documents			<ul style="list-style-type: none"> <li>Provide all HREC submission letters for the lifetime of the study</li> </ul>
Protocol			<ul style="list-style-type: none"> <li>Required for all projects</li> </ul>
Participant Information and Consent Forms (master and site-specific)			<ul style="list-style-type: none"> <li>Applicable for all studies where the HREC has not approved a waiver of consent</li> <li>Must be NHMRC Template</li> </ul> <p><u>Site-specific PICFs</u></p> <ul style="list-style-type: none"> <li>Must include GenesisCare Logo</li> <li>Must specify correct GenesisCare site name</li> <li>Site-specific contact information to be included (as below)</li> </ul> <p><b>Complaints Contact Person:</b>            Position: Research Ethics and Governance Manager            Telephone: 1800 316 635            Email: <a href="mailto:research@genesiscare.com">research@genesiscare.com</a></p> <p><b>Research Governance Office Contact:</b>            Position: Research Ethics and Governance Specialist            Telephone: 1800 316 635            Email: <a href="mailto:research.ethicsgovernance@genesiscare.com">research.ethicsgovernance@genesiscare.com</a></p>
Contract			<ul style="list-style-type: none"> <li>Material Transfer Agreement/Data Transfer Agreement/Collaborative Agreement etc</li> <li>Please discuss requirements with Research Ethics and Governance Specialist</li> </ul>
Resourcing/funding			<ul style="list-style-type: none"> <li>Provide details if resourcing/support is being sought from GenesisCare</li> </ul>
Sponsor Insurance Certificate			<ul style="list-style-type: none"> <li>Applicable for all commercially sponsored studies</li> <li>Must cover the sum of \$20mAUD for clinical trials</li> </ul>
External Research Insurance			<ul style="list-style-type: none"> <li>Public Liability for \$20mAUD</li> </ul>
PI confirmation of external researcher letter			<ul style="list-style-type: none"> <li>To be completed if external researchers are requesting access to GenesisCare sites</li> </ul>

## Appendix B

### Principal Investigator Confirmation of External Researcher (template)

Project Title:

GenesisCare Site:

Principal Investigator:

Dear GenesisCare Research Ethics and Governance Team,

**Re: External Researcher conducting study activity at GenesisCare for <Insert full title>**

Please accept the following documents to allow <insert researcher name> who is an employee of <insert employer> to conduct research activity for the above-mentioned research project:

- Curriculum Vitae
- ICH GCP Certificate
- Evidence of Vaccination/Immunisation history <applicable for those requesting patient contact>
- Signed GenesisCare Confidentiality Agreement (if not other agreement is in place)
- Copy of scope of the liability insurance including a Certificate of Currency

I can confirm that the external researcher will report to myself, <Insert GenesisCare Principal Investigator>, whilst conducting any study activity and is anticipated to be onsite for <insert months/years>. The researcher will be completing the below activities at the below site/s:

<insert Site name>

- Insert description
- Insert description
- Insert description

I can confirm that the external researcher has read and understood:

- HREC approved Protocol
- HREC approval and applicable conditions
- NHMRC Australian Code for the Responsible Conduct of Research, 2018
- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (if applicable).
- Workday training module – Privacy Awareness

I can confirm that the external researcher has been provided on-site orientation regarding emergency procedures (if applicable).

Yours sincerely,

<Insert PI>

GenesisCare

## External Researcher Acceptance

I, <insert name of researcher>, have read and understood the above.

I understand that I will remain an employee of <insert employer> during my time on site and will be covered for workers compensation and public liability by <insert name of employer>.

Should I be involved in a workplace incident whilst at GenesisCare, I will ensure this is reported to my manager at <insert name of employer> as well as <insert GenesisCare PI>.

I have read and understood the below NHMRC and GenesisCare policies, standard operating procedures, and guidelines.

- NHMRC Australian Code for the Responsible Conduct of Research, 2018
- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods, 2016 (if applicable)
- GenesisCare GCR-SOP-005 – Clinical Research Participant Informed Consent (if applicable)
- GenesisCare GCR-SOP-14 - Investigator Responsibilities
- GenesisCare GCR-SOP-017 Research Governance

I have provided the below documents to the Principal Investigator/GenesisCare:

- Curriculum Vitae
- ICH GCP Certificate
- Evidence of Vaccination/Immunisation history (if patient access is requested)
- Signed GenesisCare Confidentiality Agreement (if no other agreement is in place)
- Copy of scope of the liability insurance including a Certificate of Currency

I will ensure all my research activity undertaken on site at GenesisCare is completed as per the HREC approved protocol, GenesisCare Research Governance requirements and ICH-GCP.

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*Signature*

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*Date*