Genea Human Research Ethics Committee Terms of Reference

Purpose

The Genea's Human Research Ethics Committee (G-HREC) plays a critical role in ensuring all high-risk and some low-risk research being performed within Genea adheres to ethical standards and legal requirements as set out by the National Health and Medical Research Council (NHMRC). It reviews research proposals that assess the potential risks, benefits, and the informed consent process, ensuring that participants are fully informed about their involvement in studies. The committee also monitors ongoing research for compliance with ethical principles, including the protection of vulnerable population, ensuring that all research aligns with established ethical frameworks, regulatory standards and public trust. This oversight helps maintain the research integrity being conducted within Genea.

Governance

The G-HREC reports to the Chief Scientific Officer and Chief Executive Officer.

Responsibilities

The specific roles and responsibilities of the Genea HREC include.

- **Reviewing Research Proposals:** Independent ethical review of research involving humans conducted by the Genea, as required by the National Statement on Ethical Conduct in Human Research ("National Statement"), including review of protocols and progress reports on such research and establishing procedures for the review of high-risk research in accordance with the National Statement.
- **Ethical Case Reviews**: Independent ethical review of complex patient cases that may include situations including embryo selection, donor gametes, genetic screening, access to IVF treatment – that raises questions about patient autonomy, welfare of the future child, social justice and/or the moral status of the embryo.
- **Ensuring Compliance:** Ensure research complies with relevant ethical guidelines, laws, and regulations, including consent procedures and confidentiality.
- **Review of Internal Policies and Procedures:** Independent review of internal policies and procedures to ensure they align with current legislative requirements and ethical guidelines.
- **Risk Assessment:** Evaluate potential risks to participants, ensuring that risks are minimized and justified by the benefits of the research.
- **Informed Consent:** Ensure that participants are fully informed about the research, its risks, and their rights, and that consent is obtained properly.
- **Ongoing Monitoring:** Oversee the progress of approved research projects to ensure continued ethical conduct throughout the study.
- **Approval of Modifications:** Review and approve any changes to the research protocol or informed consent forms.
- **Reporting:** reporting annually or otherwise as required to the NHMRC and its committees on the conduct of its business, and providing a copy of the report to the Board of Directors.

- **Reviewing Authorised Prescriber Scheme Proposals:** Assess proposals and evidence for endorsement of 'unapproved' products to be used in fertility clinical practice.

It is expected that all members of Genea HREC have a sound understanding of the National statement on the Ethical Conduct in Human Research 2023 and the Authorised Prescriber Scheme (please see Key documents).

Membership

The Genea Ethics Committee comprises of independent members in such numbers and categories as required by the National Health and Medical Research Council (NHMRC) to fulfil all functions required of an institutional Human Research Ethics Committee.

A minimum of eight members that encapsulate the follow categories and gender balanced as possible.

- A chairperson, with previous HREC committee experience.
- At least two lay people, who have no affiliation with Genea and do not currently engage in medical, scientific, legal or academic work.
- At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people.
- At least one person who performs pastoral care in a community including but not limited to, an Aboriginal and/or Torres Strait islander elder or community leader, a chaplain or a minister of religion or another religious leader.
- A qualified lawyer, who may or may not be currently practicing, and where possible is not engaged to advise the institution on research-related or any other matter.
- At least two people with current research relating to reproductive biology and/or relevant experience related to the proposals have been considered at meetings.

All G-HREC members are indemnified under the insurance policies held by Genea Pty Ltd.

Genea representatives

Genea provides up to three institutional members.

- An ethics secretary (junior embryologist).
- At least one senior employee (i.e. Director of Research, Chief Scientific Officer or Risk and Compliance Officer).

Frequency of Meetings

Genea HREC meets at least two times per year with the possibility of meetings more frequently as required. A meeting schedule will be published and communicated to the membership on an annual basis (December), by the HREC Secretariat. G-HREC members can join meetings both in person (Genea Kent Street) or online (Teams). All meetings are recorded.

Preparation for each HREC meeting involves reading all material circulated to members by the ethics secretary no later than one week prior to the meeting and it is expected that all members will have read all required materials prior to the meeting.

Appointment/Term of Office
Appointment is granted for three years and reviewed, re-evaluated and reissued as required upon completion of appointment. All members will be provided with a formal notice of appointment that specifies.

- Roles and responsibilities relating to the membership.
- Category of membership they will be representing.
- Term of appointment.
- Remuneration or other benefits.
- That they are assured legal protection for any liabilities that may arise during the bona fide conduct of their duties as reviewers of research.

Remuneration
Genea HREC members are paid in recognition of the time spent preparing, attending and contributing to research meetings. Payments are made per meeting and negotiated by members with Genea. Payments are made quarterly following meetings.

Election of Chairperson
Nominations for G-HREC chairperson occurs every three years following completion of previous chairpersons' appointment. G-HREC Chairperson must have previous experience as a HREC committee member in an NHMRC registered HREC.

Quorum
A quorum consists of at least five elected members of the G-HREC.

Declaration of Conflict of Interest
The G-HREC must maintain its independence of the Company's operations (including the open disclosure by members to the chairman of the Committee of any personal or commercial matter that could cause a conflict or an appearance of a conflict with the independent operation of the Committee).

Confidentiality
All members will treat all Confidential Information as confidential and use the Confidential Information only for providing Services to the G-HREC and will not disclose, publish or use the Confidential Information for any other purpose without prior written consent.

Delegation of responsibilities
The Genea HREC may delegate some of its responsibilities to its chairperson, or one or more of its members or HREC secretary which may include.

- Expedited review of lower risk projects,
- Approvals of amendments or monitoring responsibilities,
- Some Authorised Prescriber Scheme application.

Minutes
Minutes of all meetings shall be recorded distributed to all members within fourteen days of each meeting. No business shall be considered at a meeting until the minutes of the previous meeting have been confirmed or otherwise disposed of. Minutes will be confirmed by the Chairperson at the next meeting.

Reporting

A list of all current members will be maintained by the G-HREC secretary, which can be provided for public distribution as required. The G-HREC secretary will be responsible in conjunction with members to maintain.

- Project registries.
- Approvals, amendments and project notifications to researchers.
- Reporting to NHMRC as required.
- Yearly report to the Board of Directors

Evaluation

- **Assessment of committee Performance -** The CEO will conduct an annual review of the committee's performance.
- **Annual review of the G-HREC Terms of Reference -** The Committee will conduct an annual review of the MAC's terms of reference. The evaluation will be included in the meeting minutes.

Key documents

- National statement on the Ethical Conduct in Human Research 2023.
- Authorised Prescriber Scheme – Guidance for medical practitioners, Human Research Ethics Committees, specialist colleges and sponsors.