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	NUTROMICS DIAGNOSTICS HREC TOR	2.0

1. Background

The Nutromics Diagnostics HREC (ND HREC) is a committee that was established by Nutromics in 2023 to provide ethical review for in human research. The ND HREC functions to

- Provide independent oversight of non-interventional diagnostic research in humans, and clinical studies that support the development of diagnostic tools or methods.
- Provide competent, timely review and monitoring of human research in respect of their ethical and scientific acceptability for as long as research is active;
- Determine the compliance of a human research with the *National Statement* and grant, withhold or withdraw ethical approval

The ND HREC is registered with the NHRMC and is governed by the Research Governance Office (RGO).

The RGO is comprised of a small, focused team of key individuals who ensure the highest standards of research governance and compliance. This team includes:

- Two Directors:
 - o One of these directors serves as the Chief Executive Officer (CEO), providing overarching leadership and strategic direction.
 - o The second director collaborates closely with the CEO to oversee governance and regulatory adherence, bringing complementary expertise to the team.
- NCRC Site Manager
 - o This individual is responsible for the day-to-day management of the site, ensuring that all clinical and operational aspects of the research are conducted in accordance with regulatory requirements and institutional policies.
 - o The Senior CRA acts as a bridge between the researchers and the RGO, facilitating effective communication and implementation of governance directives.

The RGO governs the ND HREC according to these Terms of Reference, and key guiding documents: HREC-SOP-01 Research Review and Monitoring, HREC-SOP-02: HREC Operations and RGO-SOP-02: Research Governance.

2. ND HREC's Objectives

The objectives of the ND HREC are:

- Protect the mental and physical welfare, rights, dignity and safety of participants of research;
- Promote ethical principles in human research related to diagnostics;
- Review research in accordance with *the National Statement on Ethical Conduct in Human Research (2023)* incorporating all updates
- Facilitate ethical research through efficient and effective review processes.

The ND HREC provides ethical review for all research protocols investigating in-human diagnostics which are submitted to the ND HREC, from researchers who are both affiliated and non-affiliated researchers. It is the role of the ND HREC to review matters relating to scientific, medico-legal and ethical issues associated with the research.

Researchers are invited to liaise with the ND HREC (via email:



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HREC@nutromics.com) regarding if their submission is within scope of research that the ND HREC can review. Alternatively, these submissions will not be reviewed, and will be considered invalid.

3. Accountability and Reporting

a. Accountability

All research which is to be conducted will be ethically and scientifically reviewed by the ND HREC. ND HREC review will be limited to refers to non-interventional diagnostic clinical studies in humans, or clinical studies that support the development of diagnostic tools or methods.

The ND HREC is accountable to the RGO at Nutromics, and shall adhere to all relevant documents and guidelines to ensure that research submissions, review and conduct comply with Australian regulations. This includes TGA regulations, ICH GCP E6(R2), ISO 14155, Australian Privacy Principles, and any other applicable Australian standards and guidelines.

Additionally, the following specific governing documents which can be found online at nd-hrec.org should be consulted and adhered to.

- RGO-WI HREC or Nutromics Clinical Research Centre SSA Submission
- HREC-SOP-02: HREC Operations
- RGO-SOP-02: Research Governance
- RGO-FORM Protocol Departure Report
- RGO-FORM Data Breach Report
- RGO-FORM Annual Report
- RGO-FORM Safety Event or Device Deficiency
- RGO-FORM Study Close Out Report
- RGO-FORM Site-Specific Assessment Application

b. Reporting

The ND HREC reports annually to the NHMRC and the RGO.

4. Membership of the Committee

The Members of the ND HREC will be selected and appointed in accordance with the National Statement, as follows:

- a Chair with suitable experience, including previous membership of a human research and ethics committee, whose other responsibilities will not impair the ND HREC's capacity to carry out its obligations under the National Statement;
- two people who bring a broader community or consumer perspective and who have no paid affiliation with Nutromics;
- a person with knowledge of, and current experience in, the professional medical care or treatment of people; for example, a nurse, counsellor or allied health professional;
- a person who performs a pastoral care role in the 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 other 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



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matters; and

two people with current in-human research experience that is relevant to the research proposals to be considered at ND HREC meetings that they will attend.

5. Role of Committee Members

The primary responsibility of each Member is to decide, independently, whether, in their opinion, that the conduct of each research proposal submitted to the ND HREC for approval minimizes and manages the potential risks to participants in research, including each participant's voluntary and fully informed consent.

a. Appointment of Committee Members

All Members will be appointed for their expertise and not as representatives of any group or organization, including Nutromics.

b. Tenure

Each Member will be appointed for a minimum term of one year.

The Chair will review each Member's membership on the ND HREC every year. New and renewed appointments allow for continuity, development of expertise within the ND HREC, and regular input of fresh ideas and approaches.

c. Liability Coverage

In accordance with the National Statement, the ND HREC has in place appropriate insurance in respect of any liabilities that may arise in the course of a member's bona fide conduct of their duties as a Member.

d. Remuneration

Each Member will be contracted to the ND HREC through Nutromics shall receive payment in accordance with fair market value, based on expertise and experience.

6. Meetings

a. Frequency of Meetings

The ND HREC will schedule meetings as required upon receipt of research submissions, and in response to agenda items proposed by the Chair or any Member. Members will be given at least 10 Business Days' notice of a committee meeting of the ND HREC along with an agenda for each proposed meeting.

b. Meeting Agenda

The finalised agenda (not including late and urgent items) for each committee meeting of the ND HREC will be distributed to all Members and attendees at least 10 Business days before the next scheduled meeting.

c. Quorum

A quorum for each ND HREC meeting shall consist of the number and expertise of the Members as is required to fulfil the minimum membership requirements as outlined in the National Statement (Sections 5.1.29- 5.1.30), being those set out in section 4(a).

If the required Members are not present the Chair must be satisfied that these members have received all the relevant papers and have had the opportunity to contribute their views and that these have been received and considered before a



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final decision is made (as per Section 5.2.30 of the National Statement).

d. Conflict of Interest

Any Member of the ND HREC who has a direct or indirect conflict of interest, including but not limited to any interest, financial, personal or otherwise (real or perceived), in any proposal or other related matter to be or that is being considered by the ND HREC, should as soon as practicable declare such an interest to the Chair of the ND HREC. The Member must withdraw from any discussion or decision relating to the proposal or any other related matter to be or that is being considered by the ND HREC in which the Member has a conflict of interest (real or perceived), unless the interest has been considered by the ND HREC and the Chair has permitted the conflicted Member to remain for the relevant discussion or determination of the ND HREC. All declarations of interest and the absence of the Member in relation to any conflicted proposals or determinations of the ND HREC must be recorded in the minutes of the relevant ND HREC meeting and recorded in the ND HREC's register of interests.

e. Decision Making

Decisions of the ND HREC will only be made after Members from each of the Member categories have had an opportunity to contribute their views during or prior to the decision-making process. Members unable to attend the meeting will be asked to forward comments to the Chair prior to the meeting.

The ND HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by general agreement. The decision need not be unanimous.

In the absence of general agreement, the Chair will ask the Members to vote on a recommendation of the ND HREC on how to proceed.

An ND HREC member or secretariat is to prepare the minutes of the ND HREC meeting in consultation with the Chair and other Members as necessary. The minutes should be subsequently approved by the Chair within 2 Business Days of the meeting.

f. Records

Records of the ND HREC's activities including agendas and minutes of all meetings of the ND HREC will be maintained and kept for 15 years following the completion of the research.

g. Confidentiality

Members of the ND HREC will treat as, and keep confidential, all information, discussions, communications and documents which relate to the business considered by the ND HREC.

7. Method of Operation

a. Procedures

The ND HREC will perform its functions according to standard operating procedures as described in Section 3 of these Terms of Reference. These procedures will be reviewed periodically and amended and updated as necessary. All ND HREC Members and researchers will have access to these procedures.

In carrying out its functions the ND HREC shall at all times:



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- ensure their enquiries of the researcher will be made in a spirit of courtesy and support, so as to develop mutual respect and a sense of partnership in the development of sound ethical practice;
- provide the decisions of the ND HREC in writing and within a reasonable timeframe to the persons nominated in the submission; and
- determine the method of monitoring appropriate to each research. Research that has received ethical approval will be monitored and may be audited in order to ensure that they conform to the protocol approved of by the ND HREC. Any proposed amendments to any approved protocols of the ND HREC must be presented to the ND HREC for approval prior to any implementation of any amendments to approved protocols.

b. Executive Committee of the ND HREC

The Executive Committee of the ND HREC must be comprised of at least:

- the Chair or their delegate; and
- at least one non institutional member.
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The ND HREC Executive Committee may undertake expedited review and approval of ND HREC business that does not require a full ND HREC review, including some or all the following:

- lower risk research reviews;
- non-substantial amendments and renewals to current ND HREC approved research;
- responses to ND HREC queries, as approved by the ND HREC for ND HREC Executive Committee review and approval;
- annual progress reports and final reports; and
- serious adverse events and suspected unexpected serious adverse reactions reports.

The minutes and decisions of the ND HREC Executive Committee and discussed at the next ND HREC meeting.

c. Suspension or withdrawal of ethical approval

The ND HREC may suspend or withdraw its ethical approval of research if it is not being, or cannot be conducted in accordance with the approved protocol. ND HREC should immediately notify the Principal Investigator of the suspension or discontinuation of the ND HREC's approval for the research.

8. Fees

Nutromics is exempt from fees associated with review by ND HREC. All non affiliated research is subject to the below fees.

	Service	\$ Amount (inc GST)
☐	New submissions that require ND HREC review	\$330
☐	ND HREC review on behalf of each additional site	\$165
☐	Review of an amendment (including those requesting an extension of approval)	\$165
☐	Further review of an amendment/requirement for resubmission of amendment (each occasion)	\$165

9. Definitions



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Affiliated Research means researchers who have formal ties, such as employment or contractual agreements, with Nutromics , which provides resources and oversight of the Nutromics' RGO to ensure adherence to ND HREC governance policies and standards.

Non Affiliated Research means researchers who operate independently and who are not formally tied to Nutromics, and which rely on private funding or external partnerships with less oversight and fewer resources than Affiliated Research.

Business Day means a day that is not a Saturday, Sunday or public holiday in Victoria, Australia or after 5pm;

Chair means the chair of the ND HREC from time to time, and at the date that these Terms of Reference were reviewed, is Lori Chiampas;

Chief Executive means the chief executive of the RGO from time to time, and at the date that these Terms of Reference were reviewed, is Peter Vranes;

Executive Committee means the executive committee of the ND HREC;

Institution means Nutromics;

Institutional Member means a member affiliated with the institution, meaning they receive compensation or are employed by the institution.

Members means members of the ND HREC;

National Statement means the NHMRC's National Statement of Ethical Conduct in Human Research (2023). The National Statement on Ethical Conduct in Human Research is the major guidance document in ethical review developed jointly by the NHMRC, the Australian Research Council and Universities Australia. Compliance with the National Statement is a pre-requisite for receiving NHMRC funding.

NHMRC means the National Health and Medical Research Council;

ND HREC means the Nutromics Diagnostics Human Research Ethics Committee;

Non-institutional Member means independent member not affiliated with the institution, who is not compensated by or employed by the institution

Non-interventional studies means research where researchers collect data without altering participants' treatment or medical care. It involves observing without altering or influencing that which is being observed. These studies aim to evaluate or validate diagnostic tools. Researchers examine and report on what is happening, without controlling the course of events. Certain outcomes are measured but no attempt is made to affect the outcome (i.e. no treatment or experimental intervention is given).

Nutromics means Nutromics Operations Pty Ltd (ACN 627 168 567) and its Related Bodies Corporate (as applicable);

Related Bodies Corporate has the meaning given to it in the *Corporations Act 2001* (Cth);



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Research means non-interventional diagnostic clinical studies in humans, or clinical studies that support the development of diagnostic tools or methods.

Researcher means a person involved in research, including the Principal Investigator, study team, ND HREC applicant, and delegates, who collectively ensure the research is conducted ethically and meets regulatory standards.

RGO means the Nutromics Research Governance Office; and

Terms of Reference means these terms of reference.

