Version Number	Version Date	Author	List of Changes
1.0	03-Feb-2023	Emily Birthisel	N/A: initial release
2.0	22-Mar-2024	Emily Birthisel	National Statement updated to 2023
3.0	14-Oct-2024	Emily Birthisel, Natasha Schot, Tim Tang, Lori Chiampas	- Clarification of Responsibilities of RGO/Chief Executive - Verbiage edits for clarity and consistency - Time for Membership review revised to every year - Policy: HREC Record Keeping integrated into Section 23 - Updates to Section 12 regarding training of new members - Definitions updated - Accountability section updated - Training of members section updated

1. Purpose

This document provides standard operating procedures for the Nutromics Diagnostics Human Research and Ethics Committee (ND HREC).

2. Introduction

This document provides standard operating procedures for the ND HREC's operations to ensure that it operates in accordance with the *(National Health and Medical Research Council) National Statement on Ethical Conduct in Human Research (2023)* (National Statement).

The ND HREC only reviews Research concerning diagnostic devices, and related Research. The ND HREC consults applicable guidelines to inform its review and approval of Research proposals.

3. Definitions

Adverse Event (AE)	Any undesirable clinical occurrence in a participant whether it is considered to be device related or not, that includes a clinical sign, symptom or condition and/or an observation of an unintended technical performance or performance outcome of the device.
Adverse Reaction (AR)	An adverse reaction is a response to an investigational device which is noxious and unintended. This includes adverse reactions which arise from: • The use of a medicinal product within the terms of the marketing authorization; • The use outside the terms of the marketing authorization, including overdose, off-label use, misuse, abuse and medication errors; and • Occupational exposure.
Affiliated Research	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 the ND HREC's governance policies and standards.
Amendment	An amendment is a formal change to the Research protocol or essential documents, made to adjust the design, procedures, or criteria of the Research.
Annual Report	A document that updates the ND HREC on Research progress, including participant data and safety information. It ensures compliance with regulatory requirements and provides transparency about the Research status.
Burden and Inconvenience	Not considered a type of harm or discomfort and therefore should not be viewed as a risk. May include the time that will need to be given to each participant to participate in the research being undertaken, for filling in forms and for costs related to travel etc. in relation to their participation in a relevant Research.
Business Day	Is a day that is not a Saturday, Sunday or public holiday or after 5pm in Melbourne, Victoria.
Chair	Means the chair of the ND HREC from time to time.
Clinical Study	Any investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and ascertaining its safety and/or efficacy.
Close Out	Close out refers to the final activity of the Research, where all Research tasks are completed, data is finalized, and the Research is officially concluded. It involves ensuring all regulatory requirements are met and all documentation is properly archived.
Consent waiver	Ethical approval from the ND HREC that allows Research to proceed without obtaining explicit informed consent from participants. This waiver is granted when the Research involves minimal risk, and obtaining consent is impractical or unnecessary for the Research's objectives.
Data Safety Monitoring Boards (DSMB)	Data Safety Monitoring Board (DSMB) is an independent and multidisciplinary group established by researchers to review, at intervals, accumulating Research data, in order to monitor the progress of the Research and to make recommendations on whether to continue, modify or stop the Research for safety or ethical reasons.
Discomfort	Considered less serious than harm. It can involve physical or psychological impacts, for example, minor side-effects of medication, discomfort related to non-invasive examinations, or tests (such as measuring blood pressure), and mild anxiety associated with an interview. However, where a person's reactions might exceed discomfort and become distress, this should be viewed as the potential for harm. Some participants may be at higher risk of harm or discomfort arising from the Research being conducted. The increased risk of harm or discomfort can express itself in different ways at different times and to different degrees and can arise from: (a) the nature, design or other contextual factors of the Research, such as the setting in which the Research will be conducted,

	the social or political implications of doing the Research and cultural factors or some combination of these factors; (b) specific attributes or characteristics of individual participants or of groups to which they belong; and/or (c) an interaction between (a) and (b).
Ethical Review Management System (ERMS)	The Ethical Review Manager (**ERMS**) website is used for submissions and reports to the ND HREC. The ND HREC utilizes the "Research Manager" ERMS.
Good Clinical Practice (GCP)	Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting studies that involve the participation of human participants.
Higher Risk Research	Research in which there is a risk of harm to and in which there may also be a foreseeable burden on participants in the Research being conducted. The risk of harm in higher risk research may or may not be a risk of significant harm and may be harm to the individual, group, community, societal or global level.
Human Research Ethics Committee (HREC)	A committee constituted under the guidance of the National Statement and registered with the NHMRC to conduct the ethical and scientific review of human research.
Investigator's Brochure (IB)	A compilation of clinical and non-clinical data on the investigational product(s) relevant to the Research of investigational product(s) in human participants.
Institution	Refers to Nutromics.
Institutional ND HREC Member	A member affiliated with the Institution, meaning they receive compensation or are employed or otherwise engaged by the Institution.
Lower Risk Research	Research in which: (a) there is no risk of harm, but in which there is a risk of discomfort and in which there may also be a foreseeable burden ; or Research in which there is no risk of harm or discomfort, but which includes a potential for minor Burden and Inconvenience (Minimal Risk Research).
Member	An individual who is a member of the ND HREC
Multi-center research	Multi-center research is Research that is conducted at more than one site.
National Statement	The National Statement on Ethical Conduct in Human Research (2023) incorporating all updates.
National Health and Medical Research Council (NHMRC)	The National Health and Medical Research Council is the main statutory authority of the Australian Government responsible for medical research.
Principal Investigator (PI)	The individual who takes overall responsibility for the Research and submits the Research for ethical and scientific review.

Praxis Training	PRAXIS Australia is a leading Australian and International not for profit education and training provider. HREC training is built upon the competencies developed by the Harvard Multi-Regional Trials Centre and aligned to competencies recommended by the NHMRC.
Non-Affiliated Research	Researchers who operate independently and who are not formally tied to Nutromics, and which rely~~ing~~ on private funding or external partnerships with less oversight and fewer resources than Affiliated Research.
Non-interventional	Refers to 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).
Non-institutional ND HREC Member	An independent Member not affiliated with the Institution, who is not compensated by or employed by the Institution.
Nutromics	Nutromics Operations Pty Ltd (ACN 627 168 567) and its Related Bodies Corporate (as applicable) (as defined in the *Corporations Act 2001* (Cth)).
Opt-out approach	A method used in the recruitment of participants into Research where information is provided to the potential participant regarding the Research and their involvement and where their participation is presumed unless they take action to decline to participate.
Participant	A participant is an individual who provides data or undergoes procedures as part of the Research, but their standard medical care remains unaffected by the Research activities.
Research	Refers to non-interventional diagnostic clinical studies in humans, or clinical studies that support the development of diagnostic tools or methods.
Researcher	A researcher is a person involved in Research, including the Principal Investigator, study team, ND HREC researcher, and delegates, who collectively ensure the Research is conducted ethically and meets regulatory standards.
Research Protocol	A document that details the objectives, design, methodology, statistical considerations and organization of Research
Risk of Harm	• Physical harm: including injury, illness, pain or death, including but not limited to: ○ psychological harm, including feelings of worthlessness, distress, guilt, anger and fear; anxiety related, for example, to disclosure of sensitive information, an experience of re-traumatization, or learning about a genetic possibility of developing an untreatable disease; ○ devaluation of personal worth, including being humiliated; or manipulated; and ○ in other ways treated disrespectfully or unjustly.

	• cultural harm: including misunderstanding, misrepresenting or misappropriating, including but not limited to cultural beliefs, customs or practices; • social harm: including damage to social networks or relationships with others; • discrimination in access to benefits, services, employment, insurance and social stigmatization; and unauthorized disclosure of personal information; • economic harm: including the imposition of direct or indirect costs on participants; and • legal harm: including discovery and prosecution of criminal conduct. Any of these types of harm can be experienced individually or collectively.
Safety Review Committee (SRC)	An independent data monitoring committee that may be established by the Sponsor to assess at intervals the progress of Research, the safety data, and the critical efficacy points, and to recommend to the Sponsor whether to continue, modify, or stop Research.

Serious Adverse Event (SAE)	Is any adverse medical occurrence that:
	• led to a death.
	• led to a serious deterioration in health of a participant, or user, such as:
	  ○ A life-threatening illness or injury;
	  ○ A permanent impairment of body function or permanent damage to a body structure;
	  ○ A condition requiring hospitalization or increased length of existing hospitalization;
	  ○ A condition requiring unnecessary medical or surgical intervention; or
	  ○ Fetal distress, fetal death or a congenital abnormality/birth defect;
	• might have led to death or a serious deterioration in health had suitable action or intervention not taken place:
	  ○ a malfunction of a device such that it has to be modified or temporarily/permanently taken out of service; or
	  ○ a factor (deterioration in characteristics or performance) found on examination of the device.

Serious Adverse Device Effect (SADE)	An adverse device effect that has resulted in any of the consequences characteristic of a SAE.
Serious Adverse Reaction (SAR)	A serious adverse reaction corresponds to any untoward medical occurrence is related to the investigational medical device and results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly/birth defect.
Significant Safety Issue (SSI)	A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the Research.

Unexpected Serious Adverse Device Events (USADE)	Serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified.
Sponsor	Is the company, Institution, organization, body or individual that takes overall responsibility for the conduct of the Research and usually initiates, organizes and supports the Research.
Therapeutic good	Defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the *Therapeutic Goods Act 1989* (Cth)). Therapeutic use means a product for use in humans in connection with: • preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; • influencing inhibiting or modifying a physiological process; • testing the susceptibility of persons to a disease or ailment; • influencing, controlling or preventing conception; • testing for pregnancy; • used as an ingredient or component in the manufacture of therapeutic goods; or • replacement or modification of parts of the anatomy.
Therapeutic Goods Administration (TGA)	The Therapeutic Goods Administration (TGA) is the medicine and therapeutic regulatory agency Australia.

4. Objectives

The objectives of the ND HREC are to:

- 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, as amended from time to time; and
- Facilitate ethical Research through efficient and effective review processes.

5. Functions

The ND HREC functions to:

- Provide independent oversight of human Research that are focused on medical diagnostics;
- Provide competent, timely review and monitoring of human Research r in respect of their ethical and scientific acceptability for as long as Research is active; and
- Determine the compliance of a human Research with the National Statement and grant, withhold or withdraw ethical approval.

6. Accountability

The ND HREC is directly accountable to the Nutromics Research Governance Office (RGO) under which it is constituted.

The minutes of ND HREC meetings are made available to the RGO via researchgovernance@nutromics.com email.

The ND HREC provides a report annually to the National Health and Medical Research Council (NHMRC). The NHMRC annual report comprehensively outlines the Institution's Research activities, outcomes, and compliance with ethical and regulatory standards set forth by the NHMRC. It ensures transparency and accountability to stakeholders and regulatory bodies overseeing health and medical research in Australia, facilitating informed decision-making and continuous improvement in Research governance practices.

The ND HREC is also required to prepare and submit an annual report to the Nutromics RGO by annually summarizing all activities, decisions, and outcomes during the reporting period. Alternatively, the ND HREC may submit a copy of its annual report forwarded to the NHMRC to meet this requirement. Upon submission, the Nutromics RGO will review the report to ensure adherence to institutional and regulatory standards. Any discrepancies identified will be promptly addressed by the ND HREC. The ND HREC will maintain records of all submitted annual reports and NHMRC reports and submissions as part of its compliance and reporting obligations.

7. Scope of responsibility

- The ND HREC provides ethical and scientific review of Research.
- The Chair is responsible for the conduct of the ND HREC's business and for ensuring that the ND HREC reaches decisions on all matters. Where the Chair is unavailable, the meeting will be chaired by the Deputy Chair if available, or by the alternate Deputy Chair if not.
- The ND HREC has an executive committee comprising at least the ND HREC Chair or their delegate and at least one non-institutional HREC member (Executive Committee). The ND HREC Executive Committee is delegated to undertake expedited review and approval of business that does not require the review of the ND HREC, including some or all the following:
    - Lower Risk Research Reviews;
    - Amendments and renewals to current ND HREC approved Research;
    - Documents resubmitted as part of ND HREC approval that is contingent upon particular amendments;
    - Responses to ND HREC queries, as approved by the full ND HREC for ND HREC Executive Committee review and approval;
    - Annual reports and final reports;
    - Serious adverse events and suspected unexpected serious adverse reactions report; and
    - The minutes and decisions of the ND HREC Executive Committee are to be noted at the next ND HREC meeting.

Refer to *HREC-SOP-01 Research Review and Monitoring* for detail regarding ND HREC review pathways for applications for Research.

8. ND HREC Composition

- The composition of the ND HREC is in accordance with the National Statement.
- Minimum membership comprises eight Members. As far as possible, genders are represented in equal numbers and at least one-third of the Members are external to the Institution for which the ND HREC is reviewing Research.

  The Membership comprises representatives from the following categories:

- a Chair with suitable experience, including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
- two people who have a broader community or consumer perspective and who have no paid affiliation with the Institution;
- a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional;
- a person who performs a pastoral care role 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 matters; and
- two people with current Research experience that is relevant to the Research proposals to be considered at the meetings they attend.

To ensure the ND HREC is equipped to address all of the relevant considerations arising from the different categories, no individual may represent more than one of the categories at any individual meeting of the ND HREC but may fill a different category at a separate meeting, so long as all minimum membership categories are represented at each meeting.

The ND-HREC is comprised of staff and affiliates of Nutromics, and Members who are external to Nutromics. ND HREC Members affiliated with Nutromics who are not involved in review of the Research, will not be privy to details regarding the ND HREC review prior to its finalization. HREC Members affiliated with Nutromics must complete and declare a *RGO-FORM HREC Member Conflict of Interest Declaration.*

9. Membership Selection Criteria

General criteria:

- experience of a broad range of community activities;
- able to understand/learn and apply Research ethics principles;
- Interest in health and health research issues ;
- able to read and understand ND HREC submission documents and policies;
- able to appreciate the interests of potential Research Participants and the potential risks and benefits of Research proposals, and to assess the balance between the two;
- able to actively participate in and contribute to ND HREC meeting discussions on Research proposals and other Research ethics issues; and
- able to attend meetings and able to participate in and respond to delegated ND HREC submissions when required.

Specific Criteria:

- Community/Consumer:
  - interest in and awareness of health consumer issues;
  - not otherwise involved in health Research or health services delivery;
  - not directly associated with any Research; and
  - not a lawyer or minister of religion (or equivalent).
- Qualified Lawyer:
  - legal qualifications and experience in the practice of law; and
  - interest in and knowledge of legal issues to health services or health Research is desirable.

- Pastoral Care provider:
    - experience as a minister of religion, spiritual leader or Aboriginal elder; and
    - interest in and knowledge of religious or spiritual issues relevant to health services or health Research is desirable.
- Professional Care Provider:
    - experience in the delivery of health or community services; and
    - particular experience of service delivery in a hospital setting or a community setting, depending on the vacancy being filled.
- Research Expert:
    - experience in the conduct of health Research; and
    - experience in clinical, social science, epidemiological or laboratory Research, depending on the vacancy being filled.

10. Appointment of Members

ND HREC Members are recruited by direct approach, nomination or by advertisement through an open and transparent process by the ND HREC.

Prospective Members may be invited to observe a meeting of the ND HREC.

Prospective Members are asked to provide a copy of their curriculum vitae to a selection committee comprising of the Chair, and at least one other ND HREC Member or Nutromics RGO representative who will interview prospective Members, and make a recommendation on new appointments to the RGO.

Members are appointed as individuals for their knowledge, qualities and experience and not as representatives of any organization, group or opinion.

ND HREC Members shall receive payment in accordance with reasonable value, based on expertise and experience.

Upon appointment, Members are asked to sign a statement undertaking:

- that all matters of which they become aware during the course of their work on the ND HREC will be kept confidential;
- that any conflicts of interest (real or perceived), which exist or may arise during their tenure on the ND HREC will be declared to the ND HREC.

Members are appointed for a period of 1 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.

Membership automatically lapses if a member fails to attend:

- Three consecutive ND HREC meetings without reasonable excuse/apology or exceptional circumstances; and
- At least two thirds of all ND HREC meetings held each year, barring exceptional circumstances.

The Chair will notify the Member of a lapse of membership in writing. Steps will then be taken to fill the vacancy.

Members seeking to resign or to take a leave of absence for an extended period from the ND HREC are asked to give notice to the Chair. Steps will then be taken to fill the vacancy.

The appointment of any Member of the ND HREC may be terminated if the Chair is of the opinion (and has discussed with the RGO accordingly) that:

- It is necessary for the proper and effective functioning of the ND HREC;
- The person is not a fit and proper person to serve on an ND HREC; or
- The person has failed to carry out their duties as an ND HREC Member.

11. Training of Members

New ND HREC Members are provided with training involving the following.

- Meeting with the Chair to explain their responsibilities as an ND HREC Member and the ND HREC processes, procedures and policies;
- Praxis Australia Training for Members new to being a Member of a Human Research Ethics Committee.
    - Praxis Training is the “HREC for Busy People” course.

Members must carefully review and adhere to all relevant documents, policies and guidelines of the ND HREC and that relate to the review and consideration of Research to ensure Research submissions comply with Australian regulations. This includes TGA regulations, the National Statement, the Research Code of Conduct ICH GCP E6(R2), ISO 14155, Australian privacy principles, and any other applicable Australian standards and guidelines.

Additionally, members should consult the following specific ND HREC documents which can be found online at nd-hrec.org:

- Terms of Reference for ND HREC;
- RGO-WI HREC or Nutromics Clinical Research Centre SSA Submission;
- HREC-SOP-01: Research Review and Monitoring; and
- RGO-SOP-02: Research Governance.

Training and education on ethical review should occur at least annually for all Members and a register of all training provided to Members should be maintained.

Additionally, Members shall be informed of industry, policy and guiding document updates, as well as changes to standard operating procedures. The Nutromics’ RGO shall take responsibility for providing such training materials.

12. Meeting Schedules

The ND HREC will schedule meetings as required upon receipt of Research submissions and in response to agenda items. ND HREC meetings should be held within 10 Business Days following Research submissions.

13. Meeting Agendas

The finalized agenda for each ND HREC meeting (not including late and urgent items) will be distributed to all Members and attendees approximately 10 Business Days before the next scheduled meeting.

Records of the ND HREC's activities including agendas and minutes of all meetings of the ND HREC will be maintained.

As a minimum, the agenda should include the following items:

- Attendance and apologies;
- Declarations of conflicts of interest relating to agenda items;
- Confirmation of minutes of the previous ND HREC meeting;
- Business arising since the previous meeting(s) that the ND HREC indicated it wished to reconsider;
- Minutes of meetings and any issues for noting and/or approving from;
- Amendments to documents or modifications to submissions (including renewals);
- Annual progress reports and final reports;
- Reports of serious adverse events and suspected unexpected serious adverse reactions;
- New submissions for review and, if applicable, the spokesperson or lead reviewer nominated by the ND HREC to lead the discussion on each submission;
- General business; and
- Notification of the date, time and venue of the next scheduled meeting.

The agenda and all documentation are confidential.

14. Attendance of the Principal Investigator

At the request of the Chair, the Principal Investigator is invited to make a formal presentation or to respond directly to requests from the ND HREC for further information, clarification or reassurance.

Where the Principal Investigator is unable to attend, another key investigator or collaborator is invited to attend, if appropriate. Representatives of the Sponsor may attend the meeting in place of the Principal Investigator. Other members of the Research team may attend with the Principal Investigator.

15. Quorum Requirements

A quorum is required at each meeting for the ND HREC to reach a final decision on any agenda items. The quorum for meetings is the minimum requirement from each category as specified in the National Statement attending via videoconference.

A meeting can proceed where there is less than a full attendance of the minimum membership at a meeting but only if the Chair is satisfied that the views of those absent who belong to the minimum membership have been received and considered, for instance through prior submission of written comments. Written comments must be received prior to the meeting.

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

16. External Expert Reviewers

If ND HREC is unable to make a decision on a Research submission or is without the necessary expertise, the ND HREC is able to consult experts identified in the area, as approved by the Chair.

Advice from other external expert reviewers should be sought through the following procedure:

- Notification is sent to the Principal Investigator either before or following the ND HREC meeting explaining that a final decision will not be made on the Research submission until advice is obtained from an expert reviewer. The letter notifies the Principal Investigator of the issues of concern to the ND HREC but does not need to request further information or clarification;
- A suitable expert reviewer is identified by the Chair or by the ND HREC during the relevant ND HREC meeting;
- The Chair initially contacts the prospective expert reviewer(s) by telephone or email to establish whether they are available to provide expert advice within the required time frame and to confirm that they have no connection with the Research that might give rise to a conflict of interest. The expert reviewer is advised about confidentiality requirements and must be bound by an appropriate confidentiality agreement.; and
- The Chair specifies in writing the issues of concern to the ND HREC and the expert advice required and requests the external expert's written advice and/or attendance (but not voting) at the ND HREC meeting. The Chair ensures that the expert reviewer declares any conflict of interest and signs a declaration and confidentiality agreement.

A copy of the submission form is provided together with any supporting documentation required by the expert reviewer. The considers the advice of the expert reviewer and makes an independent decision on the ethical and scientific acceptability of the submission. The advice is recorded in the minutes.

17. Declaration of Interest

An ND HREC Member must declare to the ND HREC any conflicts of interest (real or perceived) that they have in relation to a Research submission for ethical and scientific review or any other matter for consideration at a ND HREC meeting. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on the Research outcomes.

Declarations must be made to the Chair prior to at the meeting using the RGO-FORM *HREC Member Conflict of Interest Declaration* or captured in the meeting minutes. The Chair shall determine whether the level of interest results in:

- A substantial conflict of interest:
    - a Member must be excluded from the meeting where there is a substantial conflict of interest until the ND HREC has concluded consideration of the matter. Being a Principal Investigator on a research is considered to represent a substantial conflict of interest;
- A non-substantial conflict of interest:
- the Member will have the discretion to leave during the discussion of the matter; and
- The minutes of the meeting must record all declarations of interest and the decision of the ND HREC for management of the conflict. This may include one or more of the following:
    - Implement closer supervision;
    - Take no further action but continue to monitor the conflict;
    - Limit access to systems, information or assets of the Research/ND HREC (as applicable);
    - Remove the declarant from the relevant Research submission review;
    - Exclude declarant from certain discussions or meetings;

- Exclude declarant from critical recordkeeping functions;
- Remove declarant's access to electronic or physical records in regard to the Research/ND HREC (as applicable); and
- Declarant to resign if the conflict of interest cannot be otherwise managed to the satisfaction of the Chair.

18. Confidentiality

Confidentiality of ND HREC meetings:

- The confidentiality of ND HREC proceedings and meetings is essential as:
  - Research submissions need to be discussed freely; and
  - Research submissions may have commercial implications;
- ND HREC meetings are held in private, and Members are encouraged to raise matters of concern;
- Confidentiality is addressed in two ways:
  - The ND HREC Terms of Reference; and
  - Members signing a statement of undertaking upon appointment; and
- Attendance of visitors or observers at a meeting, as appropriate and approved by the Chair, is conditional on the attendee signing a confidentiality agreement.

Confidentiality of Research submissions:

- Research submission, supporting documentation and correspondence are to be treated confidentially at all times;
- External expert reviewers providing advice to the ND HREC are asked to sign a confidentiality agreement;
- ND HREC correspondence is addressed to the Principal Investigator and the relevant contact person identified on the Research submission. Correspondence is not released to the Sponsor or any other parties; and
- Principal Investigators must forward information about matters raised in the ethical review to Sponsors or other parties where necessary.

19. Decision Making

Members present are allowed reasonable opportunity to express relevant views on matters on the agenda. Research submissions to ND HREC are reviewed in accordance with *SOP: HREC Research Review and Monitoring.*

The ND HREC endeavors to reach a decision concerning the ethical and scientific acceptability of a Research submission by unanimous agreement.

Where a unanimous decision is not reached, the Chair will need to facilitate the expression of opinion of all Members, identify points of agreement and of disagreements and judge when a sufficient degree of general agreement has been reached. Any significant minority view (i.e., 2 or more members) should be noted in the minutes.

Discussions of significant issues and decisions should be recorded in the minutes.

Where Members wish, a record of their formal dissent from the decision of the ND HREC is to be recorded in the minutes.

An ND HREC Member unable to attend a meeting may submit comments in writing on agenda items to the Chair prior to the meeting. Submission of written comments are to be recorded in the minutes.

20. Decisions available to ND HREC

The ND HREC selects one of the following decisions on any Research submission reviewed at a meeting and the decision is recorded in the minutes:

- To approve the research as being ethically acceptable, with or without conditions;
- To provide provisional approval to the research with requested amendments,
- To defer making a determination in regard to the research until the clarification of information or the provision of further information is provided to the ND HREC; or
- To not approve of the research.

The Chair is to ensure that one of the above decisions is made in regard to each Research submission considered at an ND HREC meeting.

21. Complaints

21.1 Complaints about the conduct of Research

If a Researcher receives or has a complaint regarding any aspect of the Research, or the way in which is Research is being conducted, the Principal Investigator should be notified. The Principal Investigator must act appropriately, impartially and in proportion to the complaint. In most cases, this person will be able to resolve the complaint by addressing the concerns of the complainant.

The Principal Investigator must also consider that they have a responsibility to determine whether to suspend/modify the Research should there be reasonable suggestion of harm to a Participant(s) and must report these concerns to the ND HREC via HREC@nutromics.com and may seek the ND HREC's assistance.

The ND HREC may impose a penalty on Researchers for not reporting relevant concerns and complaints received from Participants.

The Researchers, and participants can make complaints to the HREC directly, via email (HREC@nutromics.com), which will be addressed with the Principal Investigator, for them to resolve the complaint by addressing the concerns of the complainant. Additionally, the Principal Investigator must also report their own concerns regarding any aspect of a research, or the way a research is being conducted to the ND HREC.

Should the complaint not be resolved (or require further investigation) the Nutromics' RGO will conduct a preliminary investigation into the complaint and determine the appropriate course of action. If urgent action is deemed to be required, the Chair may take appropriate steps to ensure that the rights and welfare of Participants are protected. Such action may include suspending the approval for a Research whilst an investigation is conducted.

Following the initial review of a complaint, possible outcomes are that:

- no further action is required; or
- There are sufficient grounds to investigate the complaint further.

If a further investigation is warranted, a meeting may be required between the ND HREC Chair or full ND HREC, the RGO and the Researcher(s). The following procedures which are recommended in the National Statement, may occur:

- Invite the Principal Investigator to explain the situation to the committee and to demonstrate why the Research should not be discontinued and ethical approval withdrawn;

- Advise the Principal Investigator that they may be accompanied by one or more colleagues including their line manager;
- Reconsider the original research proposal and seek additional information from the Principal Investigator in relation to the conduct of the Research, or any other relevant factors, before making a final decision whether to revise or reconfirm the original decision to approve the Research.

Having considered the matter, the ND HREC may:

- Withdraw approval and stop the Research;
- Require amendments to the original Research proposal or to the conduct of the Research;
- Allow the Research to continue without amendment;

The ND HREC should provide the Principal Investigator and the complainant with an explanation of the outcome. In some cases (e.g., if approval is withdrawn) it may be necessary to notify the other Research Participants.

In some circumstances, it is recommended that the complainant address the ND HREC or meet with Members of the ND HREC, depending on whether the complainant would be comfortable in this situation and nature of the complaint, to discuss the concerns.

If a PICF is used in the Research, the ND HREC and Nutromics' RGO must ensure, as part of its ethical review and site review, that it contains contact details for submitting complaints concerning matters relating to the site (site contact person) and matters relating to an aspect of the Research or the conduct of the Research .

21.2 Complaints regarding the ND HREC review process or outcome

Any concern or complaint about the ND HREC review process is to be submitted to the ND HREC Chair. This is done in writing via email and must detail the grounds of the concern or complaint, and all the material relating to the Research and the complaint will be considered by the ND HREC Chair.

If the complaint is regarding a Research submission which has not already been approved by ND HREC, then there are further opportunities to negotiate the details involved in the Research to ensure compliance with ethical issues. If a Research submission has had conditions placed upon it, in which the Researcher feels adversely affects the quality of the Research, the Researcher may request that the ND HREC reconsider its decision. This may involve the Researcher s being asked to attend a meeting to discuss the Research. The Committee may wish to also obtain expert advice at this stage.

The National Statement advises that if the matter is not thereby resolved to the satisfaction of the complainant, that the complainant may take further steps, including an appeal against the decision and seek a meeting with the ND HREC Chair, for further clarification.

The complainant(s) may be accompanied by one or more support persons, or, in the case of Researchers, one or more colleagues. A record of any such meeting should be kept. The Chair will investigate the appeal and recommend to the ND HREC the appropriate course of action within 4 weeks from the date of the appeal being lodged. The ND HREC will notify the appellant of the course of action and determination in a timely manner.

Following an appeal being lodged to the ND HREC Chair, if the appellant considers that the ND HREC has not followed due process or remains unsatisfied with the outcome, they may choose to lodge an appeal with the Nutromics' RGO.

The Chair will provide the Nutromics' RGO with all relevant material, including:
- Details of the appeal;
- Material reviewed by the ND HREC; and
- The outcome/decision of the ethical review process by the ND HREC.

The RGO will determine if further investigation of the appeal is necessary. If so, a panel will be established to consider the appeal. The panel will include the following members:
- The Chief Executive Officer / delegate of the Institution;
- At least one nominee with relevant expertise in human research ethics; and
- Expert(s) in a discipline of research related to the submission

The panel will allow the ND HREC and the appellant the opportunity to make submissions. The Nutromics RGO will notify the ND HREC and the appellant of the outcome of the investigation. The possible outcomes include:
- The appeal is dismissed;
- The appeal is upheld, and the panel makes recommendation to resolve the issues
    - based on the findings of the panel; or
- Referral of the Research submission to an independent ethics committee for re-review.
- The panel or the Nutromics' RGO / delegate cannot reverse the final determination of the ND HREC.

22. Minutes

A ND HREC Member or secretariat is to prepare the minutes of each ND HREC meeting in consultation with the Chair and other Members as necessary.

The minutes should reflect each item listed for discussion on the agenda:
- Attendance and apologies;
- Declarations of conflicts of interest relating to agenda items;
- Confirmation of minutes of the previous ND HREC meeting;
- Business arising since the previous meeting(s) that the ND HREC indicated it wished to reconsider;
- Minutes of meetings and any issues for noting and/or approving from the ND HREC Executive Committee, and external expert reviewers;
- Amendments to documents or modifications to Research submission (including renewals);
- Annual progress reports and final reports; and
- Reports of serious adverse events and suspected unexpected serious adverse reactions;
- ND HREC deliberations and decisions on new Research
- Submission of written comments by Members;
- Summaries of the advice given by expert or lead reviewers;
- Summaries of the main issues considered;
- Decisions of the ND HREC on the submission; and
- Formal dissent from the decision of the ND HREC by a Member and the reason for it and/or any significant minority views (i.e. 2 or more Members)
- General business; and
- Notification of the date, time and venue of the next scheduled meeting.

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

The minutes of ND HREC meetings are made available to the RGO via researchgovernance@nutromics.com email.

23. Record Keeping

The following documents are required for all Research and should be provided when submitting a Research submission for ethical review by the ND HREC. The ND HREC will retain copies of all documentation (including any correspondence) in the form in which they were approved for 15 years following completion of the Research:

- Protocol;
- Participant Information Sheet and Consent Forms;
- Recruitment material (letters, posters, advertisements);
- Questionnaires and surveys;
- Ethics Amendment Request;
- Any other participant documents (food diaries etc.);
- Investigator Brochure;
- Other relevant HREC approvals;
- Details of other review bodies involved;
- Decision of other review bodies;
- Details of any amendments required by other review bodies;
- Insurance statements;
- Indemnity documents;
- Financial budgets;
- Researcher qualification documentation;
- Sample Case Report Forms; and
- Any other approvals or submissions (Institutional Biosafety Committee, Radiation Safety, Cellular Therapies Advisory Committee etc.)

The ND HREC maintains a record for each Research submission received and reviewed, including as to its membership, minutes and correspondence, which will be kept as secure confidential electronic files, including details of::

- The unique Research identification number;
- The Principal Investigator(s); and
- Title of the Research being undertaken/
- Correspondence between the review body and the Researcher about the ND HREC's review should include:
    - acceptance or rejection of any changes to the Research submission;
    - proposed date of completion of the Research;
    - formal advice of final ethical approval or non-approval, including the date of this decision;
    - terms and conditions, if any, of approval of any Research by the ND HREC;
    - duration of the approval;
    - mechanisms to be used to monitor the conduct of the Research; and
    - relevance, if any, of any Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.

In addition, the ND HREC will retain on file a copy each Research submission for ethical approval, including all documentation, in the form in which they were approved by the ND HREC.

The ND HREC will record decisions about approval, amendment or rejection of Research submissions in written or electronic form, with reasons for those decisions, linking those reasons to the National Statement.

To ensure confidentiality, any documents provided to ND HREC Members, which are no longer required, are disposed of in a secure manner, such as shredding or placed in confidential bins.

Records will be retained for 15 years following the completion of the Research.

24. Duration of ND HREC Approval

ND HREC approval applies for a maximum of 5 years, except where action is taken to suspend or terminate the decision by the ND HREC.

The request to extend the duration of the Research must be submitted by the Principal Investigator as an amendment for review by the ND HREC in the first instance.

Any ND HREC approval for an extension applies for a maximum of 5 years, except where action is taken to suspend or terminate the Research.

25. Review of Standard Operating Procedures and Terms of Reference

These ND HREC's standard operating procedures (SOPs) and terms of reference (ToR) shall be reviewed at least every two years and amended as necessary.

These standard operating procedures and terms of reference may be amended by following the procedure:

- The ND HREC Chair shall work with the Nutromics' RGO to make amendments to SOPs/TOR documentation; and
- The ND HREC Chair shall communicate these proposed changes and seek any feedback / recommendations and finalize with the Nutromics' RGO.