Research Ethics Submissions
Approval that a human research proposal meets the requirements of the *National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2023)* and is ethically acceptable provided before research can begin.

Site Authorisation
Site Specific Assessment (SSA) is a component of research governance and separate to the ethical review of research proposals by a recognised Human Research Ethics Committee (HREC). The SSA process involves assessing the suitability of the research proposal for the Nutromics Clinical Research Centre (NCRC at 420 Victoria St, Brunswick 3056 VIC) and ensures that adequate resources exist for satisfactory conduct and completion of the research.

The appropriate site submission form must be submitted by the researcher via email to researchgovernance@nutromics.com

The Research Governance Office (RGO) must authorise or not authorise the research occurring at the NCRC, with consideration of the RGO recommendation. Authorisation is required before research commences at the site.

HREC Submission
Submissions must be submitted by researchers via the Nutromics Diagnostics HREC Ethical Review Management System (ERMS); Research Manager. Researchers will email HREC@nutromics.com to request an account be set up for submission, after which they will be assigned an account for ERMS access.

ERMS Link: https://nutromicsdiagnosticshrec.myresearchmanager.com/

Legislation and Guidelines
Researchers should carefully review and adhere to all relevant documents and guidelines to ensure submissions 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 RGO documents which can be found online at nd-hrec.org

- Terms of Reference for ND HREC
- HREC-SOP-01: Research Review and Monitoring
- HREC-SOP-02: HREC Operations
- 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

Risk Assessment of Research
The National Statement recognizes that human research involves a wide range of activities that have variable risks and potential benefits.

Researchers and the ND HREC are required to determine the existence, likelihood and severity of potential risks based on the research methodology and design, participant population and research activity, including the complexity of the research to be undertaken. Monitoring arrangements should be put in place that are commensurate with relevant potential risks, and the size and complexity of the research to be undertaken as approved by the ND HREC.

Researchers are to specify the review pathway that they seek upon submission on the ERMS (i.e.: “Lower Risk Research” Review Pathway, or “Higher Risk Research” review).

SSA or ND HREC Submissions
For submissions to the ND HREC or RGO for SSA, the following components are to be submitted (if applicable) for review. All documents should be dated and version controlled.

If revisions occur during the course of the research, revised document must be submitted as an amendment. All amendments to documentation require edit tracking, with a comprehensive change history log, version, and date adjustments as appropriate. Researchers should also consult the appendix of this document which describes key submission requirements.

Components for submission to the Human Research Ethics Committee	YES	NO	N/A
1. Cover letter signed by the Principal Investigator. • A brief description of the research including the Phase of the research • A list of supporting documentation submitted including version dates/numbers. • For commercially sponsored research studies; the name and address of the sponsor for the HREC review.			
2. HREC Submission Questionnaire on ERMS			
3. Protocol			
4. Researcher qualification documents (CV, GCP certifications, licensure)			
5. Letters of Approval from other Human Research Ethics Committees.			
6. Participant Information Consent Form (CF) • Full letterhead with contact details. • If more than one CF e.g. different target groups of participants, it should be clear which group the CF is aimed at, e.g. stated in a header or footer with version number. • Written in plain simple English. • Researcher’s name and contact details included. (Site specific). • Consent for all procedures e.g. access to medical records, audio/video recording – dot points for non-optional items; Yes/No boxes only for optional items. • A space for research participant’s printed name and signature, and date and time of consent.			

Components for submission to the Human Research Ethics Committee	YES	NO	N/A
• A space for witness / interpreter's printed name and signature. • A space for the researcher's printed name and signature.			
7. CTN Form(s) – include original CTN forms with details for each site. (Clinical Trial Notification to TGA Form)			
8. CTA Form (Clinical Trial Application to TGA Form)			
9. Investigator's Brochure			
10. Questionnaires/surveys/interview guides/other instruments			
11. Data collection tool(s) e.g. Data Collection Form, Case Report Form.			
12. Certificate of Insurance / Indemnity Documents			
13. Clinical Trial Registration Number and public register details (such as the Australian New Zealand Clinical Trial Registry ANZCTR)			
14. Form of Indemnity (Medicines Australia HREC Review Only Form) for each participating site.			
15. Copy of the Form of Indemnity (Standard Form) for each participating site.			
16. Advertising materials (including transcript for advertisement, flyers, e-mail, website, letter, telephone calls etc).			
17. Letter of invitation / Letter to GP etc.			
18. Other correspondence e.g. FDA reviews, correspondence with other HRECs, expert independent reviews, peer review etc.			
19. Signatures • PI may sign on behalf of other investigators if applicable. • If it is impossible to ascertain original signatures and only electronic signatures can be provided; please attach a letter or email from the researcher involved as evidence of consent for the use of their electronic signature and acknowledgement of support to the research.			
20. Research budget			
21. Sample Case Report Form			
22. Data Management Plan			
23. Risk Management Plan			
20. Ionising Radiation Certificate			
21. Institutional Biosafety Committee (IBC) approval letter.			
22. License for dealings with Genetically Modified Organism (GMO)			

Appendix: Submission Requirements

1. Researcher Conflicts of Interest

Researchers should declare any conflicts of interest (actual, perceived or potential), that may influence their conducting of research, including influence over (but not limited to) the analyses of the research, recruitment or compliance.

The ND HREC will consider the declaration (in line with the relevant sections of the National Statement) and may require additional detail such as how the conflict will be managed.

2. Compensation for Injury

All PICF documentation for research within scope of the ND HREC review, must include a clause regarding compensation for injury.

"If you suffer any injuries or complications as a result of this research, you should alert the researchers as soon as possible and you will be assisted with arranging appropriate medical treatment.

There are two avenues that may be available to you for seeking compensation if you suffer an injury because of your participation in this research:

- *The medical technology industry has set up a compensation process, with which the Sponsor of this research, {Sponsor}, must comply. Details of the process and conditions are set out in the Medical Technology Association of Australia (MTAA) Guidelines for Compensation for Injury In accordance with these Guidelines, the Sponsor will determine whether to pay compensation to you, and, if so, how much. If you have any questions about the Guidelines, please ask to speak with the researchers.*
- *You may be able to seek compensation through the court."*

3. Data Management Plan

Data management plans should consider all regulatory and ethical guidelines, describing how data from research should be stored, and how privacy and confidentiality is managed. Key items for inclusion into the data management plan is outlined below;

Data Recording and Storage
- Data are securely recorded and stored.
- Storage locations are documented.
- Published data are retained for at least five years; clinical research data for 15 years.

Network and Data Security
- Network-connected systems ensure data security.
- Cross-border data transfers comply with Australian Privacy Principles (APP 8, HPP9).
    - Overseas recipients handle personal information according to these principles and are accountable for mishandling.

Data Sourcing and Documentation
- Location of original data from limited access databases or contractual sources is documented.
- Security systems support multiple researchers and handle departures.

Personal and Health Information
- Collection, use, and disclosure of personal and health information comply with legal requirements and obtain appropriate consent.
- Future use of data/tissues complies with ethical guidelines.
- Participants understand whether their information is identifiable, re-identifiable, or non-identifiable.

- Participants are informed about health record reviews by researchers, authorities, and sponsors.
- Research publications do not identify participants.

Additional Information to Include

- Security measures (physical, network, system, technological) are in place.
- Policies and procedures are documented.
- Contractual and confidentiality agreements are included.
- Data storage format is specified.
- Purposes for data use and/or disclosure are defined.
- Conditions for granting data access are outlined.

3.1 Wording for PICF

All PICF documentation for research within scope of the ND HREC review must include a clause regarding data management, such as:

"By signing this consent form, you agree to allow the researchers to collect and use your personal information. Any information that can identify you will remain confidential and will only be used for this research, disclosed with your permission, except as required by law.

Your personal information, including test samples, will have identifiers removed and replaced with a unique identification code. The researchers will be able to re-identify your information only if a necessary follow-up visit is required. The identification code will be stored electronically, and access to this code will require a password.

The collection, use, and disclosure of your personal and health information will comply with legal requirements and obtain your consent. Any future use of your data or tissues will adhere to ethical guidelines. The researchers have implemented comprehensive security measures. The purposes for which your data will be used and/or disclosed include [describe usage of data].

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the researcher, and to request corrections to any information with which you disagree. Please contact the researchers if you would like to access your information.

Published data will be retained for at least five years, and clinical research data for 15 years. The researchers' network-connected systems ensure data security, and any cross-border data transfers will comply with Australian Privacy Principles (APP 8, HPP9). Overseas recipients of your data will handle it according to these principles and will be accountable for any mishandling.

The results of this researcher may be published and/or presented in various forums, but your information will be provided in such a way that you cannot be identified, except with your express permission. If you wish to receive a copy of the published information, please request it. Research publications will not present information in a way that identifies you.

If you withdraw from the research, your personal data already collected will still be used. After your withdrawal, no new personal data will be collected or processed for the research, unless it relates to an already reported side effect."

4.0 Insurance and Indemnities

There must be insurance and indemnities in place to cover all research (refer to *NHMRC guidance; Indemnity and insurance arrangements for clinical trials*)

Anyone involved in human research, whether individuals or organizations, should have adequate insurance coverage to protect against potential liabilities.

Before research can commence, both the sponsor and the Principal Investigator must secure sufficient insurance coverage. The investigator's professional indemnity insurance should cover any gaps in the overall coverage. Liabilities may arise from initiating or sponsoring the research, including the development of the research protocol or conduct.

Researchers must provide a insurance certificate that covers the following:

- Named Insured: The Australian entity acting as the sponsor must be named as an insured party under the insurance policy.
- Coverage Evidence: Provide evidence that the insurance covers the conduct of the relevant research in Australia.
- Policy Validity: Provide evidence that the insurance policy will be current throughout the entire period of the research.
- Minimum Coverage: The Sponsor and Principal Investigator are responsible for ensuring the research has adequate coverage (National Statement on Ethical Conduct in Human Research, Sections 5.1.46-5.1.47).
- No-Fault Liability: The insurance must cover no-fault liability, recognizing that any injury would not have occurred without the participant's involvement in the research.

Sponsors must ensure that indemnities are established to cover the research, these may include (but not limited to);

- Medical Technology Association of Australia (MTAA) Form of Indemnity, which is an agreement between the sponsor and the Principal Investigator or site.
- The HREC indemnity, which is an agreement between the sponsor and the ND Human Research Ethics Committee (HREC).

Where Nutromics is the sponsor of a submission to the ND HREC, a HREC indemnity is not required.

5.0 Complaints About Research Conduct

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 .