FORM		
	Document Description	Version No.
	SITE SPECIFIC ASSESSMENT APPLICATION	**2.0**

Instructions

- This form must be completed by the Principal Investigator or delegate For studies being conducted at the Nutromics Clinical Research Centre; 420 Victoria St Brunswick VIC Australia, for submission to the Nutromics Research Governance Office (RGO). Not all sections of the form will be relevant.
- The Site Specific Assessment (SSA) application can only be submitted once the reviewing Human Research Ethics Committee (HREC) approval has been given.
- The checklist at the end of this form will assist to ensure a full submission is completed before submission to the RGO.
- This application form shall be submitted to the RGO, in addition to the documentation outlined in *RGO-WI ND HREC or Nutromics Clinical Research Centre SSA.*

Research Project

HREC reference number	
HREC approval date	
Date of this report	
Project Title	
Sponsor	
Principal Investigator	
HREC reference number	
HREC approval date	
Date of this report	
Project Title	
Sponsor	
Principal Investigator	

Research Description

Give a concise and simple of the aims of this research, the proposal research design and the methods to be used achieve those aims.

Researchers

Principal Investigator	
Title	
First name	
Surname	
Mailing address	
Organisation name	
Position in organisation	

Business hours phone number	
Fax number	
Email address	
AHPRA registration	
AHPRA expiry	

Principal Investigator	
Title	
First name	
Surname	
Mailing address	
Organisation name	
Position in organisation	
Business hours phone number	
Fax number	
Email address	
AHPRA registration	
AHPRA expiry	

Co Investigator	
Title	
First name	
Surname	
Mailing address	
Organisation name	
Position in organisation	
Business hours phone number	
Fax number	
Email address	
AHPRA registration	
AHPRA expiry	

Training

Will any of the researchers at this site require extra training to enable their participation in this project?

Researcher	Training Required	Who will provide training?

Recruitment

What process will be used to identify potential participants for the study at this site?	
Describe how initial contact will be made with potential participants at this site.	
What categories of people will be recruited at this site? (e.g. children and young people, people with an intellectual or mental impairment etc.)	

Does this study involve adults with impaired capacity to consent	☐ yes	☐ no
Have the researchers had relevant community engagement with Aboriginal and Torres Strait Islander individuals, communities and/or organisations in conceptualisation, development and approval, data collection and management, analysis, report writing and dissemination of results for this study, relevant to this site?	☐ yes	☐ no

Provide the anticipated start and finish dates for research at this site
Start date refers to the anticipated first point of recruitment i.e. the date when the advertising or screening for participants begins.

Finish date refers to when no further contact with participants/data source is foreseen including the data analysis and reporting period.

Start date (dd/mm/yyyy)	
Finish date (dd/mm/yyyy)	
Duration (months)	

Clinical Trials Registry

Is the clinical trial registered on a publicly accessible clinical trials registry database?	☐ yes Reference number: _____	☐ no
If no, please explain why the study is not registered on a publicly accessible clinical trials registry database		

Indemnity and Insurance

Is the Medicines Australia Standard Indemnity Form(s), signed by the sponsor attached?	☐ yes	☐ no
Is there evidence of adequate insurance cover attached?	☐ yes	☐ no

Research Study Agreements

Is there a written research study agreement, signed by all relevant parties attached?	☐ yes	☐ no
If Yes, please indicate what type of study agreement (ie: Medicines Australia (MA) Standard Clinical Trial Agreement)		

Intellectual Property considerations

Is there a possibility of new Intellectual Property to be developed from this project?	☐ yes	☐ no
Has a search of patent databases been undertaken?	☐ yes	☐ no
Does the contract state arrangements for the use of existing intellectual property and the parties' rights in relation to ownership?	☐ yes	☐ no
Does the contract state arrangements for the use of all new intellectual property developed through the research project?	☐ yes	☐ no

Biosafety, chemical and radiation safety (complete only if relevant to this site)
It may be necessary for research organisations to complete notification, registration or license requirements for research involving biosafety, regulatory issues and/or radiation. If so, evidence of this is required.

Is Institutional Biosafety Committee (IBC) notification and/or license application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms required?	☐ yes	☐ no
Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment? CTAC (Cellular Therapies Advisory Committee)	☐ yes	☐ no
Will the project require application for a license to the NHMRC Licensing Committee to conduct embryo research?	☐ yes	☐ no
For projects where Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code compliance is required, is additional State-specific radiation safety approval and registration required?	☐ yes	☐ no

Declaration by the Principal Investigator

1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.
2. I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC);
3. I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (2023) and the Australian Code for the Responsible Conduct of Research.
4. I undertake to conduct this research in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
5. I undertake to conduct this research in accordance with relevant legislation and regulations.
6. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC
7. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
8. I will inform the HREC if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
9. I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, the sponsor or an independent body for audit and monitoring purposes.

Principal Investigator name	
Principal Investigator signature	
Date	