Revised 1/6/21: NIH Toolbox added

ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project Number: HREC/69184/Alfred-2021 (Local Reference: Project 594/20)

Project Title: A Phase 2 Randomised Controlled Trial of Sodium Selenate as a Disease Modifying Treatment for Probable Progressive Supranuclear Palsy

Coordinating Principal Investigator: Professor Terence O'Brien

*was considered under the National Mutual Acceptance (NMA) scheme by the Ethics Committee on **18-DECEMBER-2020**, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on **13-APRIL-2021.***

It is the Coordinating Principal Investigator's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Coordinating Principal Investigator is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Coordinating Principal Investigator to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Coordinating Principal Investigator is required to submit

- A Progress Report on the anniversary of approval and on completion of the project.

The Ethics Committee may conduct an audit at any time.

All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).

The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).

SPECIAL CONDITIONS

1. **All research projects approved by the Alfred Hospital Ethics Committee are subject to, and must be carried out in compliance with, the most recent applicable COVID-19 government and relevant institution's restrictions.**

2. Clinical trial registration ID, when available.

APPROVED DOCUMENTS
Documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Protocol (SEL003)	1	19-Oct-2020
Investigator's Brochure for Sodium Selenate	5.0	Oct-2019
Master Participant Information Sheet & Consent Form – Main	1	31-Mar-2021
Master Participant Information Sheet & Consent Form – Person Responsible/Medical Treatment Decision Maker	1	31-Mar-2021
Master Participant Information Sheet & Consent Form – Support Person/Caregiver	1	31-Mar-2021
Master Participant Information Sheet & Consent Form – Main – Imaging at the Alfred (for Victorian sites)	-	12-Apr-2021
Master Participant Information Sheet & Consent Form – Person Responsible/Medical Treatment Decision Maker – Imaging at the Alfred (for Victorian sites)	1	12-Apr-2021
Master Participant Information Sheet & Consent Form – Support Person/Caregiver – Imaging at the Alfred (for Victorian sites)	1	12-Apr-2021
Medical Treatment Decision Maker Checklist	-	08-Mar-2018
Alfred Health Lumbar Puncture: Information for Patients	-	Jun-2010
Participant Adverse Event Diary Card	1	10-Dec-2020
NIH Toolbox – iPad App Version	1.10	2006-16
Questionnaire - Clinical Global Impression (CGI)	-	undated
Questionnaire – FAB	-	undated
Questionnaire – TMT Adult Stimuli	-	undated
Questionnaire – WAIS IV Record Form Digit Span Forward & Backward	-	undated
Questionnaire – ORL/CFT	-	undated
Questionnaire – Victoria Stroop Stimuli	-	undated
Questionnaire – Victoria Stroop Form	-	undated
Questionnaire – the Hayling and Brixton Tests	-	undated
Questionnaire – Brief Informant Report	-	undated
Questionnaire – Progressive Supranuclear Palsy Rating Scale	-	undated
Medical Physics Report – Alfred Health	-	20-Oct-2020
Radiation dose and risk assessment – Royal Adelaide Hospital	1	21-Oct-2020
Radiation Risk Assessment Report – St Vincent's Hospital Sydney	1.0	Signed 16-Nov-2020
Radiation Dosimetry Report – Brain and Mind Centre	-	01-Dec-2020
Radiation Dose Assessment from Nuclear Medicine & Specialised PET Services - QLD | Royal Brisbane and Women's Hospital	-	Signed 18-Mar-2021
NSW Privacy Form	-	Provided 05-Nov-2020

APPROVED SITES
Approval is given for this research project to be conducted at the following sites and campuses:

1. The Alfred (Alfred Health) (Site PI: Prof Terence O'Brien)
2. Royal Melbourne Hospital (Melbourne Health) (Site PI: Dr Andrew Evans)
3. Royal Adelaide Hospital (Site PI: A/Prof Thomas Kimber)
4. St Vincent's Hospital Sydney (Site PI: Dr Stephen Tisch)
5. University of Sydney (Site PI: Prof Simon Lewis)
6. University of Queensland (Site PI: Prof John O'Sullivan)

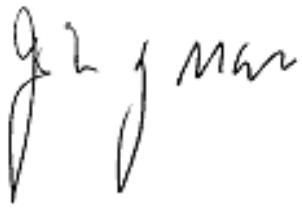
The Alfred Hospital Ethics Committee has approved the study but does not take responsibility for research governance processes at the participating sites. It is the responsibility of each participating site to create and implement research governance practices to adequately authorise, monitor and oversee the conduct of the study at their site.

Site-Specific Assessment (SSA)
SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site-Specific Assessment Form and a copy of this ethics approval letter must be submitted to the Research Governance Officer for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

The HREC wishes you and your colleagues every success in your research.

SIGNED:



Chair, Ethics Committee

Please quote project number and title in all correspondence