Queensland Government

Metro South Health

Research

Enquiries to: Metro South Human Research Ethics Committee
Telephone: 07 3443 8049
Our Ref: HREC/2020/QMS/61872 (SR)
Email: MSH-Ethics@health.qld.gov.au

Prof Raymond Chan
Division of Cancer Services
Princess Alexandra Hospital

Dear Prof Chan,

HREC Reference: HREC/2020/QMS/61872 (Apr ver 2)
Protocol title: Partnering with General practitioners to Optimise Survivorship for PatiEnts with Lymphoma: A Phase II randomised controlled trial (The GOSPEL I Trial)

Thank you for submitting the above research protocol to the Metro South Human Research Ethics Committee for ethical and scientific review. This protocol was first considered by the Human Research Ethics Committee (HREC) at the meeting held on 3 March 2020.

I am pleased to advise you that the research protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)* and ethical clearance has been granted. This HREC clearance is valid from 14 April 2020.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the Hospital Health Service Chief Executive (CE) or Delegate of that site has been obtained.

A copy of this approval must be submitted to the Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the CE or Delegate to conduct this research at Princess Alexandra Hospital.

If this study currently receives grant funding, please remember to forward a copy of this approval letter to the relevant Grants Office of the Administering Institution(s) for the grant.

The documents reviewed and approved include:

Document	Version	Date
HREA Form submitted via Ethical Review Manager (ERM)	2	01.04.2020
CVs – Chan, Gordon, Turner, Simonsen, Teleni	N/A	2020
Cover letter	1.0	12.02.2020
Brochure_Patient_GOSPEL	1.0	12.02.2020
Case Report Form_GOSPEL	1.0	12.02.2020
Brochure_GP_GOSPEL	1.0	12.02.2020
PICF_GOSPEL	1.3	31.03.2020
Protocol_GOSPEL	1.0	31.03.2020
SDL_GOSPELIntwerviewSchedule	1.0	12.02.2020

Response to ethics	1	31.03.2020

Ongoing approval is for the duration of the project, conditional on:

1. Prior to commencement of the study, the Principal Investigator must conduct a risk assessment relative to the feasibility to commence the research, and to what degree the safety of all relative parties will be impacted, if the research were to proceed during the COVID-19 pandemic. As part of this assessment, the Principal Investigator should address the relevant considerations which include (but are not necessarily limited to) the following;
    - The most recent information available pertaining to the conduct of research during the COVID-19 pandemic, has been investigated, considered and is understood by the research team;
        - For the latest state-wide information from the Health Innovation, Investment and Research Office (HIIRO), please refer to the following:
            - https://www.health.qld.gov.au/hiiro/html/regu/regu_home
        - For the latest Metro South-specific information: https://metrosouth.health.qld.gov.au/research/researchers
    - The safety of all parties involved in the research (either directly or indirectly) is afforded or has been assured insofar as could be reasonably known at the time. This may include some or all the following: patients, research participants and their families, health care professionals, researchers and other staff involved in patient care.
    - Staff and resources dedicated to the research would not unreasonably impact the public health systems' ability to respond to more critical needs of the community during the COVID-19 pandemic. The Principal Investigator should weigh the importance and/or justification of the research, against any known need to re-allocate research staff or resources to clinical care and other areas of patient support.
    - Planning has been afforded to account for the expectation that the end-point of COVID-19, and its ongoing impact on clinical research, is unknown, unprecedented and inconclusive at this present stage. To this effect, the Principal Investigator holds responsibility for the reassessment and adaptation to initial risk assessment strategies, as advice relative to COVID-19 is re-evaluated and subjected to change over time. Moreover, the Principal Investigator should endeavor to stay abreast of new information brought to light, specific to COVID-19, that could thereby have implications for the research and the safety of those involved. The Principal Investigator should update and document new versions of the risk assessment, which should be maintained/stored as per the standard record-keeping process.
2. In accordance with Section 5.5.6 (b) of the National Statement, the Principal Investigator will report to the HREC annually (**Due by 30 April each year)** in the specified format with a final report to be submitted on completion of the study.
3. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol as per the National Health and Medical Research Council's (NHMRC) guidance on *Safety Monitoring and Reporting in Clinical Trials involving Therapeutic Goods (2016)* and its supplementary documents.
4. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review electronically via Ethical Review Manager (ERM). Major amendments should be reflected in revised study documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study.
5. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.

6. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
7. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically via ERM. These should include a cover letter from the Principal Investigator or Study Co-ordinator providing a brief description of the changes and the rationale for the changes and accompanied by all relevant updated documents with tracked changes.
8. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
9. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.
10. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

Please note: The Metro South HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007, updated 2018), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. The composition of the Metro South HREC is attached on the final page of this letter.

Should you have any queries about the HREC's consideration of your protocol please contact Ethics Secretariat on 07 3443 8049.

The Metro South HREC wishes you every success in your research.

Yours sincerely,

A/Prof Scott Campbell
Chair
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Metro South Research
_14_/_04_/_2020_

TO WHOM IT MAY CONCERN

The following is the current composition of the Metro South Human Research Ethics Committee as at 1 January 2020. It is advised that the Committee abides by the guidelines of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*.

COMPOSITION OF METRO SOUTH HUMAN RESEARCH ETHICS COMMITTEE	MEMBER
Category A – Chairperson	Scott Campbell
Category A – Deputy Chairperson	Mary Boyde
Category B - Lay Female	Beverley Kurkowski
Category B - Lay Female	Jaye Buswell
Category B – Lay Female	Judith Wardell
Category B - Lay Male	David Milne
Category C - Knowledge of Professional Care	Kelly Perkins
Category C - Knowledge of Professional Care	Jenny Jones
Category C – Knowledge of Professional Care	Bena Brown
Category C – Knowledge of Professional Care	Lisette Brock
Category C – Knowledge of Professional Care	Megan McKerrow
Category C – Knowledge of Professional Care	Andrew Wheaton
Category C – Knowledge of Professional Care	Melissa Arneil
Category C – Knowledge of Professional Care	Vera Meeusen
Category D – Pastoral Care Role in Community	Bruce Monley
Category D – Pastoral Care Role in Community	Cindy Sinclair
Category D – Pastoral Care Role in Community	David McEwan
Category D – Pastoral Care Role in Community	Trevor Jordan
Category E – Lawyer	John Bennett
Category E – Lawyer	Susan Gardiner
Category F - Knowledge of Research	Adam La Caze
Category F - Knowledge of Research	Marianne Wyder
Category F – Knowledge of Research	Theo Theodoros
Category F - Knowledge of Research	Ayesha Shah
Category F – Knowledge of Research	Nicole Warrington
Category F – Knowledge of Research	Aideen McInerney-Leo
Category F – Knowledge of Research	Dariusz Korczyk
Category F – Knowledge of Research	Rahul Ladwa
Category F – Knowledge of Research	Victoria Atkinson
Category F – Knowledge of Research	Tatiane Yanes
Category F – Knowledge of Research	Shivanand Hebbandi

Should you require further information, please do not hesitate to contact our office on the telephone number listed above. Attendance at the Committee meeting was in accordance with Guidance of the National Statement 5.2.30.