Monash Health

Research Support Services
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17 July 2020

Dr Kirsten Palmer
Monash Health and Monash University
Department of Department of Obstetrics & Gynaecology
246 Clayton Road
Clayton VIC 3168

Dear Researcher,

Study Title: Determining the Pharmacokinetics of Oral Creatine in Human Pregnancy
NMA/ERM Reference Number: 59861
Monash Health Reference: RES-20-0000-138A

The Monash Health HREC reviewed the above application at the meeting held on 05 March 2020. In addition, the HREC is satisfied that the responses to our correspondence of 06 March 2020 have been sufficiently addressed.

The HREC approved the above application on the basis of the information provided in the application form, protocol and supporting documentation.

This reviewing HREC is accredited by the Victorian Department of Health and Human Services under the National Mutual Acceptance, single ethical review system.

Approval

The HREC approval is from 15 July 2020.

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2018)*. The HREC has ethically approved this research according to the Memorandum of Understanding between the Victorian Department of Health and Human Services and the participating organisations conducting the research.

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

- Monash Health;
- Hudson Institute;
- Monash University;

You must comply with the following conditions:

The Chief Principal Investigator is required to notify the Manager, Human Research Ethics Committee, Monash Health of:

1. Any change in protocol and the reason for that change together with an indication of ethical implications (if any)
2. Suspected Unexpected Serious Adverse Reactions (SUSARs), Serious Adverse Events (SAEs) or Significant Safety Issues (SSIs) in accordance with the NHMRC safety guidelines as adopted by Monash Health that occur with a Monash Health participant or with a participant from a site that Monash Health has provided HREC review.
3. Any unforeseen events that might affect continued ethical acceptability of the project.
4. Any expiry of the insurance coverage provided in respect of sponsored trials.
5. Discontinuation of the project before the expected date of completion, giving reasons.
6. Any change in personnel involved in the research project including any study member resigning from Monash Health &/or the study team.

At the conclusion of the project or every twelve months if the project continues, the Principal Investigator is required to complete and forward an annual progress report to the Committee.

Reminders to submit annual progress report forms will be forwarded to the researcher.

The Coordinating Principal Investigator is responsible for notifying Principal Investigators. The Coordinating Principal Investigator and Principal Investigators should forward a copy of this letter to their site's Research Governance Officer.

Approved documents

Documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Human Research Ethics Application	HREC/59861/MonH-2020-223283(v2)	14 July 2020
Victorian Specific Module	-	10 February 2020
Protocol	2	01 July 2020
Participant Information and Consent Form – Stage 1	2	01 July 2020
Participant Information and Consent Form – Stage 2	1	01 July 2020
Participant Information and Consent Form – Stage 3	1	01 July 2020
Invite to Participate Non-pregnant	1	February 2020
Certificate of Analysis	-	08 January 2018
Highly Purified CrM Lab Analysis	-	28 January 2020
IFS Certificate	-	21 June 2019

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.

If you should have any queries about your project please contact the Research Support Services team on 03 9594 4611 or via email research@monashhealth.org and request to speak with a team member. The HREC wishes you and your colleagues every success in your research.

Yours sincerely

DEBORAH DELL
Manager, Human Research Ethics Committee
& Research Support Services

Cc: MUHREC

All correspondence in regard to this study must be uploaded on ERM with both the Monash Health Reference Number and the Project ID.
Upon uploading, please also email the documents via email to research@monashhealth.org, along with the Monash Health Reference Number ERM Project ID and study title.

Checklist: Post-ethics approval requirements that must be met before a research project can commence at a study site.

Please ensure that as a PI (including the CPI) the following are completed at each study site.

Requirements	**Yes/No/NA**
Ethics approval notification The PI must send a copy to the RGO at that study site.	Yes
HREC Review Only Indemnity The PI must forward a copy of the signed HREC Review Only Indemnity to the RGO at that study site.	N/A
CTN Acknowledgement for Commercially Sponsored Studies The PI must forward a copy of the CTN Acknowledgement to Research Support Services.	N/A
CTN Lodgement for Collaborative Group/Investigator Driven Studies The PI or nominated delegate is requested to make an appointment with the Monash Health Research Support Services contact for the study deborah.dell@monashhealth.org or michael.kios@monashhealth.org so that the lodgment may be completed by both the investigator and Research Support Services. The banking details for payment to the TGA will need to be brought along to this appointment, in order to finalise notification to the TGA. The fee for lodging a CTN is $335.	N/A
SSA authorisation notification The PI must forward the SSA form and attached documents (e.g. CTRA) to the RGO so the authority approving the conduct of the trial, at that site, can complete and sign.	Yes
Radiation If applicable, the RGO must contact the Medical Physicist so that the study may be notified to the Radiation Risk Section of the Department of Health and Human Services.	N/A
Other Commonwealth statutory requirements Ensure compliance with the following e.g. Office of the Gene Technology Regulator, NHMRC Licensing Committee, NHMRC Cellular Therapies Advisory Committee.	N/A