MonashHealth

Research Support Services
Monash Health
Level 2, I Block
Monash Medical Centre
246 Clayton Road
Clayton Victoria 3168

Tel (03) 9594 4611
Fax (03) 9594 6306
Email: research@monashhealth.org

21 June 2019

Prof Peter Kerr
Monash Health
Department of Nephrology
Level 3, E Block
Clayton Vic 3168

Dear Researcher,

Study title: Dialysis membrane choice in nocturnal haemodialysis.

NMA HREC Reference Number: HREC/51556/MonH-2019-166657(v1)
NMA SSA Reference Number: SSA/51556/MonH-2019-172287(v1)
Monash Health Ref: RES-19-0000173A

Thank you for submitting a Site Specific Assessment Application for authorisation of the above project at Monash Health.

I am pleased to inform you that authorisation has been granted for this project to be conducted at:

- Clayton and Dandenong campus of Monash Health;

The following conditions apply to this research project at your site. These conditions are additional to those imposed by the Human Research Ethics Committee that granted ethical approval.

The Principal Investigator is required to notify Research Support Services, Monash Health of the following:

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 report to Research Support Services.

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List of Approved Documents:

Document	*Version*	*Date*
Site Specific Assessment Form	1	24/4/2019
Monash Health Participant Information Sheet and Consent Form based on Master Participant Information Sheet and Consent Form V3 dated 23/4/2019	3	23/4/2019

If you should have any queries about your project please contact us at research@monashhealth.org or ask to be transferred to the relevant officer via 03 9594 4611.

Research Support Services wishes you and your colleagues every success in your research.

Yours sincerely

DEBORAH DELL
Manager, Human Research Ethics Committees
Research Support Services

Attachments:
Research Agreement x 1

Cc: MUHREC

Please Note: It is requested that correspondence be forwarded electronically to research@monashhealth.org with the local Monash Health reference number inserted.

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

Requirements	Yes/No/NA
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
Clinical Trial Research Agreement The PI must forward an original fully executed copy of the CTRA to Research Support Services	Yes
Indemnity The PI must forward an original fully executed copy of the Indemnity to Research Support Services	N/A
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
Declaration of Interest /Gifts and Benefits It is recommended that the Monash Health Principal Investigator and research team are familiar with the "HR - Conflict of Interest (Operational)" policy and the "HR – Declaration of Gifts, Benefits & Hospitality" procedure available on PROMT. In the event that a member of the Monash Health research team for this project has an item to declare, a Declaration Form available on PROMPT should be completed and submitted to Human Resources.	N/A