Research Support Services
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17 September 2021

Dr Ayse Zengin
Monash University - Monash Medical Centre
Department of Medicine, School of Clinical Sciences at Monash Health
246 Clayton Road
Clayton VIC 3168

Dear Researcher,

Study Title: The Haemophilia Osteoporosis Registry (THOR)
ERM Reference Number: 77116
Monash Health Reference: RES-21-0000-387A

The Monash Health HREC reviewed the above application at the meeting held on 01 July 2021. In addition, the HREC is satisfied that the responses to our correspondence of 06 July 2021 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 Jobs, Precincts and Regions, Victoria under the National Mutual Acceptance, single ethical review system.

Approval

The HREC approval is from 17 September 2021.

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, VIC;
- Alfred Health, VIC;
- Monash University, VIC;

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/77116/ MonH-2021-279487(v4)	25 August 2021
Victorian Specific Module	-	13 August 2021
Protocol	2	13 August 2021
Participant Information and Consent Form	2	13 August 2021
Eligible and Invited to Participate	1	13 August 2021
THOR Study Patient Contact Log Book	1	13 August 2021
THOR Ad for social media	2	27 July 2021
THOR Ad A4 Flyer	2	15 July 2021
REDCap Form – Screening	-	-
REDCap Form – Consent	-	-
REDCap Form – Anthropometry	-	-
REDCap Form – Sidedness	-	-
REDCap Form – Bloods	-	-
REDCap Form – General Questionnaire	-	-
REDCap Form – General Medical History Update	-	-
REDCap Form – PROBE, BSPA + IPAQ	-	-
REDCap Form – Gilbert Score	-	-
REDCap Form – HR-pQCT	-	-

REDCap Form – DXA	-	-
REDCap Form – Jumping Mechanography	-	-
REDCap Form – Hand Grip Strength	-	-
REDCap Form – Safety Event	-	-
REDCap Form – Withdrawal of Participation	-	-
Radiation Report (updated)	3	17 August 2021

This study involves ionising radiation. If the radiation dose exceeds the dose constraints specified in Table 1 of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes, then it is the responsibility of the Principal Investigator at the site to add the study to the Radiation Risk licence. This notification must be made by the Radiation Safety Officer within 14 days of Site Specific Authorisation being granted.

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 via email research@monashhealth.org or via telephone: Sarah Niazmand on 9594 4747, Katharine Mahoney on 9594 4748 (NB Katharine is out of the office on Mondays), Julie Gephart on 9594 4090.

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

Yours sincerely

D. Dell

Deborah Dell
Interim Director, Research Operations

Cc: Ms Cat Shore-Lorenti
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.	Yes
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