2020/ETH02388: Application HREA - Approved

Publications/BCL6

no_reply@regis.health.nsw.gov.au

Fri, 18 Dec 2020, 12:13

to me

Date of Decision Notification: 18 Dec 2020

Dear Alison Bryant-Smith

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2020/ETH02388: B-cell lymphoma 6 protein (BCL6) as a potential biomarker for endometriosis: can it be used to predict endometriosis' presence and/or severity?

Thank you for your correspondence, received 14 December 2020, responding to the Northern Sydney Local Health District HREC's request for additional information/modification for the above project, which was first considered by the HREC at its meeting held on 12 October 2020.

This application was assessed as a greater than low risk project.

I am pleased to advise that the Committee at a meeting of the Executive on 16 December 2020 has granted ethical and scientific approval of the above multi centre project. The HREC were satisfied that this project meets the requirements of the National Statement.

This project has been approved to be conducted at the following sites:

- Royal North Shore Hospital
- North Shore Private Hospital
- Royal Prince Alfred Hospital
- The Mater Hospital
- Concord Repatriation General Hospital
- Nepean Hospital

The following documentation was reviewed and is included in this approval:

- Protocol, Version 3, Dated 14 December 2020
- Participant Information Sheet and Consent Form - already planned for D&C, Version 3, Dated 17 December 2020.
- Participant Information Sheet and Consent Form - NOT planned for D&C, Version 3, Dated 17 December 2020.
- EHP-30 questionnaire, Version 1, Dated 14 December 2020

Application Documents - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:
Version: 1.03
Date: 14 Dec 2020

This email constitutes ethical and scientific approval only.
This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution under whose auspices the research will be conducted at that site.

This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007). The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council. No HREC members with a conflict of interest were present for review of this project.

Please note the following conditions of approval:

- HREC approval is valid for 5 years from the date of approval and expires on 18 December 2025. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
- The Co-ordinating Investigator will provide an annual progress report at the anniversary date of the project as well as a final study report at the completion of the project at all sites. This will be through the submission of a milestone report within the Research Ethics and Governance Information System (REGIS).
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by study participants regarding the conduct of the study.

- Proposed changes to the research protocol including; the general conduct of the research, changes to CPI or site PI, and extension to HREC approval, or the addition of research sites must be provided to the HREC for review, in the specified format before changes can take effect. This will be through a notification of an amendment in REGIS.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a university course are advised to contact the relevant university HREC regarding any additional requirements for the project.

Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trial Registry www.anzctr.org.au) if applicable.

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this application with you throughout the project lifecycle.

Regards

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