08-Jun-2021

Dear Dr Jacqueline Tan-Showyin,

<table>
<thead>
<tr>
<th><strong>Project Title</strong></th>
<th>A randomized, placebo-controlled, double-masked, multicenter, dose-ranging study to evaluate the safety, and efficacy of UNR844 in subjects with presbyopia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HC No</strong></td>
<td>HC210270</td>
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<tr>
<td><strong>Re</strong></td>
<td>HC210270 Notification of Ethics Approval</td>
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<td><strong>Approval Period</strong></td>
<td>04-Jun-2021 - 03-Jun-2026</td>
</tr>
</tbody>
</table>

Thank you for submitting the above research project to the HREC Executive for ethical review. This project was considered by the HREC Executive at its meeting on 03-Jun-2021.

I am pleased to advise you that the HREC Executive has granted ethical approval of this research project. The following condition(s) must be met before data collection commences: Main ICF V2 dated 25May2021

UNSW Pregnancy FU ICF 1 1-Feb-2021

UNR844 IB Edition 5 29-Sep-20 (Safety cut-off 04Sep2020)

DDO001B (FocalView) IB Edition 1 15-Dec-20 (review cut-off 02Dec2020)

Cert of ins- CUNR844A2202, exp 6Jun2025 NA 11-Jan-2021

FocalView App 2.1 CUNR844A2202 Screenshots

FocalView App CUNR844A2202 Start guide for participants 1

PRO_CUNR844A2202 Screenshot-TFQ (Trial feedback questionnaire) Section A 0.2
Conditions of Approval:

Conditions of Approval - All Projects:

- The Chief Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Chief Investigator will seek approval from the HREC Executive for any modifications to the protocol or other project documents.
- The Chief Investigator will notify the HREC Executive immediately of any protocol deviation or adverse events or safety events related to the project.
- The Chief Investigator will report to the HREC Executive annually in the specified format and notify the HREC Executive when the project is completed at all sites.
- The Chief Investigator will notify the HREC Executive if the project is discontinued before the expected completion date, with reasons provided.
- The Chief Investigator will notify the HREC Executive of his or her inability to continue as Coordinating Chief Investigator including the name of and contact information for a replacement.
The **HREC Executive** Terms of Reference, Standard Operating Procedures, membership and standard forms are available from [https://research.unsw.edu.au/research-ethics-and-compliance-support-recs](https://research.unsw.edu.au/research-ethics-and-compliance-support-recs).

For questions or concerns, please contact the Ethics Administrator using the contact details below.

Telephone: [Human Ethics team telephone contacts](https://research.unsw.edu.au/human-research-ethics-home)
Email: humanethics@unsw.edu.au
Website: [https://research.unsw.edu.au/human-research-ethics-home](https://research.unsw.edu.au/human-research-ethics-home)

Kind Regards,

This 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)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.