

Enquiries to: Metro North HREC  
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File Ref: ERM: 107054 Approval

Metro North Health

11 June 2024

Dr Abigail Walker  
Royal Brisbane and Women's Hospital  
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Dear Dr Abigail Walker

**Re: Project ID: 107054; HREC/2024/MNHA/107054; A pilot study to evaluate the effectiveness of intranasal Botulinum Toxin Type A Spray for patients with Rhinitis**

Thank you for submitting the above research project for ethical review. This project was considered by the Metro North Health Human Research Ethics Committee (HREC) A (EC 00172) at its meeting held on 21 May 2024.

I am pleased to advise that this research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2023)* and that the HREC granted final ethical approval of this research project.

**Note:** If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

**This letter constitutes ethical approval only.** This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

The reviewed and approved documents include:

<b>Document</b>	<b>Version</b>	<b>Date</b>
Form Reference: HREA	May ver 2	01 May 2024
Cover Letter	-	29 Apr2024
Appendix A. ARTG Public Summary 67311 Botox 100iu injection vial	-	29 Apr 2024
Appendix B. Aust Product Info - Botox Powder for Injection	-	-
Appendix C. Consumer Medicine Info - Botox purified neurotoxin complex for injection	-	Dec 2023
Appendix D. Package Leaflet - Allergan QA_Botox_100U_PIL (1)	-	-

Appendix E1. Device. ARTG Public Summary 294634 Atomizer 4 Oct 2017	-	04 Oct 2017
Appendix E2. Device. ARTG Public Summary 293175 Atomizer 25 Aug 2017	-	25 Aug 2017
Appendix F. MAD Device	-	-
Appendix G. MAD-Nasal-User-Guide_MC_MC001925_Rev1	-	-
CRF Document: Screening	1.0	27 Mar 2024
CRF Document: Baseline	1.0	27 Mar 2024
CRF Document: Phone Review	1.0	22 Mar 2024
CRF Document: End of Study Visit	1.0	27 Mar 2024
CRF Document: Unscheduled Visit	1.0	27 Mar 2024
CRF Document: Early Termination Visit	1.0	03 Apr 2024
CRF Document: Medical History	1.0	03 Apr 2024
CRF Document: Inclusion & Exclusion List	1.1	29 Apr 2024
CRF Document: Informed Consent	1.0	27 Mar 2024
CRF Document: Drug Dispensing Accountability Log	1.0	27 Mar 2024
CRF Document: Adverse Event Log	1.0	27 Mar 2024
CRF Document: Concomitant Medication Log	1.0	27 Mar 2024
CRF Document: Demographics Source Document	1.0	27 Mar 2024
CRF Document: Endoscopic Assessment	1.0	27 Mar 2024
CRF Document: Treatment Administration	1.0	27 Mar 2024
CRF Document: Vital Signs	1.0	27 Mar 2024
CRF Document: Physical Examination	1.0	27 Mar 2024
Participant Facing Document: VAS & TNSS	1.0	22 Mar 2024
Participant Facing Document: PGICS	1.0	22 Mar 2024
Curriculum Vitae - Abigail Walker	-	29 Mar 2023
Curriculum Vitae - James Earnshaw	-	06 Dec 2023
Curriculum Vitae - James Bates	-	25 Aug 2023
GCP - Abigail Walker	-	04 Jan 2023
Response to Further Information Requested: Form Reference: HREA	Jun ver 3	05 Jun 2024
Response cover letter	-	03 Jun 2024
RBWH Participant Information and Consent Form	1.0	03 Jun 2024
Investigator Brochure	2.0	03 Jun 2024
Response to Further Information Requested: Form Reference: HREA	Jun ver 4	10 Jun 2024
Response cover letter	-	10 Jun 2024
Study Protocol	1.1	10 Jun 2024

This information will be tabled for noting at the next HREC meeting to be held on 23 July 2024.

Ongoing approval is for the duration of the project, conditional on:

1. In accordance with Section 5.5.6 (b) of the National Statement the Principal Investigator will report to the HREC annually (**Due by 30 April each year**) in the specified format and a final report is to be submitted on completion of the study.  
[www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp](http://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp)
  2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
    - a. Unforeseen events that might affect continued ethical acceptability of the project.
    - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
  3. Amendments to the research project are to be submitted to the HREC for review. Amendments should be reflected in a cover letter from the principal investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Further advice on submitting amendments is available from:  
[www.health.qld.gov.au/metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting](http://www.health.qld.gov.au/metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting)
  4. The Principal Investigator will notify the HREC if the project is discontinued at the participating site(s), with reasons provided.
  5. If additional sites are engaged prior to the commencement of, or during the research project, the Principal Investigator is required to notify the HREC. Notification of the withdrawn sites should also be provided to the HREC in a timely fashion accompanying a close out report for that site.
- **Please advise the HREC of the date you commence the research project for the approved site(s) using the Notification of Commencement Form:**  
[www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp](http://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp)
  - The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from: [https://www.health.qld.gov.au/hiiro/html/regu/regu\\_home](https://www.health.qld.gov.au/hiiro/html/regu/regu_home)

The nominated participating sites for this project are:

No.	Site
1.	Royal Brisbane and Women's Hospital

The Metro North Health HREC wishes you every success in your research.

Yours sincerely,

**Dr Lynn Woodward**  
**Deputy Chairperson, Metro North Health Human Research Ethics Committee A (EC 00172)**  
Metro North Office of Research  
Metro North Health

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 (2023)*, NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.