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File Ref: ERM: 92215 Approval

Metro North Health

4 April 2023

Dr William Steadman  
Royal Brisbane and Women's Hospital  
E: [William.Steadman@health.qld.gov.au](mailto:William.Steadman@health.qld.gov.au)  
Cc: [Beat.Schmutz@health.qld.gov.au](mailto:Beat.Schmutz@health.qld.gov.au)

Dear Dr William Steadman,

**Re: Project ID: 92215; HREC/2023/MNHA/92215; Digital-powered healthcare: Improving communication, engagement and treatment compliance in patients with implant-related infections**

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 13 March 2023.

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 (2007)* 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 Notification of withdrawn sites should also be provided to the HREC in a timely fashion.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	Mar ver 2	28/03/2023
Visual Analogue Scale (VAS)	-	-
XIAOMI Smart Band 7 User Manual	-	-
PEP Health – Remote Monitoring via Connected Devices	1.0	05/10/2022
Patient Activation Measure Questionnaire	-	-
NIISQ – JTI Trauma App	-	-
App Data Safety - Google Fit: Activity Tracking	-	-
App Data Safety – Zepp Life	-	-
EQ-5D-3L Health Questionnaire	2.1	-
Risk Register – Trauma Patient App – Cloud Service	-	-

Declaration – Form of Indemnity ( <i>noted</i> )	-	-
Email - Cyber Security “Outcome re: POS for Trauma Patient App”	-	26/10/2022
Email - Cyber Security “Outcome re: POS for Trauma Patient App”	-	20/02/2022
Third-Party Security Questionnaire: Cloud Computing	-	07/07/2022
Australian Hospital Patient Experience Question Set	-	-
Curriculum Vitae for Arpita Dias	-	-
Curriculum Vitae for Beat Schmutz	-	-
Curriculum Vitae for Bonnie Woods	-	-
Curriculum Vitae for Brett Droder	-	-
Curriculum Vitae for Jason Brown	-	-
Curriculum Vitae for Kevin Tetsworth	-	-
Curriculum Vitae for Michael Schuetz	-	-
Curriculum Vitae for Paul Chapman	-	-
Curriculum Vitae for Shannon Dias	-	-
Curriculum Vitae for William Steadman	-	-
Curriculum Vitae for Uwe Dulleck	-	-
Approved by RBWH ICT Governance Committee - Trauma Patient Engagement Platform ( <i>noted</i> )	-	-
Response to Request for Further Information	-	28/03/2023
Cover letter & response	-	28/03/2023
Participant Information Sheet & Consent Form	1.1	March 2023
Protocol	1.1	March 2023
Good Clinical Practice Certificate – William Steadman	-	22/03/2023

This information will be tabled for noting at the next HREC meeting to be held on 15 May 2023.

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.	Jamieson Trauma Institute, RBWH

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

Yours sincerely,



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

