

2 August 2018

Professor Ian Hickie  
The University of Sydney  
Building F, Level 4  
94 Mallett Street  
Camperdown, NSW, 2050

Dear Professor Hickie,

**NSLHD reference: RESP/17/349**

**Title: PROJECT SYNERGY: A Clinical Trial To Validate The Synergy Online System**

**HREC reference: HREC/17/HAWKE/480**

Thank you for submitting a request for an amendment to the above project, dated **10 July 2018**. This was considered by the Northern Sydney Local Health District (NSLHD) Human Research Ethics Committee (HREC) at its Executive meeting held on **01 August 2018**. This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the document/s reviewed and approved at the meeting was/were:

Document	Version	Date
Trial Protocol – Clean and Tracked	3.0	16 July 2018
Investigational Plan – Clean and Tracked	2.0	16 July 2018
Opt-Out PCF – Clean and Tracked	4.0	16 July 2018
Participant Withdrawal Form – Clean and Tracked	3.0	16 July 2018

**For multi-site projects reviewed by the HREC after 1 July 2007 a copy of this letter must be forwarded to all Principal Investigators at every site approved by NSLHD HREC for submission to the relevant Research Governance Officer along with a copy of the approved documents.**

Should you have any queries about your project please contact the Research Office, Tel: 9926 4590, email [NSLHD-Research@health.nsw.gov.au](mailto:NSLHD-Research@health.nsw.gov.au) . The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website: <http://www.nslhd.health.nsw.gov.au/AboutUs/Research/Office>

Please quote NSLHD reference **RESP/17/349** in all correspondence.

Yours sincerely



Jodi Humphreys  
Research Manager, Clinical Research, Governance and Support