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25-May-23

Professor Mark Hutchinson
The University of Adelaide
ACEP Clinic, Hughes Building, North Terrace
Adelaide SA 5005

Dear Professor Hutchinson,
Re: Application No: 2023-03-238
Study Title: Evaluation of the psychoneuroimmunological state of healthy humans following intramuscular injection of the influenza (FluQuadriTM) vaccine, a two-way crossover double-blinded placebo-controlled trial
Application Type: NEW
Type of Review: FULLBOARD

Name of the Documents Submitted & Approved: Attachments

36936-H-2023_Flyer Advertisement_V3_CLEAN VERSION_10MAY2023
36936-H-2023_Participant Recruitment Screening Quesionnaire_V2_CLEAN_20APR2023
36936-H-2023_Participant Information Consent Form_V2_CLEAN VERSION_23APR2023
36936-H-2023_Participant Information Sheet_V3_CLEAN VERSION_10MAY2023
36936-H-2023_BA G4_Protocol Development_V2_CLEAN_01MAY2023

Includes:
Receipt of the following documents has been noted:
2023-03-238 (M Hutchinson) Fully executed HREC Indemnity
Mark Hutchinson CV March 2023
36936-H-2023_Human Research Project Adverse Event Report Form_V1_08Mar2023
36936-H-2023_Adverse Events Procedures_V2_CLEAN VERSION_17APR2023
36936-H-2023_Brief summary continued_V107Mar2023
36936-H-2023_Recruitment and selection criteria_V1_07Mar2023
36936_H-2023_Letter for UofA approving Bellberry_Hutchinson and Bajic_V1_07Mar2023
36936-H-2023_ACEP Clinic Space - Hughes Building Level 2 Floorplan_V1_06Mar2023
36936-H-2023_Biospecimen Research Form_V1_06Mar2023
36936-H-2023_Data Management Plan_V2_07Mar2023
36936-H-2023_Blood Processing and Storage Outline_V1_06Mar2023
36936-H-2023_Return Notes Comments_V1_15Mar2023
36936-H-2023_DMP_Stage 1_HISS-KNOW Project_V2_23APR2023_FINAL
36936-H-2023_Hutchinson GCP certificate_V1_26APR2023
36936-H-2023_Redenlab Desktop Manual_Speech and voice_V1_20APR2023
36936-H-2023_Medical and Biomechanical Ax_V1_06Mar2023
36936-H-2023_KNOW Project_Anticipated Study Day Timeline and personnel_V1_06Mar2023
36936-H-2023_Participant Screening Database REDCap_V1_06Mar2023
36936-H-2023_Pre-vaccination consent tool for pharmacist_V1_08Mar2023
36936-H-2023_KNOW Project_Anticipated Study Day Timeline and personnel_V2_26APR2023
36936-H-2023_Drugs to be Administered_V1_06Mar2023
36936-H-2023_Consumer medicine information summary_V1_08Mar2023
36936-H-2023_HISS RCT Protocol Violation Log_V1_08Mar2023

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36936-H-2023_Psychometric Test Battery_V1_06Mar2023

Date of Meeting: 05-Apr-23
Date of Approval: 25-May-23
Period of Approval: 25-May-23 - 25-May-24

Thank you for submitting the above-mentioned application.

I wish to advise that the Bellberry Human Research Ethics Committee has approved this project and that the application meets the requirements of the National Statement subject to the conditions mentioned below. For clarity, the 'Date of Meeting' is a system-generated field. Please only take note of the 'Date of Approval' and 'Period of Approval' as relevant.

CONDITIONS:-

- **This letter constitutes ethical and scientific approval only. You must not commence the research project at any site until your Research Governance Office/ Institution/Organisational delegate has granted their approval. Sites are responsible for ensuring there are executed indemnities, contracts, and appropriate insurance in place before the commencement of the study at the site. Sites are also responsible for ensuring their site-specific documents are based on the current Master approved documentation**.
- All changes to the approved study documentation must be submitted to Bellberry via an Amendment Form for review and approval prior to implementation.
- Safety reporting and Serious Breaches should be reported to the Bellberry Human Research Ethics Committee as per the monitoring guidelines posted on the website www.bellberry.com.au
- A progress report must be completed annually for the duration of the trial. The due date for all additional sites will fall in line with the lead sites original approval date. Submission of the progress report is to be within 30 days before the due date. Requests for an annual extension will be granted upon successful completion and noting of a progress report.
- A final report is due on completion of all closeout activities (clinical trials) or final reconciliation of study activities (non-clinical trials)The site must also provide a copy of the Sponsor's final report where there are study outcomes that the HREC should be aware of such as issues related to participant safety
- The Principal Investigator must inform the HREC, by way of an amendment, of the outcomes of any audit by a regulator or organisation/body.
- The data collected for the purpose of this research project cannot be used for any other purpose without the approval of a Human Research Ethics Committee. Requests to use this data for other purposes must be made in the form of a formal research proposal
- All research data, including electronic data is to be stored by the Principal Investigator for 15 years after the research has been completed or after the last contact, whichever is the later. Data must be recorded in a durable and appropriately referenced form and comply with relevant privacy protocols.
- Copies of all Master/Site specific documentation and any other data used in this research may be inspected at any time by representatives of the Bellberry Human Research Ethics Committee. This may be in the form of a Bellberry site monitoring visit or requested electronically via a desktop audit.
- Bellberry Human Research Ethics Committee approval is conditional upon your meeting any statutory and licensing obligations; data custodian or other organisational authorisations that you may have with this project.

Details of Ethics Committee:

The Bellberry Human Research Ethics Committee (HREC) reviewed this study in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates) on the above meeting date. Bellberry Human Research Ethics Committees do not disclose personal details of its reviewing members. A member listing is available as an attachment in eProtocol. Please note that the Principal Investigator and Co-Investigators were not members of the Bellberry Human Research Ethics Committee that reviewed this study.

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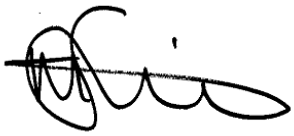
This study has been given the above reference number. Please remember to log on to eProtocol for all further correspondence with the Committee.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely



Mark Slee
Chair, Committee B
BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

Committee Name/NHMRC Codes: A/ EC00372; B/ EC00419; C/ EC00430; D/ EC00444;
E/ EC00450; F/ EC00455; G/ EC00458; H/ EC00459; I/ EC00468; J/ EC00469; K/ EC00470; L/ EC00471.

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