From: Daniela Von Hieber
Sent: Monday, 2 May 2022 5:37 PM
To: Vince Pang
Cc: Research; Ann Liebert; Dr Geoffrey Herkes
Subject: RE: [EXT] FW: For Daniela today

AHCL Research Office – Acknowledgement of Documents

Dear Ann, Geoff and Vince

AHCL reference ID: 2019-032
STUDY TITLE: Evaluation of dose of Photobiomodulation (Light) Therapy and Physiotherapy for improving quality of life outcomes and mobility in Parkinson's Disease (Sydney)
PI: Dr Ann Liebert

Thank you for emailing the below note-to-file for above study regarding a technical issue requiring an extension of the study period for part of the study population (Protocol Deviation).

> Reviewed by the AHCL Research Office on 02-May-2022 .
> **Action:** Below email has been **NOTED**. No further actions are required.
>
> Please remember to include the study identifiers in all communication with the Research Office to enable us to process your submission in a timely manner.
>
> Please note this email should be retained in the study record.

Kind regards,

Daniela von Hieber
BSc. MolecMed, MSc. MolecMed, CertIV TAE, CertIV Incl Leadership
Manager, Research Governance & Ethics **(Monday | Tuesday | Wednesday (half day))**

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From: Vince Pang <vincent.pang87@gmail.com>
Sent: Wednesday, 13 April 2022 11:59 AM
To: Daniela Von Hieber <Daniela.VonHieber@sah.org.au>

Cc: Ann Liebert <ann.liebert@outlook.com>; Dr Geoffrey Herkes <geoffrey.herkes@sah.org.au>
Subject: [EXT] FW: For Daniela today

Hi Daniela,

Hope you're doing well! Ann requested that I forward you the following email regarding an extension to the study.

Please let me know if you need anything on my part to complete for this to go through.

Many thanks!

Vincent

From: Ann Liebert
Sent: Wednesday, 13 April 2022 11:18 AM
To: Vincent Pang
Subject: For Daniela today

Dear Daniela ,

As a followup up to our phone conversation on this trial protocol consideration Professor Geoff Herkes and myself as Coordinating Chief Investigator would like to request a small variation in our trial procedures for a small subset of participants (both Sham and active) that involves our ethics approved trial protocol .
In our evaluation this variation does not substantially affect the triple blinding protocol or the total time frame of the trial which is proceeding according to the ethics approved protocol .

The request is for a small number of participants (both sham and active helmet device protocol recipients) who have missed between 1 to 4 weeks of home treatment due to a loose USB connection between to the helmet .

To counteract the potential affect of measurement of efficacy of the device we request permission to administer an identical additional 12 week treatment assessment after the full 12 weeks of treatment has been administered .

This assessment will be in the wash out period that all participants have been scheduled to have before washout reassessment .

Thanking you for your further consideration of this matter ,

Kind Regards ,

Ann

Sent from my iPhone