Women's & Children's Hospital

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6th July 2016

Dr A Wright
Research Officer
Knowledge & Innovation
Novita Children's Services
171 Days Road
REGENCY PARK SA 5010

Dear Annemarie

Re: A randomised controlled trial on the impact of the paediatric WalkAide® (a drop-foot stimulator) and motor learning-based, gait focused physiotherapy on advanced motor skills and physical activity participation in children with hemiplegic cerebral palsy. HREC/16/WCHN/78. Ethics expiry date: 31/07/2019.

Lead HREC for the above study for the following institutions/sites:

Novita Children's Services

I refer to your emails dated 16th June 2016 and 1st July 2016 in which you responded to matters raised by the WCHN Human Research Ethics Committee at its 25th May 2016 meeting. I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

Specifically, the following documents have been noted/approved:

Document	*Version*	*Date*
Patient Information Sheet/Consent Form: Appendix8_InformationSheet_AssessingPhysio_v2	2	9 June 2016
Patient Information Sheet/Consent Form: Appendix11_ConsentForm_ParentsChildren_v2	2	9 June 2016
Peer Review Submission: Appendix2_2015_05_10_NovitaRPSC_ApprovalLetter	1	10 May 2016
Sample Diary/Patient Card: Appendix3_WalkAideWearSchedule_v2	2	15 June 2016
Appendix19_2015_05_10_6MWT Secondary outcome measure - walking endurance	1	10 May 2016
Appendix17_2015_05_10_AnkleROM Secondary outcome - ankle movement	1	10 May 2016
Interview Schedules / Topic Guides: Appendix26_2015_05_10_InterviewQ_Orthotist_v1	1	10 May 2016
Patient Information Sheet/Consent Form: Appendix5_InformationSheet_ChildrenYoungPeople_v3	3	1 July 2016
Patient Information Sheet/Consent Form: Appendix6_InformationSheet_Parents_v3	3	1 July 2016
Appendix1_2015_05_10_WalkAide_Information	1	10 May 2016
Appendix16_2015_05_10_BBGA Secondary toucome - Gait assessment	1	10 May 2016
Appendix 15_2015_05_10_Challenge-20 Primary outcome measure - advanced gross motor skills	1	10 May 2016
Appendix18_2015_05_10_SCALE Secondary outcome measure - selective muscle control	1	10 May 2016

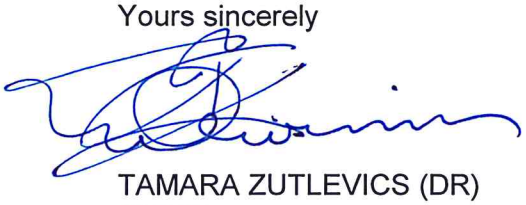
Questionnaire/s: Appendix21_2015_05_10_PAQ-C Secondary outcome measure - subjective physical activity	1	10 May 2016
Interview Schedules / Topic Guides: Appendix24_2015_05_10_InterviewQ_Parents_PostInt_v1	1	10 May 2016
Patient Information Sheet/Consent Form: Appendix7_InformationSheet_TreatingPhysio_v2	2	9 June 2016
Patient Information Sheet/Consent Form: Appendix9_InformationSheet_Orthotist_v2	2	9 June 2016
Patient Information Sheet/Consent Form: Appendix12_ConsentForm_TreatingPhysio_v2	2	10 June 2016
Patient Information Sheet/Consent Form: Appendix13_ConsentForm_AssessingPhysio_v2	2	10 June 2016
Patient Information Sheet/Consent Form: Appendix14_ConsentForm_Orthotist_v2	2	10 June 2016
Appendix4_2015_05_10_AE_Checklist_v1	1	10 May 2016
Appendix10_ABC_StudyAdvert_v2	2	9 June 2016
Response to Request for Further Information: Response email		1 July 2016
Questionnaire/s: Appendix20_2015_05_10_COPM Primary outcome measure - goal accomplishment	1	10 May 2016
Interview Schedules / Topic Guides: Appendix22_2015_05_10_InterviewQ_Children_PostInt_v1	1	10 May 2016
Interview Schedules / Topic Guides: Appendix23_2015_05_10_InterviewQ_Children_PostFU_v1	1	10 May 2016
Interview Schedules / Topic Guides: Appendix25_2015_05_10_InterviewQ_Parents_PostFU_v1	1	10 May 2016
Interview Schedules / Topic Guides: Appendix27_2015_05_10_InterviewQ_TreatingPhysio_v1	1	10 May 2016
NEAF Application: AU/1/D806212		11 May 2016

The Committee has approved the study on the understanding that it does not involve any WCHN patients or staff and that the research is not carried out at any SA Health site. This letter therefore constitutes advice on ethical consideration only. All research governance matters, including indemnification, are the responsibility of Novita Children's Services and it is recommended that you obtain appropriate governance approval from Novita Children's Services before proceeding. If the study is amended to include the WCHN or any SA Health site, separate authorisation from the Chief Executive or delegate of that site must be obtained through a Site Specific Assessment (SSA) request. For information on this process at the WCHN, please contact the WCHN Research Governance Officer, Ms Camilla Liddy (telephone 8161 6688, email camilla.liddy@health.sa.gov.au).

I remind you approval is given subject to:
- immediate notification of any serious or unexpected adverse events to participants;
- immediate notification of any unforeseen events that might affect continued ethical acceptability of the project;
- submission of any proposed changes to the original protocol. Changes must be approved by the Committee before they are implemented;
- immediate advice, giving reasons, if the protocol is discontinued before its completion;
- submission of an annual report on the progress of the study, and a final report when it is completed to the WCHN Research Governance Officer. It is your responsibility to provide these reports, without reminder. The proforma for the report may be found on the WCHN Research Governance and Ethics website.

Approval is given for three years only. If the study is more prolonged than this, an extension request should be submitted unless there are significant modifications, in which case a new submission may be required. Please note the expiry date in the title above and include it in any future communications.

Yours sincerely



TAMARA ZUTLEVICS (DR)
CHAIR
WCHN HUMAN RESEARCH ETHICS COMMITTEE

WOMEN'S AND CHILDRENS HEALTH NETWORK (WCHN)

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

REGISTERING OF CLINICAL TRIALS

The WCHN Human Research Ethics Committee (HREC) and Drug and Therapeutics Committee Clinical Trials Group (DTC) would like to draw researcher's attention to a joint editorial issued by members of the International Committee of Medical Journal Editors (ICMJE) which appeared in *The New England Journal of Medicine* June 9, 2005. ICMJE members stated that,

In September 2004, the members of the International Committee of Medical Journal Editors (ICMJE) published a joint editorial aimed at promoting registration of all clinical trials. We stated that we will consider a trial for publication only if it has been registered before the enrolment of the first patient. This policy applies to trials that start recruiting on or after July 1, 2005.

For further information regarding the registering of trials researchers are directed to the above mentioned editorial – http://content.nejm.org/cgi/reprint/352/23/2436.pdf

In Australia, the National Health Medical Research Committee has set up the Australian Clinical Trials Registry (ACTR) which researchers can access. It is a national online register of clinical trials being undertaken in Australia. The ACTR includes trials from the full spectrum of therapeutic areas. It has nationwide coverage of all clinical trials involving Australian researchers or Australian participants. General information on the registry can be found at http://www.actr.org.au

Any project that prospectively assigns human participants to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome (ICMJE definition) should be registered, including early phase uncontrolled trials (phase I) in patients or healthy volunteers (WHO Recommendation). If in doubt, registration is recommended. The REC is unable to register clinical trials. Consequently, those researchers seeking to register their trials will need to do so themselves.

Please bring this notice to the attention of all researchers and potential researchers in your department.

In keeping with the above, it is a WCHN HREC requirement for trials to be registered before enrolment of the first patient.

Newsletter Issue 2, Dec 2006 for the Registry may be accessed at http://actr.org.au/docs/ACTRNewsletterIssue221Dec06.pdf