University Health Network
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Received Date

Research Ethics Board
Amendment Form

Please consult the UHN REB website for current submission procedures and requirements.

See the Guidelines for Submitting Proposed Amendments, Administrative Changes and Changes in Principal Investigator for more information, including definitions of capitalized terms.

[**Note:** *The REB reminds you to update your research protocol any time that changes are proposed to the design or conduct of your study and attach them to your amendment submission.*]

SECTION 1 – Study Identification

UHN REB Number: 14-7554

Study Title: Wizard of Oz study using humanoid NAO in "An Intelligent Prompting System to Help Teach Self-Care Skills to Children with Autism Spectrum Disorder"

SECTION 2 – Contact Information

NOTE: For a change in Principal Investigator, please use the "Change in Principal Investigator Form"

Principal Investigator: Alex Mihailidis

PI Telephone: (416) 946-8565 PI Email Address: Alex.Mihailidis@utoronto.ca

Name of Person Completing the Form: David Xue

Telephone: (416) 399-2202 Email Address: davidxue1989@gmail.com

SECTION 3 – Review Background Information

1. Are you requesting review of this request at a 'Full Board' meeting (a convened meeting of the REB)?
☐ Yes ☒ No
If "Yes", please explain why:

2. Has this amendment already been implemented to eliminate an apparent immediate hazard to one or more study participants? ☐ Yes ☒ No
[*If "Yes", please include details about this in your answer to #2 in* ***Section 4****.*]

3. Will the number of study participants change due to this amendment? ☐ Yes ☒ No
[*If "Yes", please include details about this in your answer to #2 in* ***Section 4****.*]

4. Is this study regulated by Health Canada? ☒ Yes ☐ No
a) If "Yes" , do these changes require authorization from Health Canada? ☐ Yes ☒ No
b) If "Yes", has Health Canada authorization been received? ☐ Yes ☐ No
[*If "Yes" please attach. If "No" please specify expected date of authorization (NOL, ITA, NOA, etc.) in your answer in* ***Section 6****.*]

5. On what page(s) of the protocol are the changes to the study described? Page(s): 4, 5, 7, 8, 9, 10 ☐ N/A

6. Enrollment status (for UHN participants **only**):
☒ No enrollment to date
☐ Currently enrolling participants

☐ Enrollment complete but study is ongoing at UHN (i.e. – participants receiving intervention, ongoing data collection)
☐ Intervention and follow-up complete for all UHN participants; however, data clarification, analysis and/or transfer ongoing
☐ Study does not involve enrollment of participants at UHN
☐ Other (describe):

7. If approved, would the implementation of this amendment have any implications for the study budget (due to changes in recruitment, sample size, methodology, participant compensation or participant reimbursement?): ☐Yes ☒No
a) If "Yes", attach revised budget: ☐ Attached

SECTION 4 – Amendment Summary

1. Summarize the changes to the study:

Study setup

1) Mounting location of Kinect camera:

-The Kinect camera will be placed on the sink coutnertop underneath the mirror and behind the tap rather than being placed on a tripod.

2) The scene camera:

- Will not be connected to the laptop via USB
- Will be used to record the audio instead of the overhead camera

Study procedure

1) The order of prompts during tasks of hand-washing :

- Task Prompt (TP) will be delivered first, then the 1st Attention Grabber (AG) prompt, then the 2nd AG prompt, then the 2nd TP (in the original protocol, it was proposed to have the 1st AG prompt --> the 2nd AG prompt --> the 1st Task Prompt --> the 3rd AG --> the 4th AG --> the 2nd Task Prompt)

2) The Reward prompt:

- The NAO robot/virtual avatar will deliver a short verbal reward after each completed task instead of providing a long verbal reward with gestures

3) Adding the Intro, Re-intro, and Outro prompts:

- These prompts are added at the start of each trial, after parent assisting the child , and at the end of each trial respectively

4) The specified wait times:

- The length of wait time before the 1st prompt (i.e. task self-initiation wait time) and the length of the wait time between prompts (response to prompt wait time) will be determined from baseline phase based on the amount of time the parent allows the child to start a task before prompting and the child's response time to the parent's prompts.

Compensation:

- Compensation will be given for each child participant instead of each participated family.

2. Provide justification/rationale for the change(s):

The changes in the study setup are to help with better data collection.

- The change of the position of the Kinect camera will provide a better track of the face, which will be important to help build the gaze tracker.
- The use of the scene camera to record both audio and video is for easier implementation.

The changes in the study procedure during the intervention phases are to help with a better flow, less distractions and smoother transition between tasks of hand-washing.

The change in compensation: In case a family with more than one children with autism participate in the study, the family will then be compensated based on the number of children participated in the study.

3. Will study participants be informed of the change(s)? ☐ Yes ☒ No

If "Yes" describe how study participants will be informed:

The study has not started with the recruitment yet. The recruitment will start after this amendment is approved. Therefore, participants do not need to be informed any changes from this amendment.

If "No", please explain why study participants need not be informed about the change(s):

SECTION 5 – Documents Attached for Review

☐ Amendment to Protocol/Summary of Changes	Version Date(s):
☒ Protocol	Version Date(s): v3, June 1, 2014
☒ Consent Form(s) (please list):	
Appendix F_Consent_Form_Child_v3_June_1_14	Version Date(s): v3, June 1, 2014
Appendix G_Consent Form_Parent_v3_June_1_14	
☐ Direct Data Collection Tools (Questionnaires, Diaries)	Version Date(s):
☐ Recruitment Material (Posters, Telephone Scripts)	Version Date(s):
☐ Documentation of Health Canada authorization of the proposed changes	
☐ Study Budget	Version Date:
☐ Other (please list):	Version Date(s), If Applicable:

SECTION 6 – Additional Information (any additional details or context not supplied in other sections; if the protocol has been modified, please specify the page[s] that have been modified in this section)

Pages: 4, 5, 7, 8, 9, 10

Important Information

⇒ If the study is governed by one or more research agreements or contracts with external parties, please inform Grant and Contract Services (gcs@uhnresearch.ca) if the changes outlined above may impact current agreements.

⇒ If the study involves research support departments (such as the Joint Department of Medical Imaging, Investigational Pharmacy Services, Laboratory Medicine Program, etc.) or committees that support research (Cancer Registry Data Access Committee, Nursing Research, etc.) please inform the affected departments or groups of any changes that may impact them.

SECTION 7 – Principal Investigator Attestation