



# Health Research Authority

National Research Ethics Service

## NRES Committee West Midlands - The Black Country

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21 March 2014

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Ms Rosanna Laverick

<b>Study title:</b>	<b>Cognitive Rehabilitation of Apraxia and Action Disorganisation Syndrome</b>
<b>REC reference:</b>	<b>12/WM/0220</b>
<b>Protocol number:</b>	<b>TBC</b>
<b>Amendment number:</b>	<b>02</b>
<b>Amendment date:</b>	<b>01 February 2014</b>
<b>IRAS project ID:</b>	<b>105447</b>

The amendment proposes:

1. Include an Assent form for those unable to complete the consent form on their own
2. Include a recruitment flyer
3. Add an evaluation sheet
4. Include additional information sheets – for research sites when using CogWatch system
5. Include additional consent form - – for research sites when using CogWatch system

Minor amendments:

1. Additional members to the research team – Bogna Drozdowska and Rosanna Laverick
2. Add contact information and CogWatch logo to the Trial Entry Form
3. Change contact details on information sheets
4. Changes to the consent form to keep in line with the amended information sheets

Thank you for submitting the above amendment, which was received on 21 March 2014. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

## Documents received

The documents to be reviewed are as follows:

Document	Version	Date
Participant Consent Form: fMRI (Tracked)	1.5	01 January 2014
Notice of Substantial Amendment (non-CTIMPs)	02	01 February 2014
Participant Information Sheet: Card	1.1	03 January 2014
Assent form - fMRI	1	01 January 2014
Participant Consent Form: fMRI	1.5	01 January 2014
Participant Information Sheet: Card CogWatch system	1	01 February 2014
Participant Information Sheet: Sheet (Tracked)	1.1	01 January 2014
Assent form - teaMaking	1	01 January 2014
Investigator CV		22 October 2013
Participant Information Sheet: Sheet CogWatch system	1	01 February 2014
Participant Consent Form: teaMaking	1.5	01 January 2014
Advertisement	1	01 February 2014
Participant Information Sheet: Sheet	1.1	03 January 2014
Participant Consent Form: teaMaking - CogWatch System	1	01 February 2014
Trial entry form	1.0	01 January 2014
Participant Information Sheet: Card (Tracked)	1.1	03 January 2014
Participant Consent Form: teaMaking (Tracked)	1.5	01 January 2014
Evaluation of CogWatch system	1.0	01 February 2014
Investigator CV	Bogna Anna Drozdowska	28 February 2014

## Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

## R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

**12/WM/0220:**

**Please quote this number on all correspondence**

Yours sincerely



**Miss Diane Catterall**  
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