



# Health Research Authority

National Research Ethics Service

## NRES Committee West Midlands - The Black Country

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02 April 2014

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Ms Rosanna Laverick

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|--------------------------|--|
| <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 proposed:

1. Include an Assent form for those unable to complete the consent form on their own
2. Include a recruitment flyer
3. Include a trial entry form to collect more demographic information. Add contact information and CogWatch logo to the form
4. Add an evaluation sheet
5. Include additional information sheets – for research sites when using CogWatch system
6. 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. Change contact details on information sheets
3. Changes to the consent form to keep in line with the amended information sheets

The above amendment was reviewed by the Sub-Committee in correspondence.

### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

## Approved documents

The documents reviewed and approved at the meeting were:

| Document  | Version               | Date             |
|---|-----------------------|------------------|
| 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 |
| 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  |
| Assent form - teaMaking                               | 1                     | 01 January 2014  |
| Investigator CV                                       |                       | 22 October 2013  |
| Participant Information Sheet: Sheet CogWatch system  | 1                     | 01 February 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  |
| 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  |

## Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

## 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 of the research.

## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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/>

Yours sincerely

  
SP

**Signed on behalf of:  
Dr Hiliary Paniagua  
Chair**

E-mail: [nrescommittee.westmidlands-blackcountry@nhs.net](mailto:nrescommittee.westmidlands-blackcountry@nhs.net)

Enclosures: List of names and professions of members who took part in the review

Copy to: Professor Alan Wing  
Brian Laverty ([b.w.laverty@bham.ac.uk](mailto:b.w.laverty@bham.ac.uk)).

## NRES Committee West Midlands - The Black Country

### Attendance at Sub-Committee of the REC meeting on 02 April 2014

| <i>Name</i>             | <i>Profession</i>  | <i>Capacity</i> |
|-------------------------|--|-----------------|
| Dr Joseph Arumainayagam | Consultant and Honorary Senior Clinical Lecturer in HIV and GUM        | Expert          |
| Dr Hilary Paniagua      | Chair of the research ethics committee, School of Health and Wellbeing | Expert          |

#### Also in attendance:

| <i>Name</i>          | <i>Position (or reason for attending)</i> |
|----------------------|---|
| Miss Diane Catterall | REC Assistant                             |