CogWatch – Cognitive Rehabilitation of Apraxia and Action Disorganisation Syndrome

D6.3.1 Ethical and Safety Issues 1

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EXECUTIVE SUMMARY

This report describes the steps taken in CogWatch to meet ethics requirements at UOB and TUM in order to conduct research with human participants.

Section 1 introduces the UK national ethical bodies and application procedures and how they lead through to patient recruitment in local hospitals. Patient inclusion/exclusion criteria and informed consent are reviewed, followed by a section on the UOB ethics process for elderly controls. The section on ethics at TUM explains how testing limited to STKM (under third party agreement) which is a teaching hospital for TUM, simplifies the ethics. The relations between the two ethical reviews are summarised. While there are a number of differences, both maintain key principles such as informed decision, privacy, risk assessment, confidentiality.

Section 2 enumerates the behavioural tasks being carried out in CogWatch for which ethical approval was established and reviews safety precautions taken to minimise the risks associated with heating water in a kettle.

Section 3, describes data management to meet ethical requirements including data storage, handling, protection, and anonymity.

Finally, in Section 4, wider issues of system ethics are briefly considered as a preliminary to developing a more detailed analysis in relation to the future scenario of the system being installed in a home environment.

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REVISION HISTORY

Revision no.	Date of Issue	Author(s)	Brief Description of Change
V1	11.04.2013	Danni Sims (UOB)	Initial Draft
V2	15.04.2013	Danni Sims, Dicle Dovencioglu (UOB)	Initial Draft
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V9	30.04.2013	Alan Wing, Danni Sims, Dicle Dovencioglu (UOB)	Appendices extended, final formatting
V10	09.05.2013	Jigar Jogia, Danni Sims, (UOB)	Text insertion; final formatting
V12	30.05.2013	Danni Sims, Jigar Jogia (UOB)	Peer review changes

LIST OF ABBREVIATIONS AND DEFINITIONS

Abbreviation	Abbreviation
Technische Universität München	TUM
University of Birmingham	UoB
Technical University of Madrid	UPM
Städtisches Klinikum München	STKM
Patient Advice & Liaison Service (UK)	PALS
Birmingham University Imaging Centre	BUIC
National Health Service (UK)	NHS
Research Ethics Committee (UK)	REC
Integrated Research Application System (UK)	IRAS
National Research Ethics Service (UK)	NRES
Comprehensive Clinical Research Network	CLRN
Coordinated System for Gaining NHS Permission (UK)	CSP
Site Specific Information (UK)	SSI

1. INTRODUCTION

As outlined in the DOW (B4 Ethics Issues) the CogWatch consortium is sensitive to ethical principles and data protection regulations at national, European and international level, such as the Data Protection Directive, Charter of Fundamental Rights of the European Union and the opinions of the European Group of Ethics in Science and New Technologies. The following sections consider ethics applications carried out by UOB and TUM in their respective countries, with procedural differences between the two countries considered in a final section.

1.1 UK Ethical Application

This section details the ethical application process conducted at UOB, first for testing participants recruited as NHS patients, then healthy volunteers.

1.1.1 NRES Ethics

Health and community care research in the UK involving access to NHS staff or patients are required to apply for ethical approval from National Health Service (NHS) Research Ethics Committees (REC) in the National Research Ethics Service (NRES, http://www.nres.nhs.uk/) using an online system, Integrated Research Application System (IRAS – www.myresearchproject.org). This procedure is underpinned by the Research Governance Framework (2nd ed 2006) that sets out responsibilities and obligations of individuals and organisations involved in health and social care research. This system streamlines multiple approvals for the same project while creating an integrated dataset and producing sufficient information for each additional research site, and future amendments to the project (see appendix 1 and 2 for applications).

The initial step for CogWatch ethics approval in the UK was to acquire permission from NRES Ethics Committee West Midlands – Staffordshire. The REC application form was submitted together with supplementary materials including: CogWatch research protocol, flowchart of protocol, summary CVs from the Chief Investigator and research team members, participant information sheet (PIS), participant consent form, advertisement materials (e.g. patient recruitment poster), evidence of sponsor insurance or indemnity, letter from funder, and referee's report for project review. It will be noted that the submission

requires full details of the research protocol and so could not be completed before the consortium had agreed all relevant aspects of the scenario and (first) prototype Cogwatch system (at the second CogWatch project meeting in May 2012).

After submitting the ethical application form through IRAS, we contacted the Central Allocation System (CAS) to book the application into the next available REC meeting for ethical review (typically 3 months ahead). In the meeting with the REC members in Staffordshire on 08 August 2012, the CogWatch study was discussed in detail and the committee found the application well written, however minor amendments were suggested to make the whole dataset clearer. The committee's suggestions were taken into account and final application was submitted on 11 September 2012. Confirmation of a favorable ethical opinion was received in writing on 27 September 2012. At this point, the CogWatch research team at UoB was able to start seeking management permission [Research and development (R&D) approval] from specific NHS organizations (e.g. hospitals) for letters of access to enable start of recruitment for the study.

Next, we made R&D applications to each relevant NHS organisation, starting with the Birmingham Community Healthcare NHS Trust (BCHCT). The Birmingham and Black Country (BBC) Comprehensive Clinical Research Network (CLRN) granted the NHS agreement for BCHCT research on 12 November 2012. This allowed us to advertise the CogWatch study in rehabilitation services of a specific unit (Inpatient neurological rehabilitation unit) at the Moseley Hall Hospital for which we had the required named clinical contact person. The permission was later updated (6 March 2013) to include adults and community services for patient recruitment in this site. Under the same BBC CLRN ethical approval, we have established contact with several other NHS Trusts including Royal Wolverhampton Hospital, University Hospital Birmingham, and West Heath Hospital with recruitment due to come on line in May 2013. This start date dovetails well with the completion of the Prototype 1 deliverable (required for the research protocol) in April 2013. Each site will be treated as an affiliate of the UOB CogWatch team with site file (see appendix 7) as set out in UK Good Clinical Practice (GCP) guidelines (http://www.brtc.westmidlands.nhs.uk/Training/GCPTraining.aspx) covering all aspects of the project and providing feedback on its progress.

An additional step in the ethics application process in the UK is that studies, whose funding applications have been subject to peer review, can apply to be included in the UK Clinical

Research Network Portfolio Database. The CogWatch project was added to the Portfolio on 23 October 2012 (Study ID: 13369). In addition to having a publicly available research summary and being able to advertise for recruitment online (http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13369); this Portfolio adoption provides the study with Stroke Research Network's (SRN) support (for example SRN staff can assist with patient screening and recruitment).

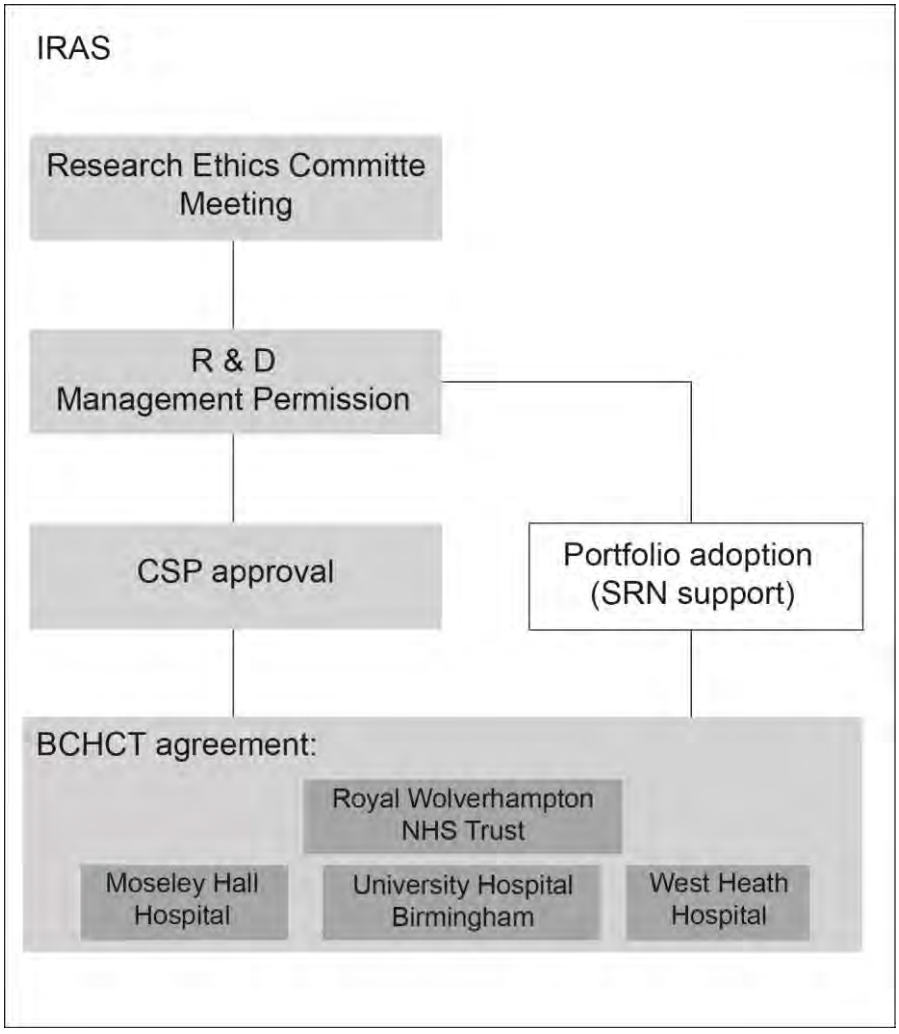

Figure 1: Flowchart summarising IRAS mechanism.

1.1.2 Recruiting patients from NHS sites

Figure 2 shows the steps required in recruiting patients at UOB

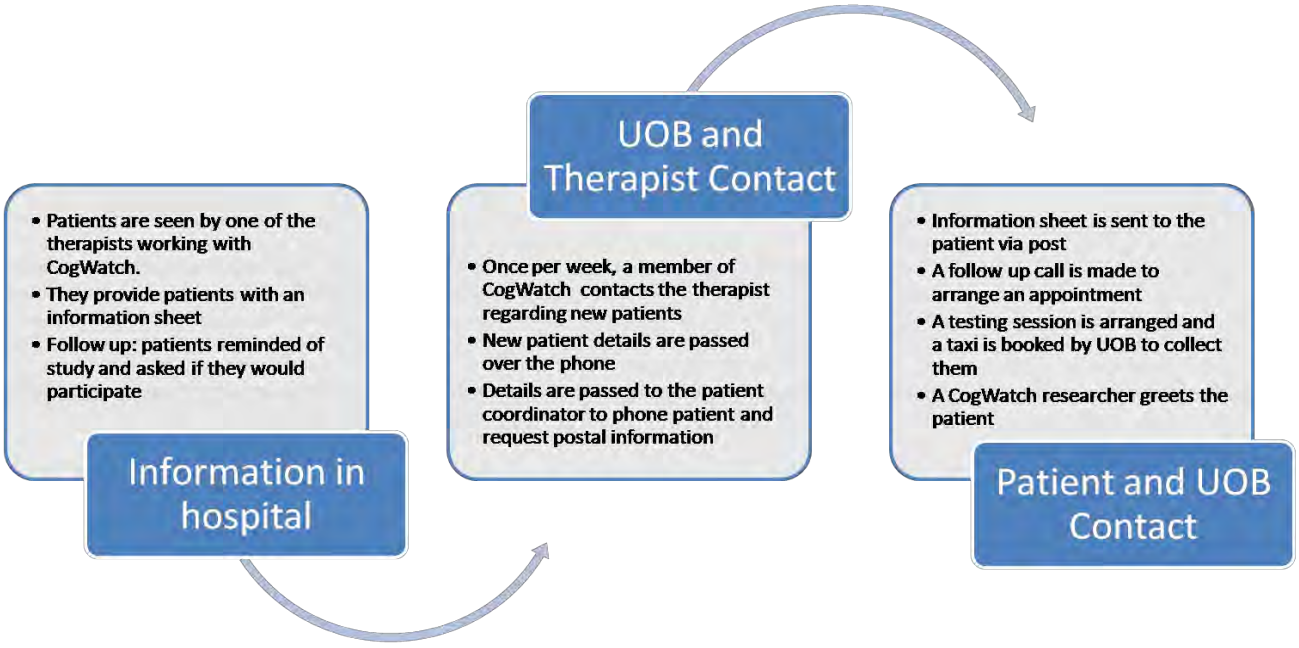

Figure 2: Flow chart describing the process of patient recruitment from an NHS site

1.1.2.1 Patient Inclusion/Exclusion Criteria

Patients will be considered for participation if they meet the following criteria:

Inclusion Criteria

- Adults aged 18+ years.
- Patients at least 14-16 days after stroke when they provide written informed consent. This time period has been chosen because it is rare for stroke survivors to be ready for testing days after stroke (e.g. Donaldson et al., 2009). To enhance integration of research into clinical management we will therefore not approach people with information about potential participation in research in this proposed trial before 7 days after stroke.
- Patients should also be clinically stable and diagnosed as suffering from cerebral infarction.

- In addition patients should be able to concentrate for at least 30 minutes while sitting.
- All patients are asked to explicitly consent by signing their name next to each section of the consent form. The experimenter goes through the information sheet and consent form with all patients and ensures patients are clear of the study. Consideration is given to the level of informed consent patients can provide. If a patients capacity to consent is questioned the experiment is not conducted.

Exclusion Criteria

- Patients who receive treatment for a current psychiatric condition.
- Participants that do not have sufficient language comprehension to provide informed consent.

1.1.2.2 Participant Information

Participants are informed in two steps:

1. Initial phone contact with the participant is made by the participant coordinator of the Birmingham participation panel. An initial introduction (provided from the information sheet) of the study is provided over the phone and if the participants (healthy controls or patients) are interested in taking part, the participant coordinator would schedule a meeting for them. In addition he/she would send via post the study information sheet and details of ethical risks if any. For patients who come from the NHS, they first receive information in person from a therapist then, they are also given the information sheet/ details of ethical risks if any before they receive a phone call or invitation letter from the Psychology Patient Coordinator
2. Secondly, at the beginning of the experimental session the experimenter presents the information sheet to all participants and discusses through the experiment and answers any questions that the participants may have.

1.1.3 Informed Consent

Ethical approval has been obtained from the NHS, Health Research Authority and the National Research Ethics Service which allows us to recruit patients and healthy controls from three sources: (i) an existing volunteer patient participation panel at UOB, (ii) by

referral from other current studies or (iii) by recruitment for the first time from UK National Health Service sources (NHS hospitals).

All participants are provided with an information sheet (see Appendix 3.6) and consent form to sign (see Appendix 3.7), both of which received ethical approval and comply with guidelines for psychological research. These guidelines ensure that informed consent details the following:

- Overall purpose of the project
- Experimental procedure
- Potential risks and benefits
- Inclusion/exclusion criteria
- End of project goals
- Reimbursements to participants
- Planned use of the data
- Possible commercial exploitation
- Rights to privacy and withdrawing from the study at anytime

1.1.3.1 Additional Consent

All participants are explicitly asked whether they consent to having their performance recorded by video. It is explained that excerpts from the videos may be shared with the CogWatch partners across the EU for research purposes or placed on the CogWatch web site as part of dissemination of research. It is explained that the nature of video data means participants may be recognisable and, in this sense, anonymity is not preserved. Patients may decline video recording but still participate in the research.

All patients are read the consent form aloud and given the time to read through and ask questions if needed. In the case where communication difficulties are present, the information sheet and consent form are read with the patient. However, if patient's capability to fully understand and therefore fully provide consent to the experiments comes under question, the experimenter will not proceed. A research project based at the University of Sheffield examined how researchers work with people with communication difficulties during

the informed consent process. They asked stroke research staff to complete a brief online survey to help understand researcher experiences of taking informed consent from people with communication disorders. Alan Wing completed this survey on behalf of the CogWatch project (see appendix 6 for information sheet).

1.1.4 University of Birmingham Ethical Process

The University of Birmingham's ethics policy maintains that all research carried out by employees be subject to ethical review by a panel of researchers and adhere to the University Code of Practice for Research. This requires submission of an application form for ethical review (see Appendix 3).

1.1.5 Recruiting patients from the panel

The University of Birmingham has an established neuropsychological patient panel consisting mainly of stroke and traumatic brain injury patients, which is managed by the patient coordinator who also coordinates patient participation in the psychology department. All patients were recruited from local community stroke networks, or word of mouth and all volunteer to be on the panel. The procedure for inviting patients from the panel to participate in the study is similar to the procedure for NHS patients whereby the patient coordinator contacts and arranges appointments and provides consent forms and information sheets prior to the patient coming in for a testing session.

1.1.6 Recruiting healthy elderly adults

The University of Birmingham has an established participation panel of healthy elderly participants, which is managed by the patient coordinator. The procedure for inviting elderly healthy participants to partake in a study can be seen in Figure 3.

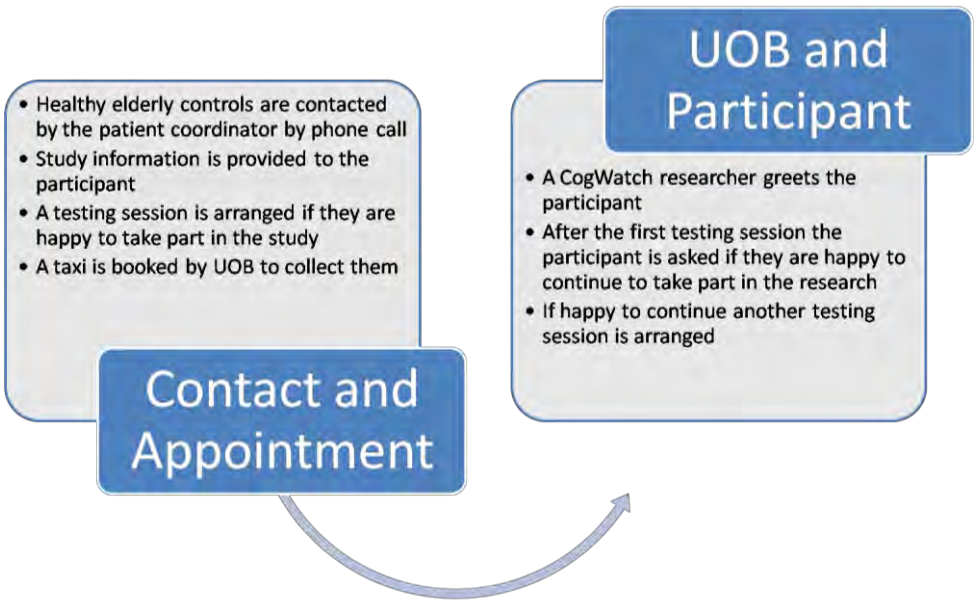

Figure 3: The process of recruiting healthy elderly adults for CogWatch

1.2 Ethical Application Process in Germany

The ethics application for CogWatch at TUM was submitted to the local ethics committee in the university (Ethikkommission der Fakultät fur Medizin der Technischen Universität München). The application form was submitted together with supplementary materials including: Statements of conflict of interest by all PIs involved at TUM and Städtisches Klinikum München (STKM), CogWatch research protocol, descriptions of recruitment processes, summary CVs from the Chief Investigator and research team members, participant information sheet (PIS), participant consent form. This application was given a favourable opinion on July 25th 2012, which allowed researchers to start patient recruitment from Klinikum Bogenhausen at the STKM.

For the German part of behavioural data collection, patients are recruited by Prof. Goldenbreg, who is the head of the Neuropsychological Department of Klinikum Bogenhausen at STKM. STKM is not a beneficiary partner of CogWatch, a third party agreement between TUM and STKM ensures access to patients and patients' clinical data by TUM investigators. Patients are informed about the project by Prof. Goldenberg and a main therapist is assigned to each patient. Further information is provided and informed consent is obtained before experiments by TUM co-workers under the supervision of the PI

at TUM. The screening session is done at the hospital, further tests and the test of CogWatch prototype is however performed at the TUM lab with similar information flows as outlined above for UOB.

Control subjects for the TUM sessions are recruited from diverse sources usually by word of mouth information.

1.3 Differences between the UK and German Ethical Application Process

Directives have been implemented in different ways in EU Member States via national legislation. These national legislations differ in complexity and are enforced by different bodies, therefore the process of ethical approval for partners may differ. For CogWatch partners UoB and TUM, similar testing protocols with patients are proposed to be conducted in two EU Member States. This section summarises differences in ethical application processes between the two institutions.

In the UK, the ethical permission for conducting a study with patients is reviewed and granted by NHS Research Ethics Committee (as described in Section 1.1). Further to this, each research site, such as universities and hospitals, has their local ethics committee and research management department to establish ethics agreements. Patient recruitment can only be initiated after these permissions are complete. Even in presence of an integrated system (IRAS), multiple centre ethical applications in the UK may be delayed due to site specific regulations and time consuming communications between research sites.

In Germany, on the other hand, the application folder is reviewed by a local ethics committee on the basis of legal fundamental principles defined in the “Arzneimittelgesetz”, “Medizinproduktegesetz”, “Strahlenschutz-“ and “Röntgenverordnung”, “GCP-Verordung”, “Bayerisches Datenschutzgesetz” (for Bavaria) and ethical principles quoted in the Declaration of Helsinki, “Stellungsnahmen des Deutsches Ethikrates”, and ICH-Guidelines. For studies at TUM ethical approval can be applied for at the local committee of the medical faculty (Ethikkommission der Fakultät für Medizin der Technischen Universität München). The Klinikum Bogenhausen of STKM, where patients for CogWatch are recruited, is an academic teaching hospital of TUM and the head of the clinical department (Prof. Goldenberg) is adjunct professor of TUM. Therefore all CogWatch studies could be covered

by the ethics commission at TUM. By applying through a local ethics committee, researchers benefit from a quicker outcome on the opinion for ethical application. In contrast to the UK system that requires obtaining site specific agreements from several hospitals, at TUM, the university and the hospital establish the research management locally.

Moreover, in TUM, young and elderly control participants are identified by word of mouth with approval under the same ethics application dataset as for patients. In UoB, control participants are identified from the School of Psychology's participation panel for which the local ethics committee approves the study separate from NRES patient identification.

Another difference between project partners is in terms of their description for compensation of participants' time. Both controls and patients are reimbursed for their travel expenses in TUM; and for some experiments, their time during the study is also compensated financially at a 10 EURO per hour rate. In UoB, although controls are reimbursed for their travel expenses and their time (6 GBP per hour), for patients, the reward is only the travel expenses compensation. This was discussed in the REC meeting and researchers were advised to keep the motivation for patient recruitment on a voluntary basis and not include any monetary reward.

2. COGWATCH: LIST OF TASKS

The CogWatch project undertakes various psychological experiments, conducted at UOB (UK), and TUM (Germany) that involve human healthy adults and stroke patients. The following tasks have been identified in the submissions approved by the local university ethical committees (UOB and TUM) and by NHS ethics (UOB). See appendix 3- 3.7).

- Clinical Screening: Activities of Daily Living (ADL) Measures
    - Barthel and NEADL (only UoB):
    - CogWatch Trial Entry Form
    - The Birmingham Cognitive Screen (BCoS, parts at TUM)
- Clinical Screening: CogWatch Screen
    - Complex Tea
    - Spontaneous Tea
    - Filing Task
- CogWatch Prototype 1 Pre Test: The Simple Tea Task
- Additional Tasks
    - Object Affordance and Selection for a Task
        - Experiment 1: Object paired affordance
        - Experiment 2: Selection of objects for a goal
    - Eye Tracking Experiment
    - Functional MRI Task
        - Experiment 1: Action observation.
        - Experiment 2: Action execution.

2.1.1 Risk to participant posed by boiling water in relation to Ethics

The UK ethics application includes specific consideration of risks to the participant which raised the issue of potential for scalding with the use of the kettle. The potential risks associated with dealing with boiling water when making tea were minimised by the following precautions:

1. At least one researcher is always present in the room when the experiments are in progress, and in general, a member of staff always accompanies the patient.
2. The use of a lightweight kettle with the amount of water limited to less than 1 litre to reduce risks of water spillage.
3. The patient's ability to safely use the kettle is assessed with cold water prior to testing. If for instance the patients show difficulty or do not show sufficient ability to use/control the kettle, they are offered a tilting kettle support that requires little strength to control the kettle. To further restrict the area of water spillage the tilting kettle support is placed on a tray preventing any spilled water to spread across the table and onto the patient. Finally, if the safety of the patient is unclear, the examiner will suggest the experiment be carried out with cold water only.
4. The kettle was limited to heat water to 85 Celsius degrees to avoid accidents caused by boiling water.
5. Initially, a tray with an elevated edge was used for safety in case of a water spillage. This has now been replaced by the addition of a raised edge on the table to stop any spills from pouring off the table onto the patients lap.

3. MANAGEMENT

Data processing associated with CogWatch research at UOB and TUM is carried out according to the local regulations in each country. This section describes the generic ethical requirement of preserving anonymity and confidentiality (whereas implementation in Cogwatch system of data security is treated elsewhere as a separate technical issue).

3.1 Data Storage and Protection at UOB

Handling of sensitive personal data in the UK is carried out according to agreements specific to each hospital site. The data processing agreement between Birmingham Community Healthcare and UoB is handled under Caldicott Principles (see appendix 4). In the case of Royal Wolverhampton NHS Trust, at the specific request of the Information Technologies Department, we follow Department of Health data processing procedures instead of Caldicott Principles.

3.1.1 Data security

Voluntary participation is central to our studies in CogWatch, and we want to take appropriate care of the information provided by the patients. Any identifiable information is kept encrypted and separate from patient performance results. To make sure that we hold this information safely and securely, we take several measures. Initially, patient contact details and medical records are transferred from the patient recruitment centres (hospitals) by researchers with research passports (see appendix 5 for the process of applying for a research passport). After patient's first visit, once the written informed consent is taken, the identifiable data is anonymised. Beyond this point, test results are kept in encrypted environments under anonymous IDs as described below.

3.1.2 Process of encoding and anonymity

Transmitting patient identifiable data is a sensitive issue and the only online way of transferring is via NHS server emails (nhs.net), which are no longer available to non-NHS sites, i.e. UoB. Hence, after recruitment, contact details (phone number, address) of the patient are acquired to make the first appointment in the university. Contact details of the patients are stored in an encrypted document list, before and separate from their study participation. After the first visit to UoB, each patient is given an anonymous participant

number and performance results are stored without identifiable data, under the anonymous participant numbers. This performance results database is mostly kept online in an encrypted folder in local servers. In the case that the study results are recorded on paper, the hard copies are kept in a locked cabinet in the School of Psychology and shredded or disposed of in confidential waste bins.

3.1.3 Process of data storage, handling and destruction

In the consent form (see Appendix 3.7), participants are asked to give consent for the data collected to be stored should they wish to withdraw from the study. Given they approve this item in the form, UoB has the right to use the data collected until the participant withdraws. If the participant does not give the consent, previously collected data will be destroyed safely (removing from the server, and shredding paper documents and disposing of them in confidential waste bins).

3.1.4 Ethics Management during the project

Even after the REC ethics approval, and establishing agreements with individual NHS Trusts, ethics processes continue to be monitored. For instance, at UOB ethics issues are discussed at weekly CogWatch project meetings. Every week, in the meeting the number of patients recruited and their performance is discussed. In order to increase recruitment, new sites are added and these are updated in the weekly meetings. Each recruitment site has a NHS member (Physiotherapist, occupational therapist) as the contact person, and they are contacted by telephone every week to exchange information on new recruits. Moreover, patient recruitment is reported to UKCRN Stroke Research Network with monthly updates on numbers and general summaries.

Approvals under local ethics arrangements covering all testing (from all partners engaging in participant testing) of volunteer participants were in place and copied to the European Commission by Glyn Humphreys before commencement of work involving participants in the relevant work packages. The applications for ethics approval declared all procedures and devices to be used and the intended data collection and processing formed a part of the ethics approval.

3.2 Data Storage and Protection at TUM

Data storage and protections at TUM is organised in a very similar way to UoB. All processes agree with the laws laid down in the “Bundesdatenschutzgesetz” and the “Bayrisches Datenschutzgesetz”. Patient data acquired from the clinical databases as well as data acquired in the project is pseudo-anonymised and the code meanings are securely stored at the Lehrstuhl für Bewegungswissenschaften at TUM. All data will be stored on secure servers using encryption. If data are exchanged between partners SSL/TLS (secure socket layer/transport layer security) encryption protocols will be used. All other process underlay the same roles as outlined for UoB above.

4. SYSTEM ETHICS

4.1.1 CogWatch in the home environment

Referring to the DOW, (B4.3.1, pp.78) when used in the home environment, the CogWatch local system will normally be on or in stand-by mode (awaiting activation by user activity). However, it will include an inactivate facility for the user that will be described to all participants to allow the user to preserve their autonomy. When inactivated no data will be collected by the system. At the user‘s option, a reminder signal will operate periodically to invite the user to re-activate the system. The CogWatch global system will be informed of activation state changes. If the system is inactive beyond some agreed level the system supervisor may contact the participant to determine if he or she wishes to withdraw from the study.

4.1.1.1 By-Stander Consent

The use of CogWatch which is envisaged both as part of research with Prototypes 1 and 2 and in the longer term in exploitation of the CogWatch concept raises the possibility that “by-standers” who neither consented (in the case of research) or requested to be included in the system monitoring (in the case of a user who installs a system) might be included in surveillance and data collection. The approach taken in the project is to provide visual indication that the system includes video recording. Furthermore clearly displayed signs will inform any third parties (e.g. relatives, friends, outside visitors/public officials) of the presence of the Cogwatch system. In addition Contact details will also be provided so that anyone interested may obtain information about the system from the system supervisor.

4.1.1.2 Ethical Issues Associated with Provision of Telecare

Further ethical issues that potentially arise from the use of the CogWatch are ones that are also being faced by the field of robots as care assistants (carebots). To what extent does the assistance restrict the user’s capabilities, freedom, autonomy and dignity? We have engaged in discussion with Prof Tom Sorrell, of the University of Birmingham, responsible for ethics considerations in WP6 in the project ACCOMPANY (http://accompanyproject.eu/) on these matters. Thus, following Draper and Sorell (2012), in the evaluation of CogWatch Prototypes 1 and 2 we propose to include consideration of points from Vallor’s (2011) review of carebot issues:

1. The objectification of the elderly as “problems” to be solved by technological means,
2. The potential for carebots to either enhance or restrict the capabilities, freedom, autonomy, and/or dignity of cared-for’s
3. The potential of carebots to enhance or reduce engagement of cared-for’s with their surroundings
4. The potential of carebots to enhance or intrude upon the privacy of cared-for’s
5. The quality of physical and psychological care robots can realistically be expected to supply
6. The potential of carebots to either reduce or enhance cared-fors’ levels of human contact with families and other human caregivers
7. The potential of carebot relations to be inherently deceptive or infantilising.

In considering points such as these in WP4 system evaluation from the user perspective one approach is to discuss the perceptions of those who have experienced the system. However to widen the approach, it will also be relevant to include discussion in focus groups where the CogWatch concept is presented and commentary is then invited, with the possibility of relating themes that emerge to the background and interests of those raising them.

4.1.1.3 Data Security in the home

The preliminary version of the security and privacy protocols for the first CogWatch prototype are detailed in chapter 5.2 of the deliverable D2.3.1 Report on networks I. In CogWatch multiple aspects of security will be considered and implemented, including:

- User authentication
- User permissions and roles
- Data encryption/decryption
- Transmission security
- Password recovery process

As indicated in the recommendation, security will be one of the major issues during second year development, even if this task cannot be solved completely during the project, a solid

security layer will be developed in order to assure the protection of patients' data during transmission.

Data security is clearly a vast topic that cannot be completely solved during the project, but we will work in order to develop a security layer able to assure the security of patient data during the CogWatch trials. Improvement in the security layer will be taken into consideration in future initiatives like CIPs for example.

ARMOR project is a good example of security management of patient sensitive data. During the next project meeting, we will discuss the possibility to share information with the ARMOR consortium and use the public work of the project to improve our security and safety layer.

Safety and security issues will be elaborated more during the second year of CogWatch project. A report about the improvements of these issues will be reported in "D2.3.2 Report on networks II".

Patient data protection will be a priority in developing CogWatch prototypes 1 and 2. This will include consideration of fire walls and encryption in storage and transfer of data at and between patient's home, hospital and research centres. Account will be taken of existing approaches such as the European project ARMOR (http://armor.tesyd.teimes.gr/en_GB), whom we will contact about the possibility of joining forces for a more comprehensive initiative.

CONCLUSIONS

Ethical review is necessary for all studies involving human participants. These reviews ensure that the participant is well informed of their rights before they give consent to participate in the study, despite differences in detail between procedures at UOB and TUM. Requirements of anonymity ensure close attention to issues of data security. Finally broader ethical issues are briefly considered in relation to pervasive surveillance implied by use of the CogWatch system in the home.

REFERENCES

Description of Work (B4 Ethics Issues)

Donaldson, C., Tallis. R., Miller. S., Sunderland. A., Lemon. & Pomeroy. V. (2009) Effects of conventional physical therapy and functional strength training on upper limb motor recovery after stroke: a randomized phase II study. *Neurorehabil Neural Repair*, 23 (4), 389-97.

Draper, H. & Sorell, T. (2012) Acceptable robotic companions for aging years. ACCOMPANY, *Deliverable 6.2*, (available at http://accompanyproject.eu/ submitted Tue, 2012-12-11 14:41).

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APPENDICES

Appendix 1: IRAS Application REC Form

Please refer to attached document entitled: APPENDIX_1_Cogwatch-RecForm.

Also see attached NHS approval letters entitled:
12 WM 0220 Wing Further Information Favourable Opinion Revised 22.10.2012
12 WM 0220 Wing Further Information Favourable Opinion 27.9.2012-2.

Appendix 2: IRAS Application Supplementary Documents

Integrated Research Application System (IRAS)

Checklist for Rec Form - Non Ctimp

The following document contains the Checklist for Rec Form - Non Ctimp.

Document Title
Covering letter on headed paper
REC application (IRAS Parts A-D)(signed/authorised copy)
Site-Specific Information Form - only if study requires SSA and main REC is also the SSA REC for a non-NHS research site (signed/authorised copy)
Research protocol or project proposal (6 copies)
Summary CV for Chief Investigator (CI)
Summary CV for supervisor (student research)
Summary CV for student(signed/authorised copy)
Research participant information sheet (PIS)
Letters of invitation to participants
GP/Consultant information sheets or letters
Statement of indemnity arrangements
Letter from sponsor
Research participant consent form
Letter from statistician
Letter from funder
Referees's or other scientific critique report
Summary, synopsis or diagram (flowchart) of protocol in non-technical language
Interview schedules or topic guides for participants
Validated questionnaire
Non-validated questionnaire
Copies of advertisement material for research participants, e.g. posters, newspaper adverts, website. For video or audio cassettes, please also provide the printed script.
Instructions for use of medical device

Checklist for Rec Form - Non Ctimp
Version - 2.0 Updated January 2009

Appendix 3: University of Birmingham Ethical Application Form

UNIVERSITY OF BIRMINGHAM
APPLICATION FOR ETHICAL REVIEW

Who should use this form:

This form is to be completed by PIs or supervisors (for PGR student research) who have completed the University of Birmingham's Ethical Review of Research Self Assessment Form (SAF) and have decided that further ethical review and approval is required before the commencement of a given Research Project.

Please be aware that all new research projects undertaken by postgraduate research (PGR) students first registered as from 1st September 2008 will be subject to the University's Ethical Review Process. PGR students first registered before 1st September 2008 should refer to their Department/School/College for further advice.

Researchers in the following categories are to use this form:

1. The project is to be conducted by:
   - staff of the University of Birmingham; or
   - a research postgraduate student enrolled at the University of Birmingham (to be completed by the student's supervisor);
2. The project is to be conducted at the University of Birmingham by visiting researchers.

Students undertaking undergraduate projects and taught postgraduates should refer to their Department/School for advice.

NOTES:

- Answers to questions must be entered in the space provided.
- An electronic version of the completed form should be submitted to the Research Ethics Officer, at the following email address: aer-ethics@contacts.bham.ac.uk. Please **do not** submit paper copies.
- If, in any section, you find that you have insufficient space, or you wish to supply additional material not specifically requested by the form, please it in a separate file, clearly marked and attached to the submission email.
- If you have any queries about the form, please address them to the Research Ethics Team.

X Before submitting, please tick this box to confirm that you have consulted and understood the following information and guidance and that you have taken it into account when completing your application:

- **The information and guidance provided on the University's ethics webpages (http://www.rcs.bham.ac.uk/ethics/index.shtml)**
- **The University's Code of Practice for Research (http://www.as.bham.ac.uk/legislation/docs/COP_Research.pdf)**

UNIVERSITY OF BIRMINGHAM APPLICATION FOR ETHICAL REVIEW	*OFFICE USE ONLY:* Application No: **ERN_12-0683** Date Received:

1. TITLE OF PROJECT

CogWatch - Cognitive rehabilitation of apraxia and action disorganisation

2. THIS PROJECT IS:

University of Birmingham Staff Research project **x**

University of Birmingham Postgraduate Research (PGR) Student project **x**

Other ☐ (Please specify):

3. INVESTIGATORS

a) PLEASE GIVE DETAILS OF THE PRINCIPAL INVESTIGATORS OR SUPERVISORS (FOR PGR STUDENT PROJECTS)

Name: Title / first name / family name	Dr Pia Rotshtein
Highest qualification & position held:	PhD, Lecturer
School/Department	Psychology
Telephone:	0121 414 2879
Email address:	p.rotshtein@bham.ac.uk

Name: Title / first name / family name	Prof Alan Wing
Highest qualification & position	PhD, Chair
School/Department	Psychology
Telephone:	
Email address:	a.wing@bham.ac.uk

b) PLEASE GIVE DETAILS OF ANY CO-INVESTIGATORS OR CO-SUPERVISORS (FOR PGR STUDENT PROJECTS)

Name: Title / first name / family name	Prof Glyn W Humphreys
Highest qualification & position	PhD, Chair
School/Department	Psychology, Oxford University
Telephone:	
Email address:	Glyn.humphreys@oxford.ac.uk

c) In the case of PGR student projects, please give details of the student

Name of student	Melanie Wulff	Student No:	1158625
Course of	PhD	Email	Mxw127@bham.ac.uk
Principal	Glyn Humphreys		
Name of student	Amy Arnold	Student No:	1132022
Course of	PhD	Email	Axa052@bham.ac.uk
Principal	Alan Wing		
Name of student	Eva Fringi	Student No:	
Course of	Master	Email	Exf111@bham.ac.uk
Principal	Alan Wing		

4. ESTIMATED START OF PROJECT Date: 1-7-2012

ESTIMATED END OF PROJECT Date: 31-9-2016

5. FUNDING

List the funding sources (including internal sources) and give the status of each source.

Funding Body	Approved/Pending/To be Submitted
FP7 CogWatch: A European collaborative projects.	Approved

If applicable, please identify date within which the funding body requires acceptance of award:

Date:

If the funding body requires ethical review of the research proposal at application for funding please provide date of deadline for funding application:

Date:

6. SUMMARY OF PROJECT

Describe the purpose, background rationale for the proposed project, as well as the hypotheses/research questions to be examined and expected outcomes. This description should be in everyday language that is free from jargon. Please explain any technical terms or discipline-specific phrases.

After a stroke, patients can suffer from a wide range of problems depending on which area of their brain was affected. Physical impairments, such as problems with motor movements, vision or balance, are addressed with physical therapy but cognitive impairments, such as problems with language, memory or problem solving are harder to identify and may overlooked during a patient's rehabilitation. Though these later cognitive problem often have negative impact on the patients' well being.

'Apraxia and Action Disorganisation Syndrome' (AADS) is a common disorder following stroke. Patients who suffer from AADS have trouble performing ordered sequences of movements, such as those required to make a cup of tea or to brush their teeth. Even patients with normal movement of their hands and arms find themselves unable to complete everyday activities because they cannot execute the correct sequence of movements necessary to complete a task.

In the UK as many as 68% of stroke patients have problems typical of AADS (Bickeron et al., 2012). AADS can have a significant effect on a patient's recovery after stroke (Bickeron et al., 2012) and on their ability to live independent lives in their own homes.

The aim of the current project is to investigate the neuro-cognitive mechanisms that support the ability to complete activity of daily leaving such as making tea, making a toast, grooming etc. This information would then be used to develop the CogWatch system. The CogWatch will be based on a computer algorithm that monitors patients behaviour while executing daily life activity, and providing the patient with online feedback when an error is detected. The current research will record the behaviour of patients and healthy controls while performing everyday life activities.

Five types of daily activities will be tested (see **¡Error! No se encuentra el origen de la referencia.** for examples of the experimental set-up):

1) Making a cup of black tea
2) Making toast
3) Documents Filing
4) Assembling a torch
5) Complex tea making task: making two different cups of teas.

We would measure the time and the type of errors made when executing the above tasks. Furthermore, we would introduce various distractions and measure their effects on the overall task performances. The distraction would include: 1) Visual-Objects distracters, here not all items on the table are necessary for task completion (see **¡Error! No se encuentra el origen de la referencia.** for examples), 2) Two types of cognitive distractions: i) reciting sequences of numbers

7. CONDUCT OF PROJECT

Please give a description of the research methodology that will be used

Stimuli:

Real objects will be used in all tasks (see Appendix 1: for example of object display). The objects will be placed on a table in front of a sited participant.

Behavioural measures:

1) Motion capture: motion detectors would be attached to the objects and hand of the participants. The motion data will be recorded while the task is performed. The markers are small light spheres (~5mm). A Qualisys system (http://www.qualisys.com/) records the location of the markers using multiple cameras located around the room. These are not video cameras and they only capture information on the spatial location of the markers.
2) Body-motion capture: Kinect technology as implemented in x-box would be used to capture movements of the participants' limbs and torso in relation to the objects on the table. Kinect is not based on video cameras, but capture objects' movement in a 3D space and display it on cartoon avatars. This technology is commonly used in video games.
3) Eye tracking and first perspective video monitoring: A head mounted eye tracking system will be used (http://www.ergoneers.com/en/products/dlab-dikablis/testprocedure.html). Participants would wear a light elastic band on their forehead with an attached infra-red camera that record the location of their gaze and a video camera that record their visual field. The information of what they see and what they look at will be recorded.
4) Video recordings excluding the face. In case eye tracking will not be feasible we will video-record the session. The camera will be positioned such that the participant's face will not be included in the frame. The videos will include the view of the torso and the two hands as they operate on the items placed on the table.
5) A tick form: would be used by the experimenter for online monitoring of the steps taken when executing each behavioural task (see **¡Error! No se encuentra el origen de la referencia.**: example of scoring sheet).

Additional data: For the neurological patients we would collect data on the structure of their brain and their general cognitive profile. This data is available as part of the Bham patients' database. We would seek an approval from the patients to use that information.

Data analyses:

The data would be analysed using inbuilt analyses tools in each of the software and would be supported by home tailored Matlab scripts. Statistical analyses would be carried out using SPSS.

The following variables will be measured:

1) Time to complete each task
2) Time between each hand movement
3) The direction of gaze and the duration of dwelling time on each object.
4) The action sequence used in the task.

8. DOES THE PROJECT INVOLVE PARTICIPATION OF PEOPLE OTHER THAN THE RESEARCHERS AND SUPERVISORS?

Yes **x** No ☐

Note: ”Participation” includes both active participation (such as when participants take part in an interview) and cases where participants take part in the study without their knowledge and consent at the time (for example, in crowd behaviour research).

If you have answered NO please go to Section 18 . If you have answered YES to this question please complete all the following sections.

9. PARTICIPANTS AS THE SUBJECTS OF THE RESEARCH

Describe the number of participants and important characteristics (such as age, gender, location, affiliation, level of fitness, intellectual ability etc.). Specify any inclusion/exclusion criteria to be used.

Participants: four group of participants will be tested:

Experimental group:

1) 30 Neurological patients who suffer from apraxia or action disorganization syndrome. These patients experience cognitive deficits that affect their ability to perform everyday tasks. Tasks that they were previously able to perform automatically. Diagnosis will be made based on their performance on the BCoS Apraxia section (Bickerton et a., 2012; www.bcos.bham.ac.uk)

Control groups:

2) 50 Young healthy participants age range 18-30y
3) 50 Elderly healthy participants – age range 50 – 90 year.
4) 30 Neurological patients who do not show problems typically associated with apraxia or action disorganization disorder.

10. RECRUITMENT

Please state clearly how the participants will be identified, approached and recruited. Include any relationship between the investigator(s) and participant(s) (e.g. instructor-student).

Note: Attach a copy of any poster(s), advertisement(s) or letter(s) to be used for recruitment.

Participants Recruitment

1) Young healthy participants will be recruited through: i) the research participation scheme and ii) advertisement in JobZone (http://www.guildofstudents.com/content/index.php?page=29305).
2) Elderly healthy participants will be recruited from: i) the School of Psychology's database (Bham Panel) for volunteer participants and ii) through recruitment posters that would be presented on public notice boards. (see **¡Error! No se encuentra el origen de la referencia.**)
3) Neurological patients will be recruited from: i) the School of Psychology's database of patients (Bham Panel). These patients volunteer on a regular base to take part in experiments run in the school; ii) through announcements and posters distributed by the stroke association (see **¡Error! No se encuentra el origen de la referencia.**), iii) from the BUCS database, and iv) from the neurological department in Mosley hall and the Queen Elizabeth hospital. We have submitted a separate ethics for the NHS for the approval of the recruitments of patients form the BUCS and the hospital wards. These later patients would not be recruited until approval would be granted by the NHS appropriate committee

11. CONSENT

a) Describe the process that the investigator(s) will be using to obtain valid consent. If consent is not to be obtained explain why**.** If the participants are minors or for other reasons are not competent to consent, describe the proposed alternate source of consent, including any permission / information letter to be provided to the person(s) providing the consent.

Consent is obtained in two steps:

1) Patients and elderly controls form the Bham panel. Initial phone contact with the participant is made by Denise Clissett who is the participant coordinator of the panel. She will provide initial introduction of the study. She would explain that we are recruiting participants for experiments that investigate the ability to perform everyday life activity, such as making tea. If the participants (healthy or patients) are interested in taking part, she would schedule a meeting for them. In addition she would post for them the study information sheet (see
2)). There is no fixed script for the phone conversion but it would contain the above information.

At the beginning of the experimental session the experimenter will present the information sheet to all participants (including the young healthy) and would discussed it with them. Participants would then be asked to sign the consent form (

Note: Attach a copy of the Participant Information Sheet (if applicable), the Consent Form (if applicable), the content of any telephone script (if applicable) and any other material that will be used in the consent process.

b) Will the participants be deceived in any way about the purpose of the study? **Yes ☐ No x**

If yes, please describe the nature and extent of the deception involved. Include how and when the deception will be revealed, and who will administer this feedback.

12. PARTICIPANT FEEDBACK

Explain what feedback/ information will be provided to the participants after participation in the research. (For example, a more complete description of the purpose of the research, or access to the results of the research).

At the end of the experiment participants would be debriefed. They would be asked the following questions: 1) how did they felt during the experiment, 2) whether the recording equipment and the monitor of their behaviour was uncomfortable in anyway, and 3) how do they think they preformed. They would receive verbal feedback on their accuracy and if needed their errors would be explained to them. In addition they would be directed to the project web site if they are interested in following up the progress of the project.

13. PARTICIPANT WITHDRAWAL

a) Describe how the participants will be informed of their right to withdraw from the project.

Participants would be informed that they can withdraw at anytime from the experiment. They would also be able to withdraw only from parts of the study, and asked that some of the information would not be recorded (for example, if they do not wish to be filmed).

b) Explain any consequences for the participant of withdrawing from the study and indicate what will be done with the participant's data if they withdraw.

If a participant asks to withdraw or partly withdraw, then they will be asked if they want their data to be deleted from the study. We would delete their data, if the participants ask for it. There will be no consequences for withdrawal.

14. COMPENSATION

Will participants receive compensation for participation?

i) Financial
Yes x No ☐

ii) Non-financial **Yes x No** ☐

If **Yes** to **either** i) or ii) above, please provide details.

Compensation:

All participants would be offered £7 per hour of participation. Taxi service will be used to bring the patients to the University.

If participants choose to withdraw, how will you deal with compensation?

Participants will be compensated for the time they have spent till they withdraw and/or for their travel expenses if needed.

15. CONFIDENTIALITY

a) Will all participants be anonymous?
Yes ☐ **No x**

b) Will all data be treated as confidential? **Yes x No** ☐

Note: Participants' identity/data will be confidential if an assigned ID code or number is used, but it will not be anonymous. Anonymous data cannot be traced back to an individual participant.

Describe the procedures to be used to ensure anonymity of participants and/or confidentiality of data both during the conduct of the research and in the release of its findings.

All participants will be given an ID number, and would be identified throughout the study using this number. The indexing of personal details, consent forms and ID numbers will be kept separately from the data in a lock file cabinet.

If participant anonymity or confidentiality is not appropriate to this research project, explain, providing details of how all participants will be advised of the fact that data will not be anonymous or confidential.

1) The data include videos of the participants performing the tasks. Hence the data cannot be completely anonymous. Participants would be informed that their performances would be recorded in video (see Appendix 4), and would be explicitly asked to agree to that in the consent forms (Appendix 5).

2) The data may be shared with our European collaborators. Note that the participants would be notified of that in the information sheet (

) and would explicitly asked to agree for the sharing of their data with our European collaborators in the consent form (Appendix 5).

16. STORAGE, ACCESS AND DISPOSAL OF DATA

Describe what research data will be stored, where, for what period of time, the measures that will be put in place to ensure security of the data, who will have access to the data, and the method and timing of disposal of the data.

The data would be stored in password locked computers placed within the SyMon lab. The data will be accessed primarily by researchers in the University of Birmingham that are involved in the CogWatch project. At the end of the project the data would be backed-up to a hard drive and kept for 10years.

As mention above, our research collaborators may be given access to some of the data. As the essence of this project is in the collaborations of different European research Centres, in which each centre contributes their expertise to the overall project.

The partners that will be given access to the data are:

1) Professor Joachim Hermsdörfer, Technische Universitat Munich. TUM's partners are running a parallel study in Germany, using an identical design. The data will be combined across centres to increase the overall study power.

2) Professor Manuel Ferre, Universidad Politecnica de Madrid. UPM's partners are responsible for developing the engineering part of the CogWatch system and would be using the data to simulate the system.

17. OTHER APPROVALS REQUIRED? e.g. Criminal Records Bureau (CRB) checks

☐ YES ☐ NO x NOT APPLICABLE

If yes, please specify.

18. SIGNIFICANCE/BENEFITS

Outline the potential significance and/or benefits of the research

The current research project would provide initial data to support the development of the CogWatch system. CogWatch aims to help and provide support for the rehabilitation of AADS patients, enabling them to regain their ability to perform activities of daily living. The current project will provide both normative data on parameters that characterised normal performances across ages of everyday life activities and the type of errors that patients are likely to make. In addition, it would facilitate patient assessment. There is no current systematic assessment and classification of AADS patients, as there is no reliable data available. We would provide systematic assessment and classification of AADS patients in two European countries, UK and Germany. The classification will result in different patient categories according to the severity of neurophysiological (e.g., identification of brain areas affected) and cognitive impairments (e.g., identification of affected ADL tasks). The perceptual and cognitive distraction manipulations would enable to test different hypotheses on the sources of AADS. Specifically, are different types of AADS associated with differential consequences of stroke such as increase of perceptual load (the introduction of object distracters) or cognitive load (introduction of secondary cognitive task) due to deficits in processing resources.

19. RISKS

a) Outline any potential risks to **INDIVIDUALS**, including research staff, research participants, other individuals not involved in the research and the measures that will be taken to minimise any risks and the procedures to be adopted in the event of mishap

There are minimal risks involved in this research as all data collecting methods are non-invasive. Participants are asked to performed tasks with objects that they are likely to encounter in their everyday life.

The tea making tasks involves pouring boiling water into a cup of tea. There is a risk of self burn if the patient fails to pour the water into the cup. To minimize this risk, we will take the following actions:

1) We will limit the amount of water in the kettle to insure it is only contained what needed for 1-2 cups of tea.

2) We will assess the participant's ability to pour cold water correctly into a cup. If the participant fails or struggles with this task, we will replace the normal kettle with a specially designed kettle tipper. This makes the kettle easier to use, and the pouring of water is restricted in space, ensuring it will only fall into the cup.

3) An experienced experimenter will be constantly present in the room to monitor for any accidents.

b) Outline any potential risks to **THE ENVIRONMENT and/or SOCIETY** and the measures that will be taken to minimise any risks and the procedures to be adopted in the event of mishap.

NA

20. ARE THERE ANY OTHER ETHICAL ISSUES RAISED BY THE RESEARCH?

Yes ☐ No x

If yes, please specify

21. CHECKLIST

Please mark if the study involves any of the following:

- Vulnerable groups, such as children and young people aged under 18 years, those with learning disability, or cognitive impairments **x**
- Research that induces or results in or causes anxiety, stress, pain or physical discomfort, or poses a risk of harm to participants (which is more than is expected from everyday life) ☐
- Risk to the personal safety of the researcher ☐
- Deception or research that is conducted without full and informed consent of the participants at time study is carried out ☐
- Administration of a chemical agent or vaccines or other substances (including vitamins or food substances) to human participants. ☐
- Production and/or use of genetically modified plants or microbes ☐
- Results that may have an adverse impact on the environment or food safety ☐
- Results that may be used to develop chemical or biological weapons ☐

Please check that the following documents are attached to your application.

	ATTACHED	NOT APPLICABLE
Recruitment advertisement	X	☐
Participant information sheet	X	☐
Consent form	X	☐
Questionnaire	☐	☐
Interview Schedule	☐	☐
Experimental protocols	X	

22. DECLARATION BY APPLICANTS

I submit this application on the basis that the information it contains is confidential and will be used by the

University of Birmingham for the purposes of ethical review and monitoring of the research project described

herein, and to satisfy reporting requirements to regulatory bodies. The information will not be used for any

other purpose without my prior consent.

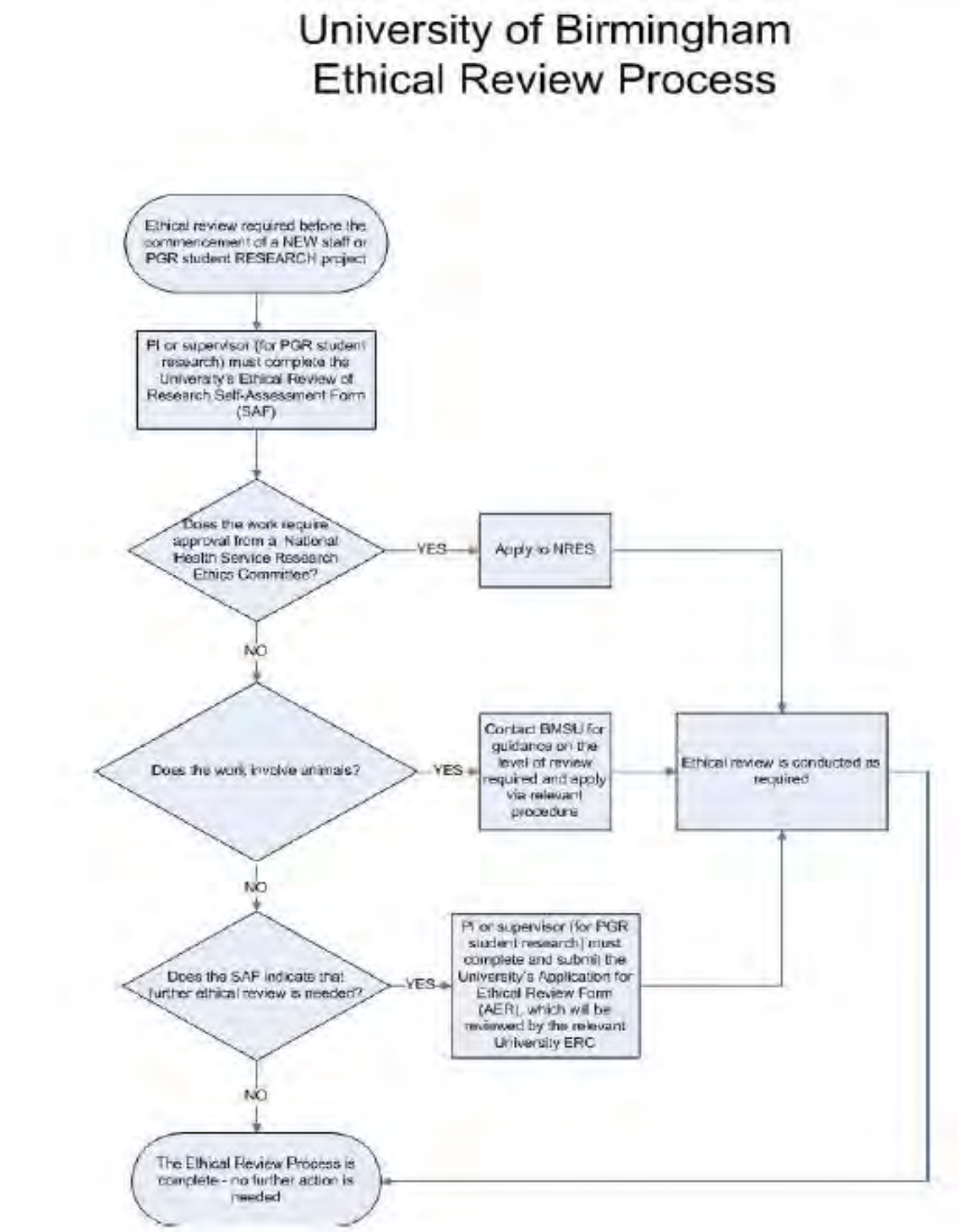
I declare that:

- The information in this form together with any accompanying information is complete and correct to the best of my knowledge and belief and I take full responsibility for it.
- I undertake to abide by University Code of Practice for Research (http://www.as.bham.ac.uk/legislation/docs/COP_Research.pdf) alongside any other relevant professional bodies' codes of conduct and/or ethical guidelines.
- I will report any changes affecting the ethical aspects of the project to the University of Birmingham Research Ethics Officer.
- I will report any adverse or unforeseen events which occur to the relevant Ethics Committee via the University of Birmingham Research Ethics Officer.

Name of Principal investigator/project supervisor:	Pia Rotshtein
Date:	5/6/2012

Please now save your completed form, print a copy for your records, and then email a copy to the Research Ethics Officer, at aer-ethics@contacts.bham.ac.uk. As noted above, please do not submit a paper copy.

Appendix 3.1 UOB Standard Operating Procedure for UOB Ethics



http://www.rcs.bham.ac.uk/ethics/review/Ethical_Review_Process.jpg 17/05/2012

Appendix 3.2: TUM Ethics

Please refer to attached document entitled: APPENDIX_3.2_CogWatch-TUMethics

Appendix 3.3: Experimental Protocols

Tea preparation

Standard Task

Target objects

- Electric kettle
- Tea spoon
- Mug
- Jar of tea bags
- Milk jug
- Sugar jar

Instructions

1. Arrange the objects as shown above
2. Show the picture of the prepared cup of tea
3. Say to the participant: "*Can you please make a cup of tea. Everything you need is here for you. Do the best you can*."
4. If after 30 sec., the patient fails to initiate any given action, then repeat the instruction and show the picture.
5. STOP if the patient still FAILS TO INITIATE any given step.

Tea preparation

Task with distracter objects

Target objects

- Electric kettle
- Tea spoon
- Mug
- Jar of tea bags
- Milk jug
- Sugar jar

Distracter objects

- Fork
- Knife
- Cereal bowl

Instructions

1. Arrange the objects as shown above
2. Show the picture of the prepared cup of tea

3. Say to the participant: "*Can you please make a cup of tea. Everything you need is here for you. Do the best you can.*"
4. If after 30 sec., the patient fails to initiate any given action, then repeat the instruction and show the picture.
5. STOP if the patient still FAILS TO INITIATE any given step.

Document Filing

Standard Task

Target objects

- 2 sheets of paper
- Folder
- Stapler
- Hole punch

Instructions

1. Arrange the objects as shown above
2. Show the picture of the filed documents
3. Say to the participant: "*Can you staple the paper together and place the paper in the folder? Everything you need is here for you. Do the best you can*."
4. If after 30 sec., the patient fails to initiate any given action, then repeat the instruction and show the picture.
5. STOP if the patient still FAILS TO INITIATE any given step.

Document Filing

Task with distracter objects

Target objects

- 2 sheets of paper
- Folder
- Stapler
- Hole punch

Distracter objects

- Pen
- Gluestick
- Tape

Instructions

1. Arrange the objects as shown above
2. Show the picture of the filed documents

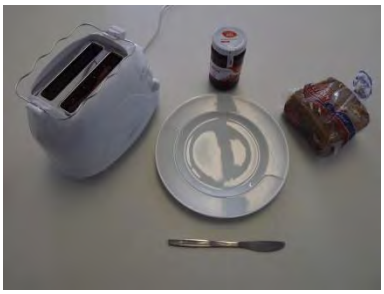
3. Say to the participant: "*Can you staple the paper together and place the paper in the folder? Everything you need is here for you. Do the best you can*."
4. If after 30 sec., the patient fails to initiate any given action, then repeat the instruction and show the picture.
5. STOP if the patient still FAILS TO INITIATE any given step.

Toast making

Standard Task

Target objects

- Toaster
- Plate
- Knife
- Bread
- Butter
- Jam



Instructions

1. Arrange the objects as shown above
2. Show the picture of the prepared toast
3. Say to the participant: "*Can you prepare a piece of toast with jam? Everything you need is here for you. Do the best you can*."
4. If after 30 sec., the patient fails to initiate any given action, then repeat the instruction and show the picture.
5. STOP if the patient still FAILS TO INITIATE any given step.

Toast making

Task with distracter objects

Target objects

- Toaster
- Plate
- Knife
- Bread
- Butter
- Jam

Distracter objects

- Spoon
- Milk
- Kettle

Instructions

1. Arrange the objects as shown above
2. Show the picture of the prepared toast
3. Say to the participant: "*Can you prepare a piece of toast with jam? Everything you need is here for you. Do the best you can*."
4. If after 30 sec., the patient fails to initiate any given action, then repeat the instruction and show the picture.
5. STOP if the patient still FAILS TO INITIATE any given step.

Complex tea-making task

Target objects

- Electric kettle
- Teaspoon
- Mug
- Transparent glass
- Jug of water
- Jar of tea bags
- Slices of lemon
- Jug of milk
- Jar of sugar cubes
- Sweetener
- Saucer for used tea bags

Distracter objects

- Dessert spoon
- fork
- Jar of coffee

Instructions

1. Arrange the objects as shown above
2. Provide the patient with the following *verbal* instructions: "Please can you make two cups of tea? One cup should be made with milk and two sweeteners and the other should be made with a slice of lemon and one sugar cube. Everything you need is here for you. Do the best you can.
3. If, after 30 seconds, the patient fails to initiate any given action then repeat the instruction *and* show the picture of the prepared cups of tea.
4. STOP if the patient FAILS TO INITIATE any given step
5. The patient should complete 2 trials of the complex tea-making task. If the patient fails to initiate the task using the verbal instructions alone they may still complete 2 further trials using both verbal and pictorial instructions.
6. Scoring for the complex tea-making task is based on the multi-step object use task (BCoS).

Picture of final goal: 

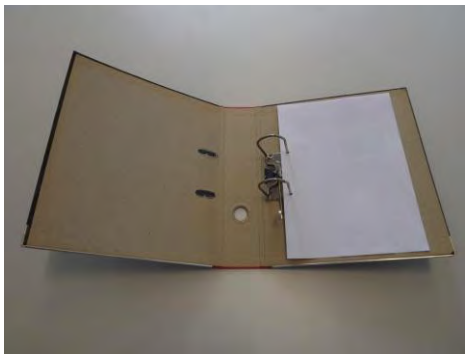
Please note: Water should be poured from the jug into the kettle. The jug should be filled with marginally more water than would be needed for 2 cups of tea. *The kettle should be placed in a safety tipper and the position of the mug/cup for safe pouring should be marked on the table and pointed out to the participant.*

Other completed Task Pictures

Torch

Cup of Tea

Filed documents



Toast preparation

Appendix 3.4: Example of Scoring Sheet for Complex Tea Making Task

Please note: Water should be poured from the jug into the kettle. The jug should be filled with marginally more water than would be needed for 2 cups of tea. *The kettle should be placed in a safety tipper and the position of the mug/cup for safe pouring should be marked on the table and pointed out to the participant.*

Scoring:

SEQUENCE 1: **Tea & milk**	Order	Description
Heat water		
Place tea bag in the cup		
Add water in the cup		
Add sweeteners		
Add milk		
Remove teabag from cup		

SEQUENCE 2: **Tea & lemon**	Order	Description
Heat water		
Place tea bag in the cup		
Add water in the cup		
Add sugar		
Add lemon		
Remove teabag from cup		

Other:

Give 1 point for each criterion achieved on first attempt.

Fill kettle with jug of water	0 point	1 point
Switch on kettle, wait for boiling	0 point	1 point

Place teabag in cup	0 point	1 point
Pour water into cup	0 point	1 point
Put two sweeteners into cup	0 point	1 point
Pour **milk** into cup	0 point	1 point
Stir tea with spoon	0 point	1 point
Remove teabag	0 point	1 point
No use of irrelevant objects	0 point	1 point
No irrelevant actions with the target objects	0 point	1 point
No perseveration	0 point	1 point

Pick another cup	0 point	1 point
Place teabag in cup	0 point	1 point
Pour water into cup	0 point	1 point
Put only one sugar into cup	0 point	1 point
Put **lemon** into cup	0 point	1 point
Stir tea with spoon	0 point	1 point
Remove teabag	0 point	1 point
No use of irrelevant objects	0 point	1 point
No irrelevant actions with the target objects	0 point	1 point
No perseveration	0 point	1 point

Hand used: _____

(B = both; L = left; R = right)

Condition of testing: _____

(1=normal;

NT or stopped due to 2=aphasia; 3=visual/spatial; 4=confusion; 5=fatigue; 6=motor; 7=other.....)

Appendix 3.5: Recruitment Posters

To be placed on notice boards:

COG WATCH

Cognitive Rehabilitation of Apraxia & Action Disorganisation Syndrome

The problem

Many stroke survivors suffer from **problems with mental processes** such as language, attention and memory.

The **CogWatch** project aims to help stroke patients who have trouble performing **ordered sequences of movements**, such as those required to make a cup of tea. These patients are diagnosed as suffering from apraxia and action disorganization syndrome (AADS)

How will CogWatch help?

The **CogWatch** researchers are investigating the specific problems faced by AADS patients and developing **new technologies** to assist them with their daily activities.

If **CogWatch** is successful it has the potential to:

- enable stroke patients with AADS to overcome the mental challenges that impair their daily lives
- improve their quality of life in the long term.

Do you want to help?

We are looking for young and old healthy volunteers to participate in our research. The research will involve completion of everyday task, like making a cup of tea.

If you would like more information, please contact:

Denise Clissett at the University of Birmingham.

Phone: 0121 414 4932; Email: D.Clissett@bham.ac.uk

To be distributed by the stroke association:

CogWatch

CogWatch

Developing rehabilitation tools for stroke survivors with mental difficulties

The problem

Many stroke survivors suffer from **problems with mental processes** such as language, attention and memory. These difficulties are harder to identify than the physical symptoms of stroke and often get overlooked during a patient's rehabilitation.

Mental difficulties can have a very **negative impact** on a stroke survivor's quality of life and can increase their **dependence** on family members for daily support.

The CogWatch project aims to help stroke patients who have trouble performing **ordered sequences of movements**, such as those required to make a cup of tea or to brush their teeth. These patients may have normal movement of their hands and arms but struggle to complete everyday activities because they cannot execute the correct sequence of movements necessary to complete a task.

This type of impairment is termed 'Apraxia and Action Disorganisation Syndrome' (AADS) by doctors and, although it is hard to diagnose, it is quite common. Recently, scientists in the UK found that perhaps as many as 68% of stroke patients have problems typical of AADS.

How will CogWatch help?

The CogWatch researchers are investigating the specific problems faced by AADS patients and developing **new technologies** to assist them with their daily activities.

The ultimate aim is to develop a personalised rehabilitation system that can be installed into the homes of stroke survivors. It will silently monitor them as they go about their daily routine and provide helpful and relevant information to guide them when they make errors.

COG WATCH
Cognitive Rehabilitation of Apraxia & Action Disorganisation Syndrome

If CogWatch is successful it has the potential to:

- **enable stroke patients with AADS to overcome the mental challenges that impair their daily lives**
- **improve their quality of life in the long term.**

How will CogWatch work?

The system will use 'intelligent' everyday objects, like cutlery or a tea kettle, that contain sensors to monitor orientation, motion and grip strength. A central processing system will wirelessly collect the object data and combine it to assess how the objects are being held and used.

During a task, such as making a cup of tea, the system will track the actions of the user through the intelligent tools. When an error is detected, it will notify the user and provide guidance to assist them in completing the task.

Guidance could be in the form of relevant images on a display screen, audible sounds or instructions, or the physical vibration of a wrist watch.

The CogWatch system will:

- **Guide user actions to help complete daily tasks.**
- **Make users more aware of the mental errors they commit.**
- **Help users learn to overcome their errors.**
- **Alert users if their safety is at risk**

Do you want to help?

We are looking for stroke survivors who experience problems with completing everyday tasks to participate in our research.
If you live in the West Midlands area and would like to move information, please contact:
Denise Clissett at the University of Birmingham.
Phone: 0121 414 4932
Email: D.Clissett@bham.ac.uk

CogWatch is funded by the European Union and coordinated by the University of Birmingham.
SEVENTH FRAMEWORK PROGRAMME

The CogWatch partners

Appendix 3.6: Participant Information Sheets

UNIVERSITY OF BIRMINGHAM

SyMon Lab, Hills Building
School of Psychology
University of Birmingham
Edgbaston, Birmingham B15 2TT
Tel: 0121 414 4932

Participants' Information Sheet: 'Making of a cup of tea'

You are receiving this letter because you have agreed to take part in this research following a phone conversation with Denise Clissett (Participants coordinator) from the School of Psychology, University of Birmingham. We would first like to thank you for agreeing to help us with this research. Below you would find more information about the research, what it involves and the expected outcomes.

What is CogWatch?

CogWatch is a European Commission funded research project whose aim is to enhance the rehabilitation of stroke patients, a third of whom will experience long term physiological and/or cognitive disabilities.

A significant proportion of these patients can suffer from Apraxia or Action Disorganisation Syndrome (AADS) which, is characterised by an impairment of cognitive abilities to carry out activities of daily living (ADL).

CogWatch is co-ordinated by the University of Birmingham, and will develop advanced and intelligent, common objects and tools which will help to re-train patients in how to carry out ADL, by providing persistent multimodal feedback to them.

Who is conducting the research?

This research is conducted by a team of researchers from the School of Psychology, University of Birmingham in collaboration with researcher groups in Munich, Germany and Madrid, Spain. The Psychology Birmingham team is led by Prof Alan Wing, Prof Glyn Humphreys and Dr Pia Rotshtein. The actual experiments would be carried out by Amy Arnold,a PhD student and Eva Fringi, a Masters student. The research would be conducted in the SyMon lab located in the Hills building.

What does the research involve?

The current research aims to understand how we performed activities of daily living. The research would focus on the following activities: making a cup of tea, making a toast, filing documents and assembling a torch. As you do these tasks we will monitor your hand movements and will track your eye gaze.

The hand movements will be monitored by attaching small (approx. 5mm sphere) markers to your hands. Special cameras will then be used to track the location of these markers in space, as you move your hands. We may also use Kinect as implemented in X-box (common used for video games) to track your movement in space. This is a special camera (not a video camera) that record the way you move in space and interacts with objects, it only record the movements and project them on an avatar body.

Eye gaze is tracked by wearing a light band over your forehead. This band holds a small camera that records the reflections of your cornea. The cornea's reflection indicates the direction of the gaze. This eye tracking device works well even if you wear glasses or contact lenses.

We will also use video cameras to records your actions and speech for a later analyses. To protect your privacy the frames will not include your face, but only your torso and your hands.

We will ask you to do these tasks multiple times. We expect that the entire sessions will last less than 2 hours. You can have breaks between the tasks. In case we are not able to collect all the data we need within 2 hours, we may ask you to come for another session on another day.

If you have participated in research in the School of Psychology before, we will ask your permeation to access pervious data that was collected with you by research in the School. This specifically applies for brain imaging data behavioural data collected as part of the BCoS screen.

Are there any risks involved?

The experiment involves performing activities that you are likely to carry out routinely at home. Hence we do not anticipate that it would expose you to any risks beyond those which are expected in everyday life. Furthermore, all measurements are non-invasive and do not pose any danger. Tea making involves boiling water in a kettle and pouring the water into a cup. In case you feel unsure about your ability to perform this task, we can provide a kettle tipper that restricts the pouring of the water. An experimenter will be present in the room throughout the experiment, monitoring for any unexpected accidents.

Why am I invited to participate in this research?

This research investigates the way people perform activities of daily leaving. We are interested to learn how healthy participants perform these activities and how patients who suffered a stroke or from any other neurological condition performs these daily activities. Therefore you are invited either because you have a neurological condition or because you are neurologically healthy.

Is the data anonymous?

Your personal details will be kept separately from the data in a locked file cabinet. You will be identified throughout the study using a random generated ID number. We will record your gender, age and health condition. However, as the sessions are being video recorded, it is impossible to keep the data completely anonymous, as the video will include information about your limbs, torso and possibly of your voice.

What will you do with my data?

The analysed data will be presented in scientific conferences and reported in scientific journals. The data collected in this research will further be used for the

development of the CogWatch system. Therefore, it is likely that it will be shared with our research partners in Munich and Madrid. If you do not want your data to be shared with our partners, please insure you tick the appropriate box in the consent form to indicate that.

We may also present the data on our web page www.cogwatch.eu. Again if you do not want your individual data be presented on the web page, please ensure that you tick the appropriate box in the consent form.

Would I be compensated for my time?

You would receive £7 per hour to compensate you for the time you spent participated in the study.

Can I withdraw from the study?

You can withdraw from the study, or parts of it, at anytime without the need to give any reason or justification. There will be no consequences for your withdrawal. You can also ask to withdraw all your data, or part of your data at any time before the project is completed. If you decide to withdraw, you would be compensated according to the time you spent doing the study till you withdraw.

What shall I do next?

Your scheduled appointment is on the _____.

Please arrive to the reception of the School of Psychology, at the Hills building, University of Birmingham. If you decide that you are not interested to take part in this research please let us know as soon as possible.

For more details:

If you required any more details please feel free to contact us:

Ms. Denise Clissett 0121 414 4932; D.Clissett@bham.ac.uk

Dr. Pia Rotshtein 0121 414 2879; P.Rotshtein@bham.ac.uk

Appendix 3.7: Participant Consent Forms

UNIVERSITY OF BIRMINGHAM

SyMon Lab, Hills Building
School of Psychology
University of Birmingham
Edgbaston, Birmingham B15 2TT
Tel: 0121 414 4932

Consent form: 'The making of a cup of tea'

Name:_____ **Date of Birth:**_____

Gender: Female / Male **Handedness: Right / Left**

	yes	No
I have read the information sheet		
I have received enough information about the study		
I had a chance to ask questions		
I have received satisfactory answers to my questions		
I understand that I am free to leave the study: · at any time? · without having to give a reason for leaving? · without affecting my medical care?		
I agree that my hand movements and eye gaze be recorded		
I agree that hand and eye movements data will be shared with the research partners in Munich and Madrid.		
I agree that my hand and gaze movement data be presented on the cogwatch webpage and be made available to the general public.		

I agree that my session will be video taped		
I understand that the videos will include information that can identify me		
I agree that the data from the videos will be shared with the research partners in Munich and Madrid.		
I agree that my data from the videos be presented on the cogwatch webpage and be made available to the general public.		
If applicable, I agree that the current research will use brain-MRI and BCoS behavioural data previously collected from me by researchers at the School of Psychology		

Participant signature: ……..……..

Name of witness: .....

Witness signature: .....

Date: ..... **Participants ID: _____**

Appendix 4: Caldicott Approval Form

Birmingham Community Healthcare NHS
NHS Trust

Section 1

Title of proposal: CogWatch: Cognitive Rehabilitation of Apraxia and Action Disorganisation Syndrome
Description of proposal (intended use of data): The study's BCHC Local Collaborator is Dr Andrew Wimperis, Specialist Physiotherapist (works at the following locations - Outpatient Brain Injury Rehabilitation Unit (MoorGreen), Brain Injury Specialist Clinic (BISC), Inpatient Neurological Rehabilitation Unit (INRU) & Moseley Hall Hospital) will screen potential participants in keeping with GCP and DPA standards. He will approach potential participants during routine clinics to establish whether they would like to find out more about the research and possible involvement, and if they are interested will refer them to the research team. The study participant coordinator from UoB will then call the patients and ask them if they'd like to visit the study team at the university. The NHS Code of Confidentiality and Data Protection Act will be complied with.
Contact details of BCHC employee requesting use of patient / service user data: Name: Job title: Division: Telephone number: Email address:
Proposed date when use or transfer of data will commence: TBC – following issue of NHS Agreement for Participant Identification **Proposed date when use or transfer of data will end**: Study end date 14/07/2015
Please tick each box to indicate the type(s) of data that will be used or transferred: ☒ Full name ☒ Surname ☒ Initials ☒ Address ☒ Post code ☒ Date of birth ☒ Age ☒ Gender ☐ Religion ☐ Ethnicity ☐ NHS number ☐ PAS number ☐ Other local identifier ☐ Clinical data ☐ Images ☐ GP / consultant details ☐ Other (please specify below): **Please indicate whether data will be combined with any other data and specify what those data sets are:** **No**

Where is the data to be sent if a transfer is to take place:

a) Is the data to be transferred between NHS organisations? ☐ Yes ☑ **No**

b) Is the data to be transferred to a non-NHS organisation / individual? ☑ **Yes** ☐ No

c) Is any data to be transferred outside of the European Economic Area? ☐ Yes ☑ **No**

d) If the data is to be transferred outside of the EEA which country will it be sent to?:

Contact details of external organisation / person requesting use of data:

Name of responsible person: Prof Alan M Wing

Job title of responsible person: Professor of Human Movement

Telephone number: 01214147954

Email address: a.m.wing@bham.ac.uk

Name of organisation: University of Birmingham

Address of organisation: School of Psychology, University of Birmingham, Edgbaston, Birmingham B15 2TT

How is the data to be transferred? Tick all boxes that apply & specify the manner of transfer:

☒ Electronic data ☐ Hard copy data ☐ Both

Electronic data

☐ FTP ☐ USB Stick / DVD / CD ☒ Email ☐ NHS Net Mail

☐ Fax ☐ Courier ☐ Internal mail ☐ External mail

☐ Other (please specify):

Hard copy data**:**

☐ Courier ☐ Internal mail ☐ External mail ☐ Other (please specify):

NB: Patient /service user data must not be transferred by unencrypted email or on unencrypted USB sticks

Please detail below what measures are in place to secure the data during transfer:

How frequently is the data to be transferred?

☐ Daily ☐ Weekly ☒ Monthly ☐ Quarterly ☐ Annually ☐ Ad hoc

☐ One off transfer

Where will the data be stored after transfer?

Electronic data:

Only anonymous data (by means of issuing each participant a unique trial number) will be shared with other organisations.

Data will be transferred from one secure destination to another secure destination in a secure manner.

If the data is to be stored on a computer is there access via a network? ☐ Yes ☒ No

Data will be stored in D. Clissett's password protected PC that has network access, but the data file won't be remotely accessible.

Hard copy data:

All data by which individuals may be identified will be kept in lockable filing cabinets within the research offices or research laboratories.

Please detail what measures are in place to ensure the data is stored securely:

Electronic data: (include access controls such as access to computer systems, password management, smart card access, protected folders on drives, physical security of hardware against theft etc)

All electronic data will have access controls restricting the data on a needs only basis.

All data stored on university desktop and laptop computers will be encrypted.

Any electronic data by which individuals can be identified will be placed in a password protected encrypted space on hard drives.

Only members of the research team directly involved in the study will have access to identifiable data but only on a need to know basis.

Personal data will be anonymous using a participant number.

The NHS Code of Confidentiality and Data Protection Act will be complied with

Hard copy data: (include physical access to premises, lockable cabinets, lockable rooms etc)

The only non-anonymous data will be held on purpose built forms and stored in lockable cabinets in lockable rooms.

Where it is necessary to share this information between organisations, e.g. when reporting a safety incident or complaint the paper form will be scanned in and encrypted, then emailed in its encrypted form to the principal investigator who will, decrypt the file, print it and destroy the electronic copy. The PI will then store the paper copy in a lockable cabinet in a lockable room.

Use of personal addresses, postcodes, faxes, emails or telephone numbers will be restricted to the minimum number of people necessary to ensure the efficient and safe running of the trial, e.g., telephone numbers will be used by members of the research team to organise appointments and addresses used to collect and return participants for appointments.

Who will have access to the data?

☐ Staff from BCHC only ☐ Other NHS staff ☑ **Non-NHS staff** ☐ Other (please specify)

Please list the names of any individuals who will have access to the data:

Prof Alan Wing

Dr Pia Rotshtein

Dicle Dovencioglu

Denise Clissett (CogWatch Participant Coordinator)

If non-NHS staff will have access to the data please tick to confirm if:

☒ They have signed a confidentiality agreement within their own organisation

☐ They have received data protection training within their own organisation

☒ Their organisation has data protection and information security policies in place

Please list those policies below:

NHS ethical approval, and research proposal includes confidentiality approvals.

Is there an information sharing protocol in place with the person / organisation who has requested the data?

☐ Yes ☐ No ☐ A protocol is required ☑ **Not applicable**

If the organisation is processing data on behalf of BCHC is there a data processing agreement in place?

☐ Yes ☐ No ☐ A data processing agreement is required ☑ **Not applicable**

How long will the data be stored, please detail below?

Personal data be stored or accessed for 6 – 12 months after the study has ended

Data will be used to invite patients to School of Psychology, and then they will be asked to give written consent. If no consent is given on their arrival, data will be disposed.

NB: Data users must comply with the Trust's Archiving & Destruction Guidelines For Business, Clinical & Corporate Records & The Data Protection Act (1998)

At the end of the usage period how will the data be disposed of securely?

Electronic data:

On completion of the study Prof Alan Wing and Dr Pia Rotshtein will have secured access to the stored data held on a named and password controlled PC within School of Psychology at the University of Birmingham

Hard copy data:

NA

Who will be responsible for ensuring the data has been disposed of securely?

Name of responsible person: Prof Alan M Wing

Job title of responsible person: Professor of Human Movement

Telephone number: 01214147954

Email address: a.m.wing@bham.ac.uk

Name of organisation: University of Birmingham

Will patients / service users be informed their data is being used / transferred?

☑ **Yes**

If yes, please detail how patients / service users will be informed of this data use / transfer?

BCHC Local Collaborator is Dr Andrew Wimperis will record the contact and leaving of the PIS will be recorded and it will also be communicated verbally to other members of the clinical team.

Personal Data management is also included & described in the Participant Information Sheet

If no, please detail why patients / service users will not be informed:

Section 2

Please provide a brief description under each of the 6 headings below for the use and / or transfer of patient identifiable information

Principle 1: Justify the purpose(s) of the proposed use or transfer of confidential information

Every proposed use or transfer of patient identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed by an appropriate guardian.

NIHR adopted research study

Principle 2: Don't use patient identifiable information unless it is absolutely necessary

Patient identifiable information items should not be included unless it is essential for the specified purpose(s) of that information flow. The need for patients /service users to be identified should be considered at each stage of satisfying the purpose(s).

Participants' information will be anonymised at the point of consent by the research team at the University of Birmingham. Use of personal addresses, postcodes, faxes, emails or telephone numbers will be restricted to the minimum number of people (Participant Coordinator, Denise Clissett) necessary to ensure the efficient and safe running of the trial, e.g. telephone numbers will be used by members of the research team to organise appointments and addresses used to collect and return participants for appointments.

Principle 3: Use the minimum necessary amount of patient identifiable information necessary

Where use of patient identifiable information is considered to be essential, the inclusion of each individual item of information should be considered and justified so that the minimum amount of identifiable information is transferred or accessible as is necessary for a given function to be carried out.

Participants' information will be anonymised at the point of consent by the research team at the University of Birmingham. Use of personal addresses, postcodes, faxes, emails or telephone numbers will be restricted to the minimum number of people necessary to ensure the efficient and safe running of the trial, e.g. telephone numbers will be used by members of the research team to organise appointments and addresses used to collect and return participants for appointments.

Principle 4: Access to patient identifiable information should be on a strict need to know basis

Only those individuals who need access to patient identifiable information should have access to it, and they should only have access to the information items that they need to see. This may mean introducing access controls or splitting information flows where one information flow is used for several purposes.

Only members of the research team directly involved in the study will have access to identifiable data, but only on a need to know basis. Use of personal addresses, postcodes, faxes, emails or telephone numbers will be restricted to the minimum number of people necessary (Participant Coordinator, Denise Clissett) to ensure the efficient and safe running of the trial, e.g. telephone numbers will be used by members of the research team to

organise appointments and addresses used to collect and return participants for appointments. (Please provide details of how access will be restricted, any auditing of access, compliance checks)
Principle 5: Everyone should be aware of their responsibilities *Action should be taken to ensure that those handling patient-identifiable information - both clinical and non-clinical staff – are made fully aware of their responsibilities and obligations to respect patient confidentiality.* Members of the researcher team have undertaken Good Clinical Practice for research (GCP) training (Please provide further details of staff confidentiality or information governance training, confidentiality and security policies in place, how those policies are communicated to staff) Ensure staff are given a copy of the rules stipulated at Appendix 2
Principle 6: understand and comply with the law *Every use of patient identifiable information must be lawful. Someone in each organisation handling patient information should be responsible for ensuring that the organisation complies with legal requirements.* (Is there a Caldicott Guardian / Data Protection Officer / IG Lead - please provide name & contact number) (Please provide details of Registration with Information Commissioner's Office)
Please detail below the supporting documentation that you are including with this application e.g. Ethics committee approval, correspondence etc; REC Favourable Opinion 27/09/2012

Declaration

To be completed by the person applying for Caldicott approval. By signing this declaration you are confirming that you will ensure the data will be processed in accordance with the agreed conditions.

I confirm that the data will be held and used according to the conditions and information given within this form and accompanying guidance.

Name: Dicle Dovencioglu Job Title: Research Fellow

Signature:…… Date: 25/10/2012

For Office Use Only

The release and use of data as described above has been:

Approved / Approved with conditions* / Not approved

Caldicott Guardian: …… Date:……..

*** please see attached sheet of further conditions**

Appendix 5: Research Passport Guidance

Research Passport Guidance

Below is a rough process of getting a research passport.

BEFORE YOUR APPLICATION FOR A RESEARCH PASSPORT

In order to apply for a research passport you may need to have the following:

1. A CRB usually though C. Tolley– if you already have one depending on how old it is, it may be okay to use but C. Tolley will assist.
2. You may require Occupational Health clearance. To do this contact Occupational Health directly by emailing occupationalhealth@bham.ac.uk
3. You may also have to provide details of your immunisation history; examples of forms online can be found via http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx These records are usually retained by yourself or your GP.

APPLICATION FOR RESEARCH PASSPORT

1. Download the research passport form through the link below: http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

2. The researcher needs to fill out Sections 1,2, 3.

3. Your supervisor needs to fill out Section 4.

4. Send to the appropriate person (to fill out Section 5):
   - For STUDENTS, they will need to have the research passport processed by Claire Tolley in Admissions who is available on 44086 or C.L.Tolley@bham.ac.uk.
   - You can either by post the Research Passport along with your CRB and Health Clearance from Occupational Health (if required) to C Tolley. She will then complete section 5. OR. Make an appointment with C. Tolley and bring in all the documents and she will do it while you wait.
   - For STAFF members Hema Parmar (HR Adviser) is able to process Research Passports h.parmar@bham.ac.uk<mailto:h.parmar@bham.ac.uk>

5. Once you have all your documentation signed off by your supervisor and C.Tolley you will need to take the research passport form and all other original documents to the lead R&D office to complete your research passport.

Appendix 6: Research with People with Communication Difficulties

Information Sheet

1. **Research Project Title: Informed Consent Online Survey**.

2. **Invitation:**

You are being invited to take part in a **research project** to collect information from staff who recruit people to research studies. Before you decide it is important for you to **understand why** the research is being done and what it will **involve**. Please take time to **read** the following information **carefully** and discuss it with others if you wish. Take time to decide whether or not you wish to take part. Thank you for reading this.

3. **What is the project's purpose?**

This research aims to find out how **research staff** work with people with **communication difficulties** during the **informed consent** process. It also aims to find out what research staff think about **training** they may have received on how to obtain **informed consent** from research participants with **communication difficulties.** We are asking people to complete a **brief online survey** to help us find out all this information.

4. **Why have I been chosen?**

You have been chosen to take part because your work involves **recruiting research participants.** You may also have **received training** in informed consent from Dr Palmer and Gail Paterson.

5. **Do I have to take part?**

It is **your decision** whether or not to take part. If you do decide to take part you will be able to **print off** this information for your records. If you decide **not** to participate or if you choose to **withdraw** from the research once you have submitted your survey information, this will **not affect** any further training opportunities offered to you. You do not have to give a **reason** if you decide to withdraw and we will **not keep** or **use** any survey information you have **already submitted**.

6. **What will happen to me if I take part?**

You will be invited to complete the **online survey**. The survey can be accessed via the **"SurveyMonkey"** website. There is a **link** to this website at the **bottom** of this information.

You will only have to complete the survey **once** and it should take you up to **20 minutes**. The survey will ask you about how you use the **Mental Capacity Act** during the informed consent process**,** how you take **informed consent**, how you work with people with

communication difficulties during the informed consent process, and what you thought about the **training** if you received it.

If you prefer to complete a **paper version** of the survey, please ask the **person who emailed you** this information sheet for a **paper survey** and a **stamped addressed envelope (SAE)** to enable you to send the completed paper survey back to us.

Participants will have **three months** in which to respond to the survey. We will ask the local organiser of your training to send one **email** to all participants after the first month and another after the second month to **remind** participants to **complete** the survey if they have not already done so. If you decide not to participate, you may still receive these emails. Please **ignore** them if you do **not wish** to **take part** in the project.

7. What are the possible disadvantages and risks of taking part?

We do not think there are any disadvantages or risks to you taking part.

8. What are the possible benefits of taking part?

There are **no immediate benefits** for people as a result of participating in this project. However, it is hoped that this work will contribute to our understanding of the informed consent process. It should also help Dr Palmer to improve training offered to others in the future.

9. What if something goes wrong?

This research project does **not involve** any special **risks**. If we receive any responses which suggest that participants need **further training** on specific aspects of the informed consent process, we will let the **local organisers** of the training know. We will **not link** these training needs to any **individual** participant.

If you want to make a **complaint** about how people have approached you or treated you during the project, please contact **Professor Pamela Enderby** at the University of Sheffield on **0114 222 0858**.

If you are **still not satisfied** with the way your **complaint** has been handled, please contact the University's 'Registrar and Secretary', **Philip Harvey** on **0114 222 1100**.

10. Will my taking part in this project be kept confidential?

The information you provide to the SurveyMonkey website is collected **anonymously** and stored **securely** on the SurveyMonkey server. SurveyMonkey's **security statement** is available at: http://www.surveymonkey.com/mp/policy/security/ Electronic information will be **stored securely** on a password-protected computer at the University of Sheffield. Despite these safeguards, online data collection is **never entirely secure** and you should consider this carefully before deciding to take part in this study. Any information we collect on paper will be **stored securely** at the University of Sheffield.

All information we collect from you during the project will remain **anonymous** and **strictly confidential**. We will keep all anonymous information **indefinitely**, to enable us to use it in

the **future** for related research projects. People **outside** the project will **not** be able to see your personal information. Your **name** will **not** be shown in any reports or publications.

11. **What will happen to the results of the research project?**

We will use the information you provide to make **improvements** to informed consent training provided in future. We may also use the results to help us write **journal articles** or **book chapters** about the informed consent process, which may be **published**. If we use information that you provide to help us write these articles, we will make sure that you **cannot be identified** from it. The information we collect from you during the course of the project might be used for **additional research** carried out by Dr Palmer and Mark Jayes in the future.

12. **Who is organising and funding the research?**

This research is being organised by the **University of Sheffield**.

13. **Who has ethically reviewed the project?**

This project has been ethically approved by the University of Sheffield's **School of Health and Related Research's** ethics review procedure.

14. **Contact for further information**

If you have any questions about this project, please contact **Mark Jayes** via telephone on **0114 222 5427**, or via email at cm4mjx@sheffield.ac.uk.

Thank you very much **for** reading **this information. Thank you very much for** taking part **in this research if you decide to do so.**

You may wish to print out **this information for your records.**

The online survey can be accessed at: https://www.surveymonkey.com/s/InformedConsent1

Please press Control and Click on the link or cut and paste it into your browser to start the survey.

Appendix 7: Check List for the Investigator Site File

Investigator Site File Contents

Section 1 Contact Details/Logs

1.1. Monitor Log
1.2. Investigator's Contact List
1.3. Study Contact Details

Section 2 General Correspondence/Communication

Section 3 Investigator/Research Staff Details

3.1. Training Log
3.2. Site Authorisation Signature Log/Delegation Log
3.3. Curriculum Vitae

Section 4 Protocol/Amendments and Working Documentation

4.1. Protocol
4.2. Protocol Signature Page
4.3. All Protocol Amendments
4.4. Protocol Amendments Signature Page
4.5. Sample Case Record Form
4.6. Related Correspondence

Section 5 Investigator Brochure

5.1. All Investigator Brochures and Receipts

Section 6 Regulatory Approvals

6.1. Medicines and Healthcare products Regulatory Agency (MHRA) Approval Letter

Section 7 Research Ethics Committee (REC) Documentation

7.1. REC Application
7.2. REC Approval Letter
7.3. R&D Trust Approval Letter
7.4. Peer Review
7.5. Related Correspondence
7.6. Ethics Committee Composition, Constitutions, and Statement of Compliance
7.7. Interim/Annual/Final Reports to Ethics Committee, Care Records Service (CRS) Receipt and EC acknowledgments

Section 8 Agreements and Sponsorship

8.1. Agreements/Contract
8.2. Insurance/Indemnity/Confidentiality Agreement

8.3. Sponsorship Letter
8.4. Investigator Agreement
8.5. Financial Contract
8.6. Financial Disclosure Agreement

Section 9 Study Medication

9.1. Instructions for Handling Study Medications
9.2. Certification for use on site – if applicable
9.3. Medication Shipment Details – if applicable
9.4. Unblinding Details – if applicable
9.5. Drug Accountability Records
9.5.1. Preparation and Dispensing Record
9.5.2. Medication Prescription Record
9.5.3. Destruction and Return Record

Section 10 Clinical Laboratory Details

10.1. Accreditation Certification and Annual Approval Letter
10.2. Normal Laboratory Values/Range of Values
10.3. CVs for Heads of Departments
10.4. Storage Instructions
10.5. Record of Shipments and/or Retained Body Fluids/Tissue Samples
10.6. Laboratory Correspondence

Section 11 Subjects

11.1. Subject Screening/Enrolment Log
11.2. Subject Identification List
11.3. Patient Information Sheet and Consent Forms –Blank/all versions
11.4. Patient Information Sheet and Consent Forms – Signed
11.5. Copy of GP letter

Section 12 Safety Reporting and Related Correspondence

12.1. Safety Reports for R&D Site
12.2. Safety Reports to Sponsor
12.3. Copies of Annual Safety Reports and Associated Documents from Sponsor
12.4. Emergency Code Break Procedures and Notification of Unblinding

Section 13 Monitoring Reports

13.1. Monitoring Visits – Confirmation and Follow up Letters

Section 14 Research Guidance

14.1. ICH GCP Guidance
14.2. Declaration of Helsinki

Section 15 Miscellaneous