CogWatch – Cognitive Rehabilitation of Apraxia and Action Disorganisation Syndrome

D6.3.2 Ethical and Safety Issues 2

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Authors (per company, if more than one company provide it together)		**UOB Rosanna Laverick, Pia Rotshtein, Alan Wing**	
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EXECUTIVE SUMMARY

This report describes the steps taken in CogWatch to meet ethics requirements at UOB, UPM and TUM for conducting research with human participants. It documents ethical amendments at UOB and information regarding changes to equipment to ensure safety.

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REVISION HISTORY

Revision no.	Date of Issue	Author(s)	Brief Description of Change
V1	02/10/14	Rosanna Laverick (UOB)	Initial Draft
V2	21/10/14	Pia Rotshtein and Rosanna Laverick (UOB)	2nd Draft and formatting
V3	24/10/14	Alan Wing and Rosanna Laverick (UOB)	Final draft and corrections

LIST OF ABBREVIATIONS AND DEFINITIONS

Abbreviation	Abbreviation
Technische Universität München	TUM
University of Birmingham	UOB
Universidad Politécnica de Madrid	UPM
Moseley Hall Hospital	MHH
Wolverhampton West Park	WWP
National Research Ethics Service	NRES
Site Specific Form	SSI
National Health Service (UK)	NHS
Prototype 1.2 (tea-making)	P 1.2
Person Identification Sites	PIC
Research and Development	R and D

1. INTRODUCTION

As outlined in the DOW (B4 Ethical Issues) the CogWatch consortium is sensitive to ethical principles and data protection regulations at national, European and international levels, 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 further ethical applications and amendments to previous applications carried out by UOB, as well as further ethical and safety considerations.

1.1 UK Ethical Process

1.1.1 UK NHS Amendments

The initial NHS applications documented in the previous deliverable (D6.3.1), defined WWP and MHH as Person Identification Centres for patient recruitment. To enable the use and evaluation of the system in a hospital, the statuses of these two hospitals were changed to Research Sites. This process involved putting in an application via the National Research Ethics Service (NRES) and adjusting these sites from identification centres to research activities. WWP and MHH SSI's are documented in Appendix 1 and 2 respectively. Further to this the approval can be found in Appendix 3 and 4 respectively.

In addition, UOB made further updates to the NHS ethics protocol and documents to be used in the project with an amendment in October 2013 (See Appendix 5). A further amendment was made in January 2014 with documents adapted and added to be used in the project (See Appendix 6).

1.1.2 UOB Ethical Applications

The University of Birmingham ethics policy maintains that all research carried out by the employees be subject to ethical review by a panel of researchers and adhere to the University Code of Practice for Research. This requires a submission of an application form for ethical review; in D6.3.1 we documented the ethical application for tea-making. Since then, we have submitted an application for tooth brushing (Prototype 2) (See Appendix 7) as well as a health and safety form as required due to the nature of the activity (See Appendix 8), both of which were accepted by the UOB ethics committee on 20th June 2014.

1.2 Participant testing

Subject testing has continued across all sites (UOB, UPM and TUM). All sites have ensured informed consent was taken (See Table 1).

Table 1- Testing since June 2013

	UOB	TUM	UPM
Patients	56	74	0
Controls	69	84	25
Informed consent	yes	yes	yes

1.3 Participant Monitoring

1.3.1 Depression and Anxiety

At UOB patients have been monitored using the Hospital anxiety depression scale[1] (See Appendix 9), to ensure that participation in experiments is not affecting their mood. The procedure we followed was that if patients went above normal threshold 0-7 and were within borderline 8-10 or abnormal, then they were met by the senior lecturer on the project at UOB, and a discussion whether the scores were due to the participation in the research or due to other reasons, advising if they needed to seek medical support. In total, 13 patients fell into the borderline or abnormal range, exhibiting depression or anxiety. None reported that these high scores were related to the participation in the research. In fact all testify that participation was helping them and making them feel better. For the about half the high scores were directly related to the stroke condition and the life impact it had; while for the rest these were problems that pre-dated the stroke. Patients were advised to contact their GP for additional support.

1.3.2 Imaging feedback

Patients that had taken part in the fMRI and structural imaging experiment, N=29, had a meeting with the senior lecturer on the project at UOB, who provided them with detailed feedback on their imaging results, including explaining and showing them the impact of stroke on their brain.

2. MANAGEMENT

2.1 Data protection and storage post project

In accordance with ethical applications at UOB and the NHS in the UK, we will keep records and documents for 10 years following the end of the project following data protection and storage regulations and procedures documented in D6.3.1.

3. P1.2 ETHICAL CONSIDERATIONS

3.1 Equipment safety

Through use of P1.2 in the UOB laboratory with recruited patients, we found that some of the P1.2 components could be made safer to those using them. We purchased a new kettle (BOSCH Styline) (See Figure 1) which allows for temperature control. It also has an automatic shut off feature to avoid overheating, boil-dry protection which stops the kettle boiling if the kettle is empty, and also a switch off function when it is lifted off the base. These safety features have become necessary functions for testing with patients. Further to this, the kettle has a one-hand lid feature, which is useful for the 50% of our patients that have hemi-paresis and only have the use of one hand to open the lid of the kettle. The kettle is also has 'cool touch' sides, which is necessary when the kettle is boiled up to 10 times during a short time period.

Figure 1- BOSCH Styline Kettle

A further safety amendment which has been made at UOB, TUM and UPM, relates to the coasters used for action recognition in P1.2. The coasters each require a lithium polymer battery; these batteries keep their charge for two hours during use and needed frequent charging. Therefore, we purchased a safety charging system Hex charger which does not allow the batteries to overcharge and become potentially dangerous when in use/and charging. A safety fire proof bag (Lipo guard) (See Figure 2) is also used in conjunction with this charger which would contain any fire or explosion caused by the charging of the batteries. These batteries are prone to expanding when over used/charged. The charger is placed into the fire proof bag, with only the wire to the electric plug leading out from the side of the bag. To avoid battery overuse, we appropriately dispose (designated battery recycling place) of the batteries when they have been charged up to 30 times or if they look like they have expanded by more than 10% of the original dimensions.

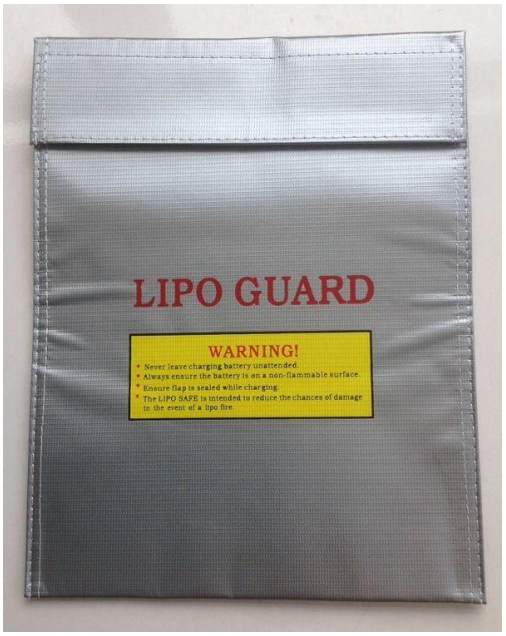

Figure 2 – Lipo Guard safety fire proof bag

3.2 UOB NHS Hospital visits

As documented, MHH and WWP were both transferred from PIC sites to Research Sites for CogWatch project so that we could carry out research activities within the NHS trusts, including computer assisted ADL. As a result, we were able to take our CogWatch system to NHS trusts for use with inpatients. All equipment was electrically tested by the NHS trust by their estates team. All patients signed consent forms approved by the respective R and D departments through our CogWatch NHS protocol; this included their agreement to be filmed using the CogWatch system and acceptance of data collection with the right to withdraw their data at any stage if they wished to. Signs were put on the door of the room that this research activity was being carried out, to warn there would be filming equipment within that room and there was a possibility that on entering the room they could be captured via the filming.

3.3 UOB Home visits

Ethical approval for home visits is being sought through the UOB ethics committee and an amendment to this effect has been submitted via a previous application. The amendment documented that the CogWatch system would be taken into three patient homes, with the consent of both the patient and their carer. Further to this, as with the hospital set up, signs would be placed outside the kitchen area, to warn there would be filming equipment within that room and there was a possibility that on entering the room they could be captured via the filming. Further to this another amendment was submitted to include qualitative research

approval to cover tooth brushing questions and evaluation related to Prototype 2, which was not covered in the previous application (previously was designed to assess prototype 1).

4. CONCLUSIONS

All ethical requirements have been complied with and no serious adverse events reported.

REFERENCES

[1] Zigmond, A.S. And Snaith, R.P. (1983) The Hospital anxiety and depression scale. *Acta Psychiatricica Scandinavica,* 67, (6), 361-370.

APPENDICES

Appendix 1: WWP SSI

Appendix 2: MHH SSI

Appendix 3: WWP Approval

Appendix 4: MHH Approval

Appendix 5: NHS amendment approval October 2013

Appendix 6: NHS amendment approval January 2014

Appendix 7: UOB Ethics application for Tooth brushing

Appendix 8: UOB Health and Safety for Tooth brushing

Appendix 9: Hospital And Anxiety Scale Questionnaire