Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
CogWatch v3 aw

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
(●) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

☑ England

- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] National Information Governance Board for Health and Social Care (NIGB)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (•) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

(•) Yes ( ) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

( ) Yes (•) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (•) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and

Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
Two named PhD students will contribute to design, data collection, analysis and writing up of the research

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Site-Specific Information Form (NHS sites)

Is the site hosting this research a NHS site or a non-NHS site? *NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.*

- (●) NHS site
- ( ) Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.

The data in this box is populated from Part A:

Title of research:
Cognitive Rehabilitation of Apraxia and Action Disorganisation Syndrome

Short title: CogWatch v3 aw

Chief Investigator:

Title	Forename/Initials	Surname
Prof	Alan M	Wing

Name of NHS Research Ethics Committee to which application for ethical review is being made:
Black Country

Project reference number from above REC: 12/WM/0220

1-2. Give the name of the NHS organisation responsible for this research site

The Royal Wolverhampton NHS Trust
If this site has not been included in the list of sites submitted to the main REC in Part C, please submit a Notice of Amendment to the main REC, copied to MHRA for information.

1-3. In which country is the research site located?

- (●) England
- ( ) Wales
- ( ) Scotland
- ( ) Northern Ireland

1-4. Is the research site a GP practice or other Primary Care Organisation?

( ) Yes (●) No

2. Who is the Principal Investigator or Local Collaborator for this research at this site?

Select the appropriate title: (•) Principal Investigator
( ) Local Collaborator

	Title	Forename/Initials	Surname
		Jane	Bisiker
Post	MSc health care professional Education		
Qualifications	DipCOT MSc Health Care Professional		
Organisation	Stroke Services, Royal Wolverhampton NHS Trust		
Work Address	Occupational Therapy Department West Park Hospital Wolverhampton		
PostCode	WV1 4PW		
Work E-mail	jane.bisiker@nhs.net		
Work Telephone	01902444286		
Mobile			
Fax			

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.03

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? (•) Yes ( ) No

A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.

3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.

Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.

	Location	Activity/facilities
1	West Park Hospital, Occupational Therapy Department	Taking informed consent

4. Please give details of all centres where potential participants for this research site will be identified.

Participant Identification Centre	Name(s) of individuals involved in identifying potential participants

5. Please give details of all other members of the research team at this site.

1

Title	Forename/Initials	Surname

	Kerry Burr
Work E-mail	Kerry.burr@nhs.net
Employing organisation	Stroke Services, Royal Wolverhampton NHS Trust
Post	Clinical Specialist Occupational therapist
Qualifications	Dip CoT qualification
Role in research team:	researcher

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.02

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? (●) Yes ( ) No

A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.

2

	Title	Forename/Initials	Surname
		Debbie	Morgan
Work E-mail	Debbie.morgan@nhs.net		
Employing organisation	The Royal Wolverhampton NHS Trust		
Post	Stroke Research Nurse		
Qualifications	RN DipHE 2001 Wolverhampton University		
Role in research team:	research nurse		

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.3

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? (●) Yes ( ) No

A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.

3

	Title	Forename/Initials	Surname
		Karla	Preece
Work E-mail	karla.preece@nhs.net		
Employing organisation	The Royal Wolverhampton NHS Trust		
Post	Stroke Research Nurse		
Qualifications	RN DipHE2007 University Central England, Birmingham		
Role in research team:	research nurse		

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*

0.3

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ◉ Yes ○ No

A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.

4

	Title	Forename/Initials	Surname
		Amy	Arnold
Work E-mail	axa052@bham.ac.uk		
Employing organisation	University of Birmingham		
Post	Doctoral Researcher		
Qualifications	MRES, Cognitive Neuropsychology and Rehabilitation 2011 Graduate Diploma Psychology 2010		
Role in research team:	researcher		

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.02

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ◉ Yes ○ No

A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.

6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

7. What is the proposed local start and end date for the research at this site?

Start date:	20/05/2013
End date:	14/07/2015
Duration (Months):	25

8-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *(These include seeking consent, interviews, non-clinical observations and use of questionnaires.)*

Columns 1-4 have been completed with information from A18 as below:

1. *Total number of interventions/procedures to be received by each participant as part of the research protocol.*
2. *If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?*
3. *Average time taken per intervention (minutes, hours or days)*
4. *Details of who will conduct the procedure, and where it will take place*

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
1-1. Birmingham Cognitive Screen (BCOS)	1	0	60 mins	Researcher Psychology Department	Dicle Dovencioglu, Melanie Wullf, Amy Arnold, UoB
1-2. Barthel Index	1	0	15 mins	Researcher Psychology Department	Dicle Dovencioglu, Melanie Wullf, Amy Arnold, UoB
1-3. Tea making	1	0	30 mins	Researcher Psychology Department	Dicle Dovencioglu, Melanie Wullf, Amy Arnold, UoB
1.4 Filing task	1	0	5 mi	Researcher Psychology Department	Dicle Dovencioglu, Melanie Wullf, Amy Arnold, UoB
2-1 Familiarisation mock scanner	1	0	30 mins	Researcher Psychology Department	Dicle Dovencioglu, UoB
2-2 Structural scan (MRI) – lying quietly and relaxed.	1	0	10 mins	Researcher Psychology Department	Dicle Dovencioglu, UoB
2-3 Functional scans (fMRI)– watching a video of making tea and detecting errors	1	0	50 mins	Researcher Psychology Department	Dicle Dovencioglu, UoB
3/4/5/6-1 Tea making	4	0	15 mins	Researcher Psychology Department	Melanie Wullf, Amy Arnold, UoB
3/4/5/6-2 Training (tea making with video or auditory cues)	4	0	30 mins	Researcher Psychology Department	Melanie Wullf, Amy Arnold, UoB
3/4/5/6-3 Post-test (tea making)	4	0	15 mins	Researcher Psychology Department	Melanie Wullf, Amy Arnold, UoB
3/4/5/6-4 Eye movements to assess attention	4	0	30 mins	Researcher Psychology Department	Melanie Wullf, Amy Arnold, UoB
3/4/5/6-5 Delayed post-test (tea making)	4	0	15 mins	Researcher Psychology Department	Melanie Wullf, Amy Arnold, UoB
Taking informed consent				Researcher, West Park Hospital, OT Dept	Jane Bisiker, Kerry Burr, Debbie Morgan, Karla Preece, Amy Arnold

8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

(●) Yes ( ) No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?
Testing protocol need not be followed through by the Royal Wolverhampton staff. Patients will be asked to give consent in the hospital. After the patients have given consent, they will be invited to UoB to conduct the protocol with the university research team.

9-1. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *(These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.)*

Columns 1-4 have been completed with information from A19 as below:

1. *Total number of interventions to be received by each participant as part of the research protocol*
2. *If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?*
3. *Average time taken per intervention (minutes, hours or days)*
4. *Details of who will conduct the procedure, and where it will take place*

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
					N/A

9-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

○ Yes ◉ No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?

10. How many research participants/samples is it expected will be recruited/obtained from this site?

Approximately 52

11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.

Participants will be identified as suitable for the project who display dyspraxia when they have their cognitive screen on the ward. The research team would then approach them to see if they would be interested in taking part in the study.

12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

Name	Expertise/training
Jane Bisker	Has had Quality assurance training on 4th December 2012 through Research Governance at the R&D Directorate this includes the informed consent process and ICH−GCP. Has had GCP training in 2010.
Kerry Burr	Has had Quality assurance training on 4th December 2012 through Research Governance at the R&D Directorate this includes the informed consent process and ICH−GCP. Has had GCP training on 21st January 2010.
Debbie Morgan	Has had Quality assurance training on 6th December 2011 through Research Governance at the R&D Directorate this includes the informed consent process and ICH−GCP. Has had GCP training on 29th December 2011
Karla Preece	Has had Quality assurance training on 17th October 2012 through Research Governance at the R&D Directorate this includes the informed consent process and ICH−GCP. Has had GCP training in March 2010
Amy Arnold	Will be receiving Quality assurance training through Research Governance at the R&D Directorate this includes the informed consent process and ICH−GCP.

15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?

Research and Development Directorate 01902 695065 or the PALS department 01902 695362

15-2. Is there a contact point where potential participants can seek further details about this specific research project?

Potential participants can speak to the research team regarding any further information. A contact number for the principal investigator, research team and a complaints number is displayed on the patient information sheet.

16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study? *A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.*

No

Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).

17. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters etc.)*

Patients who cannot understand English will be enrolled only if the normal hospital interpreter facilities are available for verbal translation and will be present at all study visits. It will be in the individual investigators' judgment whether each subject has adequate comprehension of the English language (both verbal and written) to give informed consent.

18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?

The Patient Information Sheet and Consent and study procedures will be present in the Hospital patient notes.

19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

All personnel are familiar with the study assessments and interventions and the site has the facilities needed to carry out the assessments. Personnel are trained to manage any unforeseen consequences of the study procedures including SAE's. The Research team will be available for extra support if need be during the study, and once the study is complete the patient will be under the care of the investigator as per normal practice. All SAE's will be dealt with under ICH−GCP guidelines. Patients will also be provided with a contact phone number.

20. What are the arrangements for the supervision of the conduct of the research at this site? *Please give the name and contact details of any supervisor not already listed in the application.*

Student researchers will not be working at this site

21. What external funding will be provided for the research at this site?

- ○ Funded by commercial sponsor
- ○ Other funding
- ◉ No external funding

How will the costs of the research be covered?
The Trust will absorb the research costs

23. Authorisations required prior to R&D approval

The local research team are responsible for contacting the local NHS R&D office about the research project. Where the research project is proposed to be coordinated centrally and therefore there is no local research team, it is the responsibility of the central research team to instigate this contact with local R&D.

NHS R&D offices can offer advice and support on the set-up of a research project at their organisation, including information on local arrangements for support services relevant to the project. These support services may include clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers depending on the nature of the research.

Obtaining the necessary support service authorisations is not a pre-requisite to submission of an application for NHS research permission, but all appropriate authorisations must be in place before NHS research permission will be granted. Processes for obtaining authorisations will be subject to local arrangements, but the minimum expectation is that the local R&D office has been contacted to notify it of the proposed research project and to discuss the project's needs **prior** to submission of the application for NHS research permission via IRAS.

Failure to engage with local NHS R&D offices **prior** to submission may lead to unnecessary delays in the process of this application for NHS research permissions.

Declaration:

☐ **I confirm that the relevant NHS organisation R&D office has been contacted to discuss the needs of the project and local arrangements for support services. I understand that failure to engage with the local NHS R&D office before submission of this application may result in unnecessary delays in obtaining NHS research permission for this project.**

Please give the name and contact details for the NHS R&D office staff member you have discussed this application with:

Please note that for some sites the NHS R&D office contact may not be physically based at the site. For contact details refer to the guidance for this question.

	Title Forename/Initials Surname
Work E-mail	
Work Telephone	

Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.

7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.

8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.

9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.

10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.

11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.

12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

Signature of Principal Investigator or Local Collaborator: .....

Print Name:

Date: