Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru

NISCHR

Gwasanaeth Moeseg Ymchwil | RES | Research Ethics Service

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25 September 2012

Miss Bronwen Davies
Trainee Clinical Psychologist
Cardiff and Vale Health Board
South Wales Doctoral Training Course in Clinical Psychology
11th Floor, Tower Building, Cardiff University
Park Place, Cardiff
CF10 3AT

Dear Miss Davies

Study title: **An Examination of Emotional Recognition, Regulation, Alexithymia and Challenging Behaviour in Service Users with a Learning Disability (LD)**

REC reference: **12/WA/0280**

The Research Ethics Committee reviewed the above application at the meeting held on 19 September 2012. Thank you for attending to discuss the study together with your supervisor.

Ethical opinion

1. The Committee questioned whether there was a psychology student involved as there was no mention of any student under other key investigators/collaborators.

   It was confirmed that there was an undergraduate based in Gwent who may be able to help with obtaining consent. The Committee advised you that the contact details for this person should be provided in writing in due course.

2. The Committee questioned whether lone worker policy procedures were in place.

   It was confirmed that it was a requirement for all trainees to familiarise themselves with local lone worker policy arrangements as well as the appropriate Health Board policies.

3. The Committee were unclear whether the questionnaires were validated.

   It was confirmed that the questionnaires would be validated as part of the process with validation being part of the project.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Printed name/signature to be obtained on the Consent form.
2. Name of student collaborator to be provided in writing.
3. Confirmation of lone worker policies to be followed.
4. Confirmation of insurance details which should also be included in the information sheet.

If you have any queries about the content of this letter, please contact Penny Beresford, Coordinator, in the first instance.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Investigator CV		22 August 2012
Other: CV - Neil Frude		22 August 2012
Other: CV - Dr R Jenkins		23 August 2012
Other: Appendix A - initial consent for contact	2	20 August 2012
Other: Appendix F - Non validated questionnaire	7	06 July 2012
Other: Appendix G - Validated questionnaire		
Other: Appendix H - Validated questionnaire		
Participant Consent Form: Appendix C - Service users consent form	3	06 July 2012
Participant Consent Form: Appendix E - staff/carer consent form	3.2	06 July 2012
Participant Information Sheet: Appendix B - service user information sheet	3	06 July 2012
Participant Information Sheet: Appendix D - Staff/Carer information sheet	3.2	06 July 2012
Protocol	6	22 August 2012
Questionnaire: Appendix I - Validated questionnaire		
Questionnaire: Appendix J - Validated questionnaire		
REC application		30 August 2012
Referees or other scientific critique report		17 August 2012

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

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

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views

known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/WA/0280	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Roy L. Evans
Chairman

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers" [SL-AR2]

Copy to: *Jonathon Bisson, Cardiff and Vale University Health Board*

South West Wales REC

Attendance at Committee meeting on 19 September 2012

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Ann Benton	Consultant Haematologist	No	
Dr John Francis Doran	Consultant Chemical Pathologist	Yes	
Roy L. Evans	Retired - Chairman	Yes	
Mrs Helen Goldring	Research Nurse	No	
Mr Martin Heaven	Senior Research Analyst	No	
Mrs Sharon Jones	Research Midwife & practicing midwife	Yes	
Dr Matthew Lawrence	Research Officer	Yes	
Professor Jenny Levin	Retired	Yes	
Mr Kerryn Lutchman-Singh	Clinical Lead for Gynaecological Oncology	Yes	
Dr Sue Morgan	Consultant in Palliative Medicine	Yes	
Mr Steve Newbury	Pharmacist	No	
Mr Amol Pandit	Urologist	No	
Dr Ceri Phelps	Psychology Lecturer	No	
Dr Billie Shepperdson	Lay Member	Yes	
Dr Alan Watkins	Senior Lecturer in Statistics	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Penny Beresford	Co-ordinator