

Bwrdd Iechyd Prifysgol Caerdydd a'r Fro Cardiff and Vale University Health Board

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From:

Professor JI Bisson

R&D Director

R&D Office, 2nd Floor TB2 University Hospital of Wales

Cardiff CF14 4XW

19 November 2012

Miss Bronwen Davies



Dear Miss Davies

Cardiff and Vale UHB Ref: 12/MEH/5453: An Examination Of Emotional Recognition, Regulation And Alexithymia In Service Users With A Learning Disability (LD) Who Present With Challenging Behaviours (CB)

NISCHR PCU Ref: 96305

The above project was forwarded to Cardiff and Vale University Health Board R&D Office by the NISCHR Permissions Coordinating Unit. A Governance Review has now been completed on the project.

Documents approved for use in this study are:

Document	Version	Date
Favourable Opinion Letter from South West Wales for additional documentation		15 October 2012
Favourable Opinion Letter from South West Wales REC		1 October 2012
NHS R&D Form	3.4	Received 13 July 2012
Copy of SSI for Information	3.4	Received 10 October 2012
Protocol	6.0	22 August 2012
Service User Information Sheet	4.0	21 September 2012
Service User Information Sheet: Amy	5.0	15 October 2012
Staff/Carer Participant Information Sheet	4.0	28 September 2012

Page 1 of 2

Version 1.0. 09.06.10



Emotional Recognition Questionnaire	7.0	6 July 2012
Challenging Behaviour Checklist	-	
Observer Alexithymia Scale	-	
Staff/Carer Consent Form	4.0	21 September 2012
Service User Consent Form	4.0	28 September 2012
Service User Consent Form: Amy	4.0	28 September 2012
Response to CARRS correspondence		19 November 2012

I am pleased to inform you that the UHB has no objection to your proposal. Please accept this letter as confirmation of sponsorship by Cardiff and Vale University Local Health Board under the Research Governance Framework for Health and Social Care, and permission for the project to begin within this UHB.

May I take this opportunity to wish you success with the project and remind you that as Principal Investigator you are required to:

- Inform the R&D Office if this project has not opened within 12 months of the date of this letter. Failure to do so may invalidate R&D approval.
- Inform NISCHR PCU and the UHB R&D Office if any external or additional funding is awarded for this project in the future
- Contact the R&D Office for Sponsor representative's signature prior to submission of any substantial amendments to NISCHR PCU
- Ensure that all study amendments are favourably reviewed by the R&D Office prior to implementation
- · Ensure NISCHR PCU is notified of the study's closure
- Ensure that the study is conducted in accordance with all relevant policies, procedures and legislation
- Provide information on the project to the UHB R&D Office as requested from time to time, to include participant recruitment figures

Yours sincerely,

Professor Jonathan I Bisson R&D Director

Kad Director

CC R&D Lead Prof Nick Craddock
Dr Rosemary Jenkins. Academic Supervisor
Professor Neil Frude – Academic Supervisor