

Research & Development Research Risk Review Committee

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Ms Bronwen Davies
Trainee Clinical Psychologist
Cardiff and Vale Health Board
11th Floor
Tower Building
Cardiff University
Park Place
Cardiff
CF10 3AT

Ref: RRR.314.12.October 17th October 2012

Dear Ms Davies,

,

Emotional Literacy and Challenging Behaviour

Researcher: Ms Brownwen Davies

Req: RD/1092/12

The Risk Review Committee at their meeting on the 17th October 2012 felt that overall the project did not appear to pose any risk to the Health Board and therefore your project has been approved. The Chairman also noted that the project already has received favourable MREC/Local REC opinion.

If you require an Honorary Contract please contact the Health Board R&D Manager at the above address who will make arrangements to issue you with an honorary contract.

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

- a) Inform the Health Board R&D Office if any external funding is awarded for this study in the future
- b) Inform the R&D Office of any substantial amendments/changes to your protocol
- c) Maintain a record of the number of research participants recruited into the study

- d) Complete any questionnaires sent to you by the Health Board's R&D Office regarding this project
- e) Comply fully with the Research Governance Framework, and co-operate with any audit inspection of the project files
- f) Undertake the project in accordance with ICH-GCP and the Trust's Guidelines on Good Research Practice
- g) Adhere to the protocol as approved by the Local Research Ethics Committee
- h) Ensure that your research complies with the Data Protection Act 1998
- i) Report any serious adverse events to the R&D Office
- j) Please not that approval lapses if the project does not commence within 12 months of approval

Please note that all publications arising out of your research must include the following notice: "This work was undertaken by Aneurin Bevan Health Board who received funding from the Welsh Ministers; the views expressed in the publication are those of the author/s and not necessarily those of the Welsh Minister."

"If your study is adopted onto the NISCHR Clinical Research Portfolio (CRP), it will be a condition of this NHS research permission, that you will be required to regularly upload recruitment data onto the portfolio database.

To apply for adoption onto the NISCHR CRP, please go to http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31979

Once adopted, NISCHR CRP studies may be eligible for additional support through the NISCHR Clinical Research Centre. Further information can be found at http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571 and/or from your NHS R&D office colleagues. To upload recruitment data, please follow this link: http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_recruitment Uploading recruitment data will enable NISCHR to monitor research activity within NHS organizations, leading to NHS R&D allocations which are activity driven. Uploading of recruitment data will be monitored by your colleagues in the R&D office. If you need any support in uploading this data, please contact the ABHB R&D office.

Yours sincerely

Professor Alex Anstey

Chairman

Research Risk Review Committee