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Bwrdd Iechyd Prifysgol
Abertawe Bro Morgannwg
University Health Board

R&D

RESEARCH & DEVELOPMENT
Abertawe Bro Morgannwg University Health Board

Dyddiad/Date: 5 November 2012

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

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Dear Ms Davies

Re: An Examination of Emotional Recognition, Regulation, Alexithymia and Challenging Behaviour in Service Users with a Learning Disability
IRAS Ref: 96305
Sponsor: Cardiff and Vale University Health Board

Thank you for submitting your proposal to us for approval for the above named study to be carried out within our Health Board. The attached listed documents were reviewed.

Health Board Governance checks have been completed and passed. Please accept this letter as confirmation of local Health Board approval.

As part of Research Governance, you are required to:

1. Adhere to the protocol approved and inform the R&D office of any changes (including changes to the end date of the project) and ensure any changes are reported to the Research Ethics Committee(s), for review/approval.
2. Inform the R&D office of any local adverse/serious events that may occur, whilst also reporting these according to the sponsor's protocol and procedures.
3. Complete any interim and final reports requested by the R&D office. If sponsored by this Health Board, you will be asked by the Joint Scientific Review Committee to complete a 6 monthly progress report along with your final report at study completion.
4. Ensure that your research complies with regulatory requirements and legislation relating to: Clinical Trials, Data Protection Act 1998, Health & Safety, Caldicott Guidelines, the use of Human Tissue for research purposes, Mental Capacity and ICH Good Clinical Practice (GCP).
5. Ensure that all training courses requested by the Sponsor are completed by all relevant members of the research team before any research activity is carried out. All research staff undertaking clinical trials of an investigational medicinal product (CTIMPs) must be GCP trained, and should continue to update their GCP training every 2 years. Copies of GCP certificates should be filed in the Trial Site File, with a copy forwarded to the R&D Department.
6. Ensure the research is undertaken in compliance with all Health Board R&D Standard Operating Procedures (SOPs). The latest versions of all SOPs can be obtained by contacting the R&D Department.

Bwrdd Iechyd ABM yw enw gweithredu Bwrdd Iechyd Lleol Prifysgol Abertawe Bro Morgannwg
ABM University Health Board is the operational name of Abertawe Bro Morgannwg University Local Health Board
Pencadlys ABM / ABM Headquarters, 1 Talbot Gateway, Port Talbot, SA12 7BR, Ffôn / Tel: (01639) 683344

www.abm.wales.nhs.uk

NISCHR Clinical Research Portfolio Studies

If your study has been adopted onto the NISCHR Clinical Research Portfolio (CRP), it will be a condition of our permission that the Chief Investigator uploads local recruitment data onto the portfolio database.

For more information on the process of uploading recruitment data please look at the following link:
<http://www.crnc.nhr.ac.uk/aboutus/processes/portfolio/precruitment>

Uploading of recruitment data will enable NISCHR to monitor research activity within Health Boards, resulting in NHS R&D allocations to be driven by activity.

To apply for your study to be adopted onto the NISCHR CRP, details can be found at:
<http://www.wales.nhs.uk>

For more information and advice on the NISCHR Clinical Research Portfolio please email:
portfolio@wales.nhs.uk

Should you wish to extend your study to other NHS organisations you must obtain the approval of all NHS bodies concerned. If the study is sponsored by ABMU Health Board you must notify the R&D Office of your intention to open the study in other sites.

Indemnity Arrangements

The Sponsor indemnifies and holds harmless ABM University Health Board, its employees and agents for any harm caused by negligence on behalf of the Sponsor, including any harm caused to participants by the administration of the investigational product. However, please note that the Sponsor will not indemnify ABM University Health Board for any harm caused by negligence on behalf of the research team or other individual or agent.

Researchers employed by ABM University Health Board, including those holding Honorary Contract status are indemnified against actions for negligent harm via standard arrangements with Welsh Risk Pool (WRP). Provision for 'no-fault' compensation is limited under the scheme and is only available on an ex gratia, discretionary basis where the Sponsor is a NHS Organisation.

ABM University Health Board reserves the right to suspend approval of any research study where deviation from appropriate RG & GCP standards is uncovered.

May I take this opportunity to wish you well in undertaking the research. We will write to you in the future to request updates on the progress of the research and look forward to receiving outcomes of the study.

Yours sincerely,



Professor SC Bain
Assistant Medical Director (R&D)
ABMU Health Board

Enc: List of SSI and R&D documents submitted

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SSI application documents received

Re: An Examination of Emotional Recognition, Regulation, Alexithymia and Challenging Behaviour in Service Users with a Learning Disability

Ref: 96305

Document:	Subtitle:	Version:	Date:
Other (please specify)	Dr R Parry CV recvd 23.10.12		24/10/2012
Site-Specific Information form checklist	ABM UHB checklist		28/09/2012
Site-Specific Information Form (signed/authorised pdf or hard copy)	SSI Application Form - Miss Bronwen Davies - Signed and dated	21 Aug 2012	24/09/2012

Application documents received

RE: An Examination of Emotional Recognition, Regulation, Alexithymia and Challenging Behaviour in Service Users with a Learning Disability

Ref: 96305

Document:	Subtitle:	Version:	Date:
Research participant information sheet (PIS)	Service User info sheet V5 - UPDATED with the CORRECT page references	V5 dated 15 Oct 2012	24/10/2012
Research participant information sheet (PIS)	PIS for service user - page 3 & page 5 state the incorrect Version number & date	V4 dated 21 Sep 2012	22/10/2012
Research participant information sheet (PIS)	PIS for service users - UPDATED to V5 - page 2 is included in full	V5 dated 15 Oct 2012	22/10/2012
REC favourable opinion letter and all correspondence	Research team's response to REC regarding compliance with conditions	dated 28 Sep 2012	22/10/2012
REC favourable opinion letter and all correspondence	REC Favourable Opinion letter with conditions	dated 25 Sep 2012	22/10/2012
REC favourable opinion letter and all correspondence	Confirmation from REC that compliance with conditions has been met	dated 1 Oct 2012	22/10/2012
REC favourable opinion letter and all correspondence	REC acknowledgement of amendment - amendment 1 (minor)	dated 15 Oct 2012	22/10/2012
Research participant information sheet (PIS)	PIS - Staff/Carer V4	V4 dated 28 Sep 2012	15/10/2012
Research participant information sheet (PIS)	PIS - Service User V5	V5 dated 15 Oct 2012	15/10/2012
REC favourable opinion letter and all correspondence	REC acknowledgement of a minor amendment - V4 of the ICF and V4&5 of the PIS	dated 15 Oct 2012	15/10/2012
Research participant consent form	ICF - Staff/Carer V4	V4 dated 21 Sep 2012	15/10/2012
Research participant consent form	ICF - Service User V4	V4 dated 28 Sep 2012	15/10/2012
Research participant consent form	ICF - V4 current version	V4 dated 28 Sep 2012	01/10/2012
Research participant	Staff/carer ICF V4 - current	V4 dated	01/10/2012

Application documents received

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Document:	Subtitle:	Version:	Date:
consent form	version	21 Sep 2012	
Research participant information sheet (PIS)	Staff/carer PIS - V4 current version	V4 dated 28 Sep 2012	01/10/2012
Research participant information sheet (PIS)	PIS V4 - current version	V4 dated 21 Sep 2012	01/10/2012
Summary CV for Academic Supervisor (signed/ dated)	Signed & dated CV for academic supervisor - Professor Neil Frude	dated 1 Oct 2012	01/10/2012
Summary CV for Academic Supervisor (signed/ dated)	Rosemary Jenkins - academic supervisor - signed and dated	dated 28 Sep 2012	28/09/2012
REC favourable opinion letter and all correspondence	REC Favourable Opinion letter with Conditions	dated 25 Sep 2012	28/09/2012
Summary CV for Chief Investigator (CI)(signed and dated)	CV for CI Bronwen Davies - signed copy	dated 22 Aug 2012	28/09/2012
Research participant information sheet (PIS) - local version	CV UHB - Staff/ Carer Participant Information Sheet	V3.2, 6 Jul 2012	24/09/2012
Research participant consent form - local version	CV UHB - Staff/ Carer Consent Form	V4.0, 21 Sep 2012	24/09/2012
Research participant consent form - local version	CV UHB - Service User Consent Form	V3.0, 6 Jul 2012	24/09/2012
Referee's or other scientific critique report	CV UHB - Internal Review Letter	17 Aug 2012	24/09/2012
Non-validated questionnaire	CV UHB - Emotional Recognition Questionnaire	V7.0, 6 Jul 2012	24/09/2012
Non-validated questionnaire	CV UHB - The Way I feel - Questionnaire		24/09/2012
Non-validated questionnaire	CV UHB - Emotion Regulation Questionnaire (based on CERQ)	V2.0, 20 Jul 2012	24/09/2012
Letters of invitation to participant - local versions	CV UHB - Service User Information Sheet	V4.0, 21 Sep 2012	24/09/2012
R&D Application	R&D Application Form -		24/09/2012

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Document:	Subtitle:	Version:	Date:
checklist	Checklist		
Other (please specify)	CV UHB - List of Clients	V2.0, 20 Jul 2012	24/09/2012
Other (please specify)	Challenging Behaviour Checklist		24/09/2012
Other (please specify)	Observer Alexithymia Scale		24/09/2012
R&D Form (Parts A-D) (signed/authorised pdf or hard copy)	R&D Application Form - Miss Bronwen Davies - Signed and dated	21 Aug 2012	24/09/2012
Research protocol	Research Protocol - Research Protocol	V6.0, 22 Aug 2012	24/09/2012
Summary CV for Chief Investigator (CI)(signed and dated)	CV for Miss Bronwen E. L. Davies - Not signed but dated	22 Aug 2012	24/09/2012
Summary CV for Academic Supervisor (signed/ dated)	CV for Prof. Neil Frude - Not signed and/or dated		24/09/2012
Summary CV for Academic Supervisor (signed/ dated)	CV for Dr Rosemary Jenkins - Not signed and/or dated		24/09/2012