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Email: hra.approval@nhs.net
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03 October 2019

Dear Miss Barningham

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**A questionnaire study examining the link between experiences of betrayal and Borderline Personality Disorder (BPD)**
IRAS project ID:	**266186**
Protocol number:	**00000**
REC reference:	**19/WA/0286**
Sponsor	**Clinical Trials and Research Governance (CTRG)**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **266186**. Please quote this on all correspondence.

Yours sincerely,

Penny Beresford

Approvals Specialist

Email: HCRW.approvals@wales.nhs.uk

Copy to: *CTRG*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Recruitment poster]	V1	06 August 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance letter]	1	26 July 2019
GP/consultant information sheets or letters [Recruitment email]	V1	05 June 2019
IRAS Application Form [IRAS_Form_16082019]		16 August 2019
IRAS Application Form XML file [IRAS_Form_16082019]		16 August 2019
IRAS Checklist XML [Checklist_02102019]		02 October 2019
Letter from funder [Funding arrangements]	V1	10 June 2019
Letter from sponsor [Sponsorship letter]		09 August 2019
Non-validated questionnaire [Betrayal Screening Measure]		
Non-validated questionnaire [Betrayal Screening Measure 2]		
Non-validated questionnaire [Perception of Betrayal Scale (POBS)]		
Non-validated questionnaire [Perception of Betrayal of Others Scale (POBS)]		
Non-validated questionnaire [Demographic information]	1	29 June 2019
Organisation Information Document [Organisation Information Document]	V1	07 August 2019
Other [Debrief sheet]	V2	30 September 2019
Other [Debrief sheet [tracked]]	V2	30 September 2019
Participant information sheet (PIS) [Participant Information Sheet (PIS) [tracked]]	V2	30 September 2019
Participant information sheet (PIS) [Participant Information Sheet (PIS)]	V2	30 September 2019
Research protocol or project proposal [Protocol]	V1	07 August 2019
Response to Request for Further Information		
Schedule of Events or SoECAT	1.0	12 September 2019
Summary CV for Chief Investigator (CI) [CV_CI]	v1	07 August 2019
Summary CV for student [CV CI]	1	07 August 2019
Summary CV for supervisor (student research) [Academic Supervisor PS]	1	
Summary CV for supervisor (student research) [Field Supervisor CV JS]	1	03 June 2019
Validated questionnaire [Splitting Index]	1	07 August 2019
Validated questionnaire [GAD-7]	1	07 August 2019
Validated questionnaire [IES-R]	1	07 August 2019
Validated questionnaire [OCI]	1	07 August 2019
Validated questionnaire [Work and Social Adjustment Scale]	1	07 August 2019
Validated questionnaire [PHQ-9]	1	07 August 2019
Validated questionnaire [scid-5-spq]	1	07 August 2019

IRAS project ID	266186

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
One site type identified.	PICactivities should not commence until a PIC Agreement is in place. HRA and HCRW recommend use of the standard Participating NHS Organisation to PICagreement available: https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx	HRA and HCRW recommend use of the standard Participating NHS Organisation to PIC agreement, available: https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx There is no need to submit this to HRA and HCRW for review.	No application for external funding has been made.	No LC /PI required at site.	Use of identifiable patient records held by an NHS organisation to identify potential participants without their prior consent should be undertaken by a member of the direct care team for the patient, so it would not normally be acceptable for this to be done by staff not employed by that organisation. The activities at the participating NHS organisation will be undertaken by local staff therefore it is expected that adequate contractual relationship with the host organisation are already

					in place. Where contractual arrangements are not already in place, network/external staff (or similar) undertaking research activities would be expected to obtain Honorary Research Contracts on the basis of a Research Passport (if university employed) or a Letter of Access on the basis of an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). Enhanced DBS checks (incl. appropriate barred list checks) and occupational health clearance would be appropriate.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.