Miss Laura Parkin
Trainee Clinical Psychologist
Taunton and Somerset NHS Trust
Doctorate in Clinical Psychology
Building 44
University of Southampton
SO171BJN/A

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

09 June 2021

Dear Miss Parkin

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

Study title:	**What outcomes do older people consider they gain from psychological therapy delivered within local secondary care mental health services?**
IRAS project ID:	**297238**
REC reference:	**21/WM/0126**
Sponsor	**University of Southampton**

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 **297238**. Please quote this on all correspondence.

Yours sincerely,
Rekha Keshvara

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Dr Alison Knight*

List of Documents

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

Document	*Version*	*Date*
GP/consultant information sheets or letters [GP Letter]	1	24 May 2021
Interview schedules or topic guides for participants [Topic Guide]	1	19 April 2021
IRAS Application Form [IRAS_Form_28042021]		28 April 2021
IRAS Checklist XML [Checklist_01062021]		01 June 2021
Letter from sponsor [Sponsor insurance Certificate]	1	24 May 2021
Letters of invitation to participant [Participant Invite Letter - Dorset]	1	24 May 2021
Miscellaneous [response to FOWC]		09 June 2021
Other [Debrief Form]	2	24 May 2021
Other [Participant Invite Letter - Southern Health]	1	24 May 2021
Other [Acadmeic Supervisor 2 CV]	1	29 April 2021
Participant consent form [Consent Form]	2	24 May 2021
Participant information sheet (PIS) [PIS]	2	24 May 2021
Research protocol or project proposal [Qualitative Protocol]	3	24 May 2021
Response to Request for Further Information [response to REC and Assessment]		01 June 2021
Summary CV for Chief Investigator (CI) [CV]		
Summary CV for supervisor (student research) [Supervisor CV]	1	29 April 2021

IRAS project ID	297238

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
The study is limited to NHS organisations acting as PICs.	PIC activities should not commence until a PIC Agreement is in place. HRA and HCRW recommend use of the standard Participating NHS Organisation to PIC agreement available here	PIC activities should not commence until a PIC Agreement is in place. HRA and HCRW recommend use of the standard Participating NHS Organisation to PIC agreement available here.	No application for external funding has been made.	The study is limited to NHS organisations acting as PICs and therefore, a Local Collaborator or Principal Investigator is not expected for the study.	The study is limited to NHS organisations acting as PICs and HR good practice arrangements are not expected for the trial.

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.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.