Health Research Authority

London - South East Research Ethics Committee
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0207 104 8085

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

17 June 2021

Professor Anne Slowther
Professor of Clinical Ethics
University of Warwick
WarwickMedical School
Gibbet Hill Campus
Coventry
CV4 7AL

Dear Professor Slowther

Study title:	**Evaluating the integration of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) into primary care and its impact on patient treatment and care.**
REC reference:	**21/LO/0455**
Protocol number:	**SOC18/20-21**
IRAS project ID:	**299464**

The Research Ethics Committee (REC) reviewed the above application at the meeting held on 09 June 2021. Thank you for attending to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Mental Capacity Act 2005 (England and Wales)

I confirm that the Committee has approved this research project for the purposes of the Mental Capacity Act 2005 (England and Wales). The Committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of

this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Mental Capacity Act (Northern Ireland) 2016

The Committee approved this research project for the purposes of the Mental Capacity Act (Northern Ireland) 2016. The Committee is satisfied that the requirements of Part 8 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Relevance of the research to the impairing condition

The Committee agreed the research was connected with an impairing condition affecting persons lacking capacity or with the treatment of the condition.

Justification for including adults lacking capacity to meet the research objectives

The Committee agreed the research could not be carried out as effectively if it was confined to participants able to give consent.

Arrangements for appointing consultees

The Committee considered the arrangements set out in the application for appointing consultees under Section 32 of the Mental Capacity Act 2005 (England and Wales) and the equivalent Section 135 of the Mental Capacity Act (Northern Ireland) 2016) to advise on whether participants lacking capacity should take part and on what their wishes and feelings would have likely to have been if they had capacity.

After discussion the Committee agreed that reasonable arrangements were in place for appointing consultees.

Balance between benefit and risk, burden and intrusion

The Committee agreed that the research has the potential to benefit participants lacking capacity without imposing a disproportionate burden on them.

Additional safeguards

The Committee was satisfied that reasonable arrangements would be in place to comply with the additional safeguards set out in Section 33 of the Mental Capacity Act 2005 (England and Wales) and the equivalent Section 137 of the Mental Capacity Act (Northern Ireland) 2016).

Information for consultees

The Committee was satisfied that the information to be provided to consultees about the proposed research was adequate to enable consultees to give informed advice about the participation of persons lacking capacity.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines

the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland)being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Advert for focus group participants WP2]	1.0	19 May 2021
Covering letter on headed paper [Covering Letter]		19 May 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University insurance confirmation]		24 June 2020
Interview schedules or topic guides for participants [Topic Guide WP1 Patient First Interview]	1.0	21 May 2021
Interview schedules or topic guides for participants [Topic Guide WP1 Relative First Interview]	1.0	21 May 2021
Interview schedules or topic guides for participants [Topic Guide WP1 Patient Second Interview]	1.0	21 May 2021
Interview schedules or topic guides for participants [Topic Guide WP1 Relative SecondInterview]	1.0	21 May 2021
Interview schedules or topic guides for participants [Topic Guide WP1 GPs]	1.0	21 May 2021
Interview schedules or topic guides for participants [Topic Guide WP1 Care Home staff]	1.0	21 May 2021
Interview schedules or topic guides for participants [Topic Guide WP2 faith leaders]	1.0	21 May 2021
Interview schedules or topic guides for participants [Topic Guide WP2 HCPs]	1.0	21 May 2021
Interview schedules or topic guides for participants [Topic Guide WP2 Public]	1.0	21 May 2021
IRAS Application Form [IRAS_Form_24052021]		24 May 2021
Letter from funder [NIHR131316 Agreement to fund]		19 February 2021
Letter from sponsor [Sponsorship approval letter]		12 May 2021
Letters of invitation to participant [WP1 Invitation Letter Patient first interview]	1.0	21 May 2021
Letters of invitation to participant [WP1 Invitation Letter Patient second interview]	1.0	21 May 2021
Letters of invitation to participant [WP1 Invitation Letter Relative second interview]	1.0	21 May 2021
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Letters of invitation to participant [WP1 Invitation Letter Relative where patient lacks capacity first interview]	1.0	21 May 2021
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Letters of invitation to participant [WP1 Invitation Letter Relative second interview where patient has died]	1.0	21 May 2021
Letters of invitation to participant [WP2 Email Text for HCP focus group]	1.0	19 May 2021
Letters of invitation to participant [WP1 Email text from GPs to practice staff re research]	1.0	19 May 2021
Letters of invitation to participant [WP2 Email Text for faith leader interviews]	1.0	19 May 2021
Letters of invitation to participant [WP1 Email text from GPs to care home staff re research]	1.0	21 May 2021
Letters of invitation to participant [WP2 Email Text for public focus group]	1.0	19 May 2021

Letters of invitation to participant [WP3 information and opt out option patients]	1.0	14 May 2021
Letters of invitation to participant [WP3 information and opt out option relatives where patient lacks capacity]	1.0	21 May 2021
Other [ReSPECT in Primar Care easy read PIS WP3]	1.0	21 May 2021
Other [ReSPECT in Primar Care easy read participant invitation letter]	1.0	21 May 2021
Other [ReSPECT in Primar Care easy read patient interview information sheet]	1.0	21 May 2021
Participant consent form [WP1 Consent Form Patients]	1.0	18 May 2021
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Participant consent form [WP1 Consent Form Relative first interview]	1.0	18 May 2021
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Participant consent form [WP2 Consent Form]	1.0	19 May 2021
Participant information sheet (PIS) [WP1 Information Sheet Patient First Interview]	1.0	21 May 2021
Participant information sheet (PIS) [WP1 Information Sheet Patient Second Interview]	1.0	21 May 2021
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Participant information sheet (PIS) [WP1 GP Care Homes Information Sheet]	1.0	21 May 2021
Participant information sheet (PIS) [WP1 GP Care Home Interviews Information Sheet]	1.0	21 May 2021
Participant information sheet (PIS) [WP2 Members of Public Focus Groups Information Sheet]	1.0	21 May 2021
Participant information sheet (PIS) [WP2Healthcare professionals Focus Groups Information Sheet]	1.0	21 May 2021
Participant information sheet (PIS) [WP2 Faith Leaders Interviews Information Sheet]	1.0	21 May 2021
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Summary CV for Chief Investigator (CI) [Professor Anne Slowther CV]		21 May 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language [ReSPECT in Primary Care Overall study flow chart]	1.0	21 May 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language [ReSPECT in Primary Care consent flow chart WP1]	1.0	21 May 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language [ReSPECT in Primary Care Recruitment flow chart WP1&3]	1.0	21 May 2021

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 299464 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

pp.
Dr Anthony Fox
Chair

E-mail: londonsoutheast.rec@hra.nhs.uk

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments
Copy to:	Mrs Carole Harris Confidentiality Advice Team approvals@hra.nhs.uk

London - South East Research Ethics Committee

Attendance at Committee meeting on 09 June 2021

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Joanne Apfel	Solicitor	Yes	
Dr Deborah Colson	Retired Research Manager	No	
Ms Stephanie Cooper	Retired Solicitor	Yes	
Dr Marie Fisk	Clinical Lecturer	Yes	
Dr Anthony Fox	Pharmaceutical Physician	Yes	Chair
Ms Janelle Hill	Former Banking Administrator	Yes	
Professor Atholl Johnston	Professor of Clinical Pharmacology	Yes	
Dr Morven Leese	Reader in Biostatistics	Yes	
Dr Karen Ma	Retired Consultant	Yes	
Professor Eleni Palazidou	Consultant Psychiatrist	Yes	
Mrs Carolyn Read	Senior Research Governance Officer	Yes	
Ms Brigid Tucker	Communications Consultant	No	
Dr Sharon Weldon	Nurse (Reader in Nursing Research and Education)	No	
Professor Zahur Zaman	Retired Clinical Pathologist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Dr Jane Moorhead	Observer
Miss Rebecca Morledge	Approvals Officer
Ms Kathryn Murray	Approvals Manager

Professor Anne Slowther
Professor of Clinical Ethics
University of Warwick
WarwickMedical School
Gibbet Hill Campus
Coventry
CV4 7AL

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

27 July 2021

Dear Professor Slowther

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

Study title:	**Evaluating the integration of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) into primary care and its impact on patient treatment and care.**
IRAS project ID:	**299464**
Protocol number:	**SOC18/20-21**
REC reference:	**21/LO/0455**
Sponsor	**University of Warwick**

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 **299464**. Please quote this on all correspondence.

Yours sincerely,

Kathryn Murray
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Mrs Carole Harris, University of Warwick*

List of Documents

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

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Advert for focus group participants WP2]	1.0	19 May 2021
Covering letter on headed paper [Covering Letter]		19 May 2021
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Organisation Information Document [Organisation Information Document Care Homes]		
Other [Email trail to explain re OID signatures]		
Other [Response to further clarifications]		07 July 2021
Other [ReSPECT in Primar Care easy read PIS WP3]	1.0	21 May 2021
Other [ReSPECT in Primar Care easy read participant invitation letter]	1.0	21 May 2021
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Referee's report or other scientific critique report		17 February 2021
Research protocol or project proposal [Protocol]	1.2	29 June 2021
Schedule of Events or SoECAT [SoECAT for care homes]		19 May 2021
Schedule of Events or SoECAT [SoECAT for GP practices]		19 May 2021
Summary CV for Chief Investigator (CI) [Professor Anne Slowther CV]		21 May 2021
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Summary, synopsis or diagram (flowchart) of protocol in non technical language [ReSPECT in Primary Care consent flow chart WP1]	1.0	21 May 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language [ReSPECT in Primary Care Recruitment flow chart WP1&3]	1.0	21 May 2021

IRAS project ID	299464

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
There are two site types participating in the study **Site Type 1** and **Site Type 2**. **Site Type 1 – GP Practices** **Site Type 2 – Care Homes**	**Site types 1 and 2** Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	**Site types 1 and 2** An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	**Site types 1 and 2** Study funding will be provided to sites as per the Organisational Information Document. It is noted this this study has requested inclusion on the CRN portfolio and incurs Excess Treatment Costs. The researchers have provided an AcoRD specialist authorised SoECAT for the purposes of the ETC processes in England.	**Site types 1 and 2** A Principal Investigator should be appointed at study sites	**Site types 1 and 2** It is expected that the principles of the HR Good Practice Pack are followed for researchers working in primary care. Researchers are advised to follow the processes of the local primary care management function. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to hold Letters of Access if focus groups/interviews were held in clinical areas. Letters of Access would not be expected if they were held in non-clinical/administrative buildings.

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 intend to apply for inclusion on the NIHR CRN Portfolio.

University of Warwick Evaluation of ReSPECT in Primary Care

Substantial and non-substantial amendment log

Study title	Evaluation of ReSPECT in Primary Care
Chief Investigator	Professor Anne-Marie Slowther
Sponsor internal reference	SOC.18/19-20
IRAS reference	299464

Amendment number	Date submitted	Where submitted			Classification		Purpose of amendment	Date approved (substantial amendments only)		
		REC	CAG	NHS/HSC	Substantial	Non substantial		REC	CAG	NHS/HSC
NSA1	10.08.2021	x		x		x	Minor changes to the protocol in response to comments from the funder.: Secondary outcomes of the survey analysis have been clarified, a typing error has been corrected to show that patient/carer interview participants will be paid the same voucher value as focus group participants, a sub			

							heading for the methods section in WP1 has been added, Inclusion and exclusion criteria for patients in WP1 and WP3 have been specified more clearly, the purpose of piloting questions for the surveys has been clarified.			
NSA02	06.10.2021	x		x		x	Information added to clarify that not all patients contacted will be invited for interview. Poster created for care homes to display to residents informing them about WP3 opt out			
NSA03	16.11.2021	x		x		x	Allow focus groups to take place face-to-face. Removal of patient's name for ease of printing at practice. Removal of requirement to provide personal information in opt out response form.			
NSA04	21.12.21	x		x		x	Change to focus group set-up methodology to allow more flexibilty in number and size of groups.			
NSA05							CHANGED to SA01			
NSA06							NOT SUBMITTED			
SA01	14.04.2022	x		x	x		Changes to the protocol: a) to allow for an increase in the number of practices recruited from '12' to 'a minimum of 12. b) addition of detail regarding the methodology for identification and initial approach of participants via the GP practices. c) change to protocol to allow practices to approach patients' carer/relative to participate or to inform them of their relative's inclusion in WP3 via telephone/email in the event that a postal address is not available. d) update to the participant sampling criteria used in selecting patients to be invited to WP1 interviews e) clarification of the methodology around the recruitment for and conduct of GP interviews f)	04.05.2022		12.-5.2022

							additional detail regarding the recording of data at GP practices. g) WP2 focus groups - change to the recruitment methodology for focus groups to allow recruitment through alternative GP run venues			
SA02	25.07.2022	x		x	x		Protocol changes to include additional work package focussing on experiences of people with a learning disability and their carer. Recruitment through learning disability advocacy Charity. Additional PIS, consent forms and topic guides	20.9.2022		18.10.2022
SA03	05.10.2022	x		x	x		Submission of GP survey questions for approval	28.10.2022		N/A
SA04	05.12.2022	x		x	x		Protocol change and introduction of new study documents to allow recruitment of patients for interview through care homes and recruitment of patients through GP practices to WP1 only (no WP3).	31.12.2022		16.01.2023
SA05	27.01.2023	x	x	x	x		Protocol change and introduction of new study documents for WP3 feasibility study in Care Homes	16.02.2023	03.03.2023	27.02.2023
NSA07	09.02.2023	x		x		x	Review of translated patient information documents to Gujarati			
NSA08	28.02.2023	x		x		x	Minor change to wording of participant information letter for follow up interviews of relative where patient has died since initial interview			
NSA09	05.04.2023	x				x	Notification of change to study end date from 30.06.2023 to 31.07 2023			