Professor Gavin Perkins
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Email: hra.approval@nhs.net

03 July 2017

Dear Professor Perkins

Letter of HRA Approval

Study title:	**Evaluation of the Recommended Summary Plan for Emergency Care and Treatment (RESPECT)**
IRAS project ID:	**204688**
Protocol number:	**REGO-2017-1916**
REC reference:	**17/WM/0134**
Sponsor	**University of Warwick**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The 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.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

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 Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **204688**. Please quote this on all correspondence.

Yours sincerely

Rekha Keshvara
Assessor

Email: hra.approval@nhs.net

Copy to: *Mrs Jane Prewett*
Mr Nick Denyer, Heart of England NHS Foundation Trust

Appendix A - List of Documents

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

Document	*Version*	*Date*
Covering letter on headed paper [ReSPECT Initial REC submission cover letter_21.03.2017]		21 March 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [clinical_trials_insurance_certificate-general]		22 July 2016
Interview schedules or topic guides for participants [ReSPECT_interview topic guide v1.0 17.02.17]	1.0	17 February 2017
IRAS Application Form [IRAS_Form_21032017]		21 March 2017
IRAS Checklist XML [Checklist_25052017]		25 May 2017
Letter from funder [03.05.16 v1.0_Perkins_final funding letter]	1.0	03 May 2016
Letter from sponsor [Letter confirming sponsorship - RESPECT 17.03.2017]		17 March 2017
Letter from statistician [ReSPECT_Letter from statistician v1.0 28.02.17]	1.0	28 February 2017
Other [HRA SoE WP4]	1	07 April 2017
Other [ReSPECT_Response letter to REC 25.05.17]		25 May 2017
Other [SOP 15_p1 Data management_v2.1_21.07.16]	2.1	21 July 2016
Other [SOP 15_p2 Electronic data security_v2.1_17.01.17]	2.1	17 January 2017
Other [SOP 15_p3 Data transfer_v1.0_25.06.15]	1.0	25 June 2015
Other [SOP 23_archiving_v1.4_15.08.13]	1.4	15 August 2013
Other [ReSPECT_HEFT-UoW CoSponsorship agreement_draft]		
Other [UoW Site Agreement draft template 2016_RESPECT]		
Other [ReSPECT Evaluation GP Invitation Letter v1.0 29.03.17 IRAS Project ID- 204688]	1.0	29 March 2017
Other [ReSPECT Evaluation GP Practices Invitation Letter v1.0 29.03.17 IRAS Project ID- 204688]	1.0	29 March 2017
Other [31.03.2017 ReSPECT Clinician presentation WP1 v1.0]	1.0	31 March 2017
Other [HRA SoE WP1-3]	1	07 April 2017
Other [HRA SoA WP4]	1	07 April 2017
Other [HRA SoA wp1-3]	1	07 April 2017
Participant consent form [ReSPECT_Relative ICF WP1 v1.0 17.02.17]	2.0	24 May 2017
Participant consent form [ReSPECT_GP ICF WP4 v1.0 17.02.17]	1.0	17 February 2017
Participant information sheet (PIS) [ReSPECT_ GP PIS WP4 v1.0 17.02.17]	1.0	17 February 2017
Participant information sheet (PIS) [ReSPECT_Clinician PIS WP1 v1.0 17.02.17]	2.0	24 May 2017
Participant information sheet (PIS) [ReSPECT_Patient PIS WP1 v1.0 17.02.17.docx]	2.0	17 May 2017
Participant information sheet (PIS) [ReSPECT_Relatives PIS WP1 v1.0 17.02.17]	2.0	17 May 2017
Participant information sheet (PIS) [ReSPECT_WP1 ward leaflet v1.0 17.02.17.docx]	2.0	17 May 2017
Participant information sheet (PIS) [ReSPECT_WP3 ward leaflet v1.0 17.02.17]	2.0	17 May 2017
Participant information sheet (PIS) [ReSPECT_WP1 Poster v1.0 17.02.17]	2.0	17 May 2017
Research protocol or project proposal [ReSPECT Evaluation	2.0	25 May 2017

Protocol v 1.0 21.03.2017]		
Summary CV for Chief Investigator (CI) [GD Perkins_Summary CV_February 2017]	1.0	20 February 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Summary of ReSPECT evaluation protocol_v1.0_16.03.17]	1.0	16 March 2017

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Mrs Jane Prewett
Email: sponsorship@warwick.ac.uk
Tel: 02476522746

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards?	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	University of Warwick Site Agreement will act as an agreement of an NHS organisation to participate.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the

Section	HRA Assessment Criteria	Compliant with Standards?	Comments
			activities expected of them for this research study.
4.3	Financial arrangements assessed	Yes	Financial arrangements for the study are included in the study Site Agreement.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Yes	CAG support is in place.

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There are two site-types.

1. The Secondary Care sites will carry out the study activities included in the protocol work package 1&3
2. The Primary Care sites will carry out the study activities included in the protocol work package 4.

Addition of any new sites to be submitted as an amendment.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If Chief Investigators, sponsors or Principal Investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the Chief Investigator, sponsor or Principal Investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability** to host this research.

- The sponsor should ensure that participating NHS organisations are provided with a copy of this letter and all relevant study documentation, and work jointly with NHS organisations to arrange capacity and capability whilst the HRA assessment is ongoing.
- Further detail on how capacity and capability will be confirmed by participating NHS organisations, following issue of the Letter of HRA Approval, is provided in the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor's position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Local Collaborator is expected to be in place at the participating NHS sites. Study specific training will be provided to sites. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken.
The applicant has indicated in the study supporting documents that the central research team members will have in place a Letter of Access for the participating NHS sites. The pre-engagement checks should include standard DBS check and Occupational Health Clearance.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England in study set-up.
• The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

UNIVERSITY OF WARWICK & UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST – RESPECT EVALUATION

Substantial and Non-substantial Amendment Log

Study Title:	ReSPECT Evaluation
Chief Investigator:	Professor Gavin Perkins
Sponsor Internal Reference:	REGO-2017-1916
Other reference numbers (e.g. EudraCT Number):	N/A

Substantial and Non-substantial Amendment Log

Amendment Number	Date Submitted	Where Submitted			Classification		Purpose of Amendment	Version/Date of Amended Documents		Date Approved (Substantial Amendments Only)		
		REC	CAG	NHS/HSC	Substantial	Non Substantial		New	Old	REC	CAG	NHS/HSC
01 – non-sub	21/09/2017	✓	✓	✓		✓	Addition of new site – Hampshire Hospitals NHS Foundation Trust.	N/A	N/A	2/10/17	3/11/17	21/9/17
02 – non-sub	23/10/2017	✓	✓	✓		✓	Addition of new site – Cambridge University Hospitals NHS Foundation Trust.	N/A	N/A	23/10/17	3/11/17	23/10/17
01 – sub	16/11/2017	✓	n/a	✓	✓		Protocol amendment – update to WP1a recruitment process. Addition of monitoring statement on WP1a patient/relative consent forms.	See IRAS amendment form	See IRAS amendment form	11/12/17	n/a	15/11/17
02 – sub	27/02/2018	✓		✓	✓		Protocol amendment – change to WP1a planning and timing of clinician observations. WP3 change in collection process for NHS Safety Thermometer data.	See IRAS amendment form	See IRAS amendment form	09/04/18		09/04/18
03 – non-sub	22/10/2018	✓		✓		✓	Change of PI – University Hospitals Coventry and Warwickshire	N/A	N/A			24/10/18

Substantial and Non-substantial Amendment Log

Amendment Number	Date Submitted	Where Submitted			Classification		Purpose of Amendment	Version/Date of Amended Documents		Date Approved (Substantial Amendments Only)		
		REC	CAG	NHS/HSC	Substantial	Non Substantial		New	Old	REC	CAG	NHS/HSC
03 - sub	16/10/2018	✓	n/a	✓	✓		Protocol amendment – update to WP1a to include expanded observations and informal conversations with staff. WP 2 – Change in data collection method to include addition of FOI request. WP 4 – Agreement to offer payment to GPs taking part in a focus group.	See IRAS amendment form	See IRAS amendment form	15/11/18	n/a	08/01/19
04 - sub	27/08/2019	✓	✓	✓	✓		Protocol amendment – update to WP1a to include repeated data collection. WP4 – inclusion of primary care practitioners (not just GPs) and option to conduct individual interviews and interviews via telephone/Skype. WP1b and WP3 – project extension, GDPR changes to participant information.	See IRAS amendment form	See IRAS amendment form	15/11/19	11/11/19	15/11/19
04a - Non-sub	18/10/19			✓		✓	Update of study sponsor to UHB Notification of project extension to WP1a and WP4. GDPR update to participant information for WP1a and WP4.	See email to HRA dated 18.10.19	See email to HRA dated 18.10.19	n/a	n/a	22/10/19