Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

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24 August 2021

Dear Prof Perkins

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

Study title:	**Pre-hospitAl RAndomised trial of MEDICation route in out-of-hospital cardiac arrest (PARAMEDIC3)**
IRAS project ID:	**298182**
Protocol number:	**SOC.20/20-21**
REC reference:	**21/SC/0178**
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 **298182**. Please quote this on all correspondence.

Yours sincerely,

Maeve Groot Bluemink
Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Mrs Carole Harris*

List of Documents

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

Document	*Version*	*Date*
Contract/Study Agreement template [PARAMEDIC-3_mNCA_Jan_2021_FINAL-Accessible_v1.0]	1.0	11 May 2021
Copies of advertisement materials for research participants [P3_A4Poster]	2.0	14 July 2021
Cover Letter [PARAMEDIC3_REC Cover Letter]		05 July 2021
Covering letter on headed paper [PARAMEDIC3_HRACoverLetter_v1.0_11May21]	1.0	11 May 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [clinical_trials_evidence_of_cover_2020-21]		28 July 2020
IRAS Application Form [IRAS_Form_11052021]		11 May 2021
IRAS Checklist XML [Checklist_05072021]		05 July 2021
Letter from funder [NIHR131105 Perkins - Agree to fund letter]		12 February 2021
Letter from sponsor [SOC 20 20 21 Sponsorship Approval Letter]	1.0	11 May 2021
Non-validated questionnaire [PARAMEDIC3_Questionnaire Cover Letter (Clean)]	2.0	23 June 2021
Non-validated questionnaire [PARAMEDIC3_Questionnaire Cover Letter (TC)]	2.0	23 June 2021
Organisation Information Document [Ambulance]		14 July 2021
Organisation Information Document [Hospital]		14 July 2021
Other [Letters of Support for Trial]		30 August 2020
Other [Trial_Funder_Peer_Review_Comments]		
Participant consent form [PARAMEDIC3_PatientConsentForm_v1.0_10May21]	1.0	10 May 2021
Participant consent form [PARAMEDIC3_Consultee Declaration Form (Clean)]	2.0	23 June 2021
Participant consent form [PARAMEDIC3_Consultee Declaration Form (TC)]	2.0	23 June 2021
Participant information sheet (PIS) [PARAMEDIC3_CoverLetterConsInHospital_v1.0_06May21]	1.0	06 May 2021
Participant information sheet (PIS) [PARAMEDIC3_CoverLetterPatPostDischarge_v1.0_06May21]	1.0	06 May 2021
Participant information sheet (PIS) [PARAMEDIC3_PIS_v2.1_14July21_clean]	2.1	14 July 2021
Participant information sheet (PIS) [PARAMEDIC3_PIS_v2.1_14July21_tracked]	2.1 (tc)	14 July 2021
Research protocol or project proposal [PARAMEDIC3_Protocol (Clean)]	2.0	23 June 2021
Research protocol or project proposal [PARAMEDIC3_Protocol]	2.0	23 June 2021
Schedule of Events or SoECAT [Paramedic3 validated SOECAT]	1.19	11 March 2020
Schedule of Events or SoECAT [P3_Hospitals_IRAS_schedule-events]	1 (assessed)	22 July 2021
Summary CV for Chief Investigator (CI) [GDP_CV_22Apr21]	1.0	22 April 2021
Validated questionnaire [P3_3MonthFollowUpQuestionnaire_v1.0_10May21]	1.0	10 May 2021
Validated questionnaire [P3_6MonthFollowUpQuestionnaire_v1.0_10May21]	1.0	10 May 2021

IRAS project ID	298182

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
Ambulance NHS Trusts (Site Type 1): Undertaking all research activities as described in the protocol and supporting documents.	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.	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The agreement is unmodified.	External funding has been secured from the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC). Funding will be provided to site as detailed in the Organisation Information Document.	Principal Investigators (PIs) are expected for this site type. The PIs have been identified at the NHS sites and are listed in IRAS Form [Part C].	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 obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These

					should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering interviews, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.
Hospital NHS Trusts (Site Type 2): Facilitate research paramedic access to trial participants/consultees to seek consent and support follow-up activities.	Organisations will not be required to formally confirm capacity and capability, and research procedures may begin 35 days after provision of the local information pack, provided the following conditions are met. You have contacted participating NHS organisations (see below for details) HRA and HCRW Approval has been issued. The NHS organisation has not provided a reason	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	There will be no financial provisions to the sites.	Local Collaborator (LCs) are expected for this site type.	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 obtain a Letter of Access based on standard DBS checks and occupational health clearance.

	as to why they cannot participate. The NHS organisation has not requested additional time to confirm. You may start the research prior to the above deadline if HRA and HCRW Approval has been issued and the site positively confirms that the research may proceed. You may now provide the local information pack for your study to your participating NHS organisations in England and/or Wales. If you have not already started to provide the local information packs to participating NHS organisations in Northern Ireland and/or Scotland please do so when you are ready. A current list of R&D				

	contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. The password to access the R&D contact list is Redhouse1.				

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. • Approval of the study includes approval for inclusion of all NHS Trusts as sites whether mentioned in IRAS Form [Part C] or not.