Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

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22 October 2020

Dear Professor Perkins

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

Study title:	**Paramedic Analgesia Comparing Ketamine and MorphiNe in trauma**
IRAS project ID:	**1003404**
Protocol number:	**SOC.12/19-20**
REC reference:	**20/WS/0126**
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 **1003404**. Please quote this on all correspondence.

Yours sincerely,

Kathryn Murray
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Mrs Jane Prewett, University of Warwick*

List of Documents

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

Document	*Version*	*Date*
Cover Letter [PACKMaN Initial Submission Cover Letter]	1.0	17 August 2020
EudraCT PDF [EudraCT Form]	1.0	17 August 2020
Financial Arrangements [Funding Letter]	1.0	07 August 2019
Investigator Brochure/SmPC [Ketamine SMPC]	1.0	26 June 2020
Investigator Brochure/SmPC [Morphine SMPC]	1.0	26 June 2020
Miscellaneous [Trial Data Flow Diagram]	1.0	27 July 2020
Miscellaneous [BPI-SF Questionnaire]	1.0	17 August 2020
Miscellaneous [3 Month CSRI Questionnaire]	1.0	17 August 2020
Miscellaneous [Sponsorship Approval Letter]	1.0	17 July 2020
Miscellaneous [6 Month CSRI Questionnaire]	1.0	17 August 2020
Miscellaneous [EQ-5D-5L]	1.0	17 August 2020
Miscellaneous [Electronic Prompts for Questionnaires]	1.0	17 August 2020
Miscellaneous [ED Information Leaflet]	1.0	17 August 2020
Miscellaneous [Questionnaire Cover Letter]	1.0	17 August 2020
Miscellaneous [GP Letter]	1.0	17 August 2020
Miscellaneous [CWoW ethical considerations form]	1.0	18 August 2020
Miscellaneous [Payment of compensation to participants]	1.0	18 August 2020
Miscellaneous [Response Cover Letter_Oct 2020]	N/A	07 October 2020
Miscellaneous [PACKMaN_OID_Yorkshire Ambulance NHS Trust]	N/A	07 October 2020
Miscellaneous [PACKMaN_OID_West Midlands Ambulance NHS Trust]	N/A	07 October 2020
Miscellaneous [Organisation Information Document – Hospitals]	N/A	07 October 2020
Miscellaneous [JRCALC Guidelines - morphine]	N/A	25 September 2020
Miscellaneous [JRCALC Guidelines - ketamine]	N/A	25 September 2020
Other [mNCA PACKMaN]	1.0	17 August 2020
Participant information and informed consent form [PACKMaN_PIL_Patients]	2.0	07 October 2020
Participant information and informed consent form [Brief Information Leaflet for Paramedics]	1.0	17 August 2020
Participant information and informed consent form [Cover Letter for Legal Representative]	1.0	17 August 2020
Participant information and informed consent form [Consent Form for Legal Representative]	1.0	17 August 2020
Participant information and informed consent form [Reminder Cover Letter Legal Representative]	1.0	17 August 2020
Participant information and informed consent form [Patient Consent Form]	1.0	17 August 2020
Participant information and informed consent form [Reminder Invite Letter]	1.0	17 August 2020
Participant information and informed consent form [Invite Letter]	1.0	17 August 2020
Participant information and informed consent form [Patient Information Leaflet]	1.0	17 August 2020
Proof of Insurance [Insurance]	1.0	24 June 2020
Proof of Insurance [Professional Indemnity Evidence of Cover 2020-21]	N/A	28 July 2020

Protocol [PACKMaN Protocol]	1.0	17 August 2020
Recruitment Arrangements [Recruitment and informed consent procedure]	1.0	18 August 2020
Schedule of Events or SoECAT [SoECAT]	1.0	27 July 2020
Suitability of the investigator/Investigator CV [Dr Smyth CV]	1.0	26 November 2018
Suitability of the investigator/Investigator CV [Prof Perkins CV]	1.0	11 February 2019

IRAS project ID	1003404

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 (Ambulance Trusts) and Site Type 2 (Hospital Trusts).	**Site type one (Ambulance Trusts)** 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 Type two (Hospital Trusts)** Organisations will not be required to formally confirm capacity and capability, and research procedures may begin 35 days after provision	**Site type one (Ambulance Trusts)** An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The agreement is unmodified. **Site Type two (Hospital Trusts)** An Organisation Information	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. The applicant confirmed that the research activities for both site types have been combined into one SoECAT, which	**Site type one (Ambulance Trusts)** A Principal Investigator should be appointed at study sites of this type **Site Type two (Hospital Trusts)** A Local Collaborator should be appointed at study sites of this type	**Site type one (Ambulance Trusts)** No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research/network staff (or similar) undertaking any of the research activities listed in the IRAS form (except for administration of questionnaires or surveys), 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

	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 issuedThe NHS organisation has not provided a reason as to why they cannot participateThe 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 should now provide the local information pack for your study to	Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	has been accepted as the submission was authorised by an AcoRD specialist upon submission.		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 questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate. **Site Type two (Hospital Trusts)** No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. 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

	your participating NHS organisations. 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.				checks and occupational health clearance.

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 intend to apply for inclusion on the NIHR CRN Portfolio. The applicant will be submitting New Site/PI amendments to add Hospital Trust sites into the scope of the HRA Approval.