

Mr Mathew Gane
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West of Scotland REC 1

West of Scotland Research Ethics Service
Ground Floor Ward 11
Dykebar Hospital
Grahamston Road
Paisley PA2 7DE

Date 28 April 2022

Please note: This is the date the letter was released by the REC but will not necessarily be the date of final issue.

Direct line 0141 314 0211

E-mail WoSREC1@ggc.scot.nhs.uk

Dear Mr Gane,

Study title:	Paramedic Analgesia Comparing Ketamine and Morphine in trauma
REC reference:	20/WS/0126
Protocol number:	SOC.12/19-20
EudraCT number:	2020-000154-10
Amendment number:	Substantial Amendment 04 (REC Ref AM08)
Amendment date:	24 March 2022
IRAS project ID:	1003404

The above amendment was reviewed on 27 April 2022 by the Sub-Committee in correspondence.

Summary of Amendment

The amendment included:

- Trial team details updated in protocol
- Existing exclusion criteria clarified
- Clarification provided on recruiting patients taken to non-participating hospitals
- Updates to unblinding and follow-up process
- Qualtrics privacy statement added to PIL

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Annex 2: Notification of Amendment/Amendment tool [Amendment tool]		24 March 2022
Cover Letter [SA4 REC Cover Letter]	1.0	05 April 2022
Miscellaneous [Summary of changes_SA04]	1.0	05 April 2022
Participant information and informed consent form [PACKMaN_PIL_Patients_v4.0 15.03.22_tracked]	4.0	15 March 2022
Participant information and informed consent form [PACKMaN_PIL_Patients_v4.0 15.03.22]	4.0	15 March 2022
Protocol [PACKMaN_Protocol_v5.0 15.03.22_tracked]	5.0	15 March 2022
Protocol [PACKMaN_Protocol_v5.0 15.03.22]	5.0	15 March 2022

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. 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 have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

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.

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 - 1003404:	Please quote this number on all correspondence
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Yours sincerely,

A handwritten signature in black ink that reads "R Hood". The letters are cursive and slightly slanted to the right.

On behalf of
Dr Katriona Brooksbank
Chair

Enclosures: List of names and professions of members who took part in the review

Copy to: Professor Gavin Perkins, University of Warwick

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Attendance at Sub-Committee of the REC meeting on 27 April 2022

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Katriona Brooksbank	Head of Clinical Trials, Heart Failure (Chair)	Yes	Chair of Meeting
Dr Patricia Roxburgh	Medical Oncologist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Kirsty Burt	Senior Co-ordinator
Mrs Ruth Hood	REC Assistant