



# Wales Research Ethics Committee 1 Cardiff

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<u>Please note: This is the favourable opinion of the REC only and does not allow</u> the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed

09 December 2022

Ms Chloe Norman Trial Manager Warwick Clinical Trials Unit University of Warwick Gibbet Hill Road Coventry CV4 7AL

Dear Ms Norman

Study title: Randomised trial of the clinical and cost effectiveness of a

supraglottic airway device versus intubation during in-

hospital cardiac arrest

REC reference: 22/WA/0156 Protocol number: ME/2021/7106

Amendment number: Substantial Amendment 1 (SA01)

Amendment date: 21 November 2022

IRAS project ID: 314379

The above amendment was reviewed by the Sub-Committee in correspondence.

## **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:

Document	Version	Date
Completed Amendment Tool [314379_Substantial Amendment 1 (SA01) AIRWAYS 21.22.22]	1.0	21 November 2022
Covering letter on headed paper [Substantial Amendment One Summary of Changes AIRWAYS-3 18Nov22]	1.0	18 November 2022
Research protocol or project proposal [AIRWAYS-3 Protocol V2.0 171122]	2.0	17 November 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: <a href="https://www.hra.nhs.uk/planning-and-improving-research/learning/">https://www.hra.nhs.uk/planning-and-improving-research/learning/</a>

IRAS Project ID - 314379:

08/1

Please quote this number on all correspondence

Yours sincerely

p.p.

Mr John Gibson

Chair

E-mail: Wales.REC1@wales.nhs.uk

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

Copy to: Professor Jonathan Benger - <u>Jonathan.Benger@uwe.ac.uk</u>

Ms Jessica Bisset, Confidentiality Advise Team - researchapprovals@uhbw.nhs.uk

Sandra Mulligan - sandra.mulligan@uhbw.nhs.uk

# Wales REC 1

# Attendance at Sub-Committee of the REC meeting on 07 December 2022

# **Committee Members:**

Name	Profession	Present	Notes
Mrs Kathie Fisher	Retired Company Director, Kingfisher Music	Yes	
Mr John Gibson	Specialist Trainee in Plastic Surgery	Yes	

# Also in attendance:

Name	Position (or reason for attending)
Mrs Deborah Burch	Approvals Administrator