Health Research Authority
2 Redman Place
Stratford
London
E20 1JQ

Tel: 020 7104 8100
Email: cag@hra.nhs.uk

31 October 2022

Professor Jonathan Benger

Faculty of Health and Applied Sciences,
University of the West of England
Coldharbour Lane
Bristol
BS16 1QY

Dear Professor Benger,

Application title:	**Randomised trial of the clinical and cost effectiveness of a supraglottic airway device versus intubation during in-hospital cardiac arrest**
CAG reference:	**22/CAG/0112**
IRAS project ID:	**314379**
REC reference:	**22/WA/0156**

Thank you for submitting a **research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 8 September 2022.

This outcome should be read in conjunction with the provisional support letter dated 30 September 2022.

Health Research Authority decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application, to allow the disclosure of confidential patient information from participating NHS trusts to the University of Warwick, the disclosure of confidential patient information from the University of Warwick to NHS Digital, PEDW and ICNARC and the return of a linked dataset to the University of Warwick is conditionally supported, subject to compliance with the standard and specific conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of application

This application from the University of the West of England set out the purpose of medical research that seeks to determine the clinical and cost effectiveness of a supraglottic airway device versus tracheal intubation during in-hospital cardiac arrest. In hospital cardiac arrest (IHCA) occurs in approximately 1 in 1000 hospital inpatients. It is a sudden, unpredictable and life-threatening event and has significant mortality and morbidity. Survival to hospital discharge following resuscitation for IHCA is around 24% in the UK. However, additional data collected for patients who require advanced airway management, such as the insertion of a tracheal tube or a supraglottic airway device, suggests that survival for this patient group is closer to 10%.

Effective cardiopulmonary resuscitation (CPR) is central to achieving good patient outcomes, however chest compressions alone do not provide adequate lung ventilation and effective airway management is essential. A previous trial, AIRWAYS-2, explored use of tracheal intubation versus the i-gel supraglottic airway device in OHCA. This did not detect a significant difference in functional outcome (including mortality) between the two advanced airway management techniques. Since then, updated international resuscitation guidelines support the use of supraglottic airways (SGAs) in settings where intubation success rates are lower. Changes have been made in management of airways when paramedics treat Out of Hospital Cardiac Arrest (OHCA), but not where doctors manage the airways. The applicants seek to determine whether SGAs are superior to tracheal intubation in situations where intubation success rates are assumed to be high. The applicants will conduct a multi-centre, open-label, pragmatic, individually randomised, parallel group, superiority trial and economic evaluation. Patients will be recruited by NHS clinicians, usually the member of the in-hospital cardiac arrest team who is designated to manage the patient's airway. The clinician will assess patient eligibility. Patients will be randomly allocated, at a ratio of 1:1, to receive either a supraglottic airway device (intervention arm) or tracheal intubation (control arm). The randomisation will be conducted using a phone progressive web application (PWA) which will inform the Warwick CTU that the randomisation has occurred. Patients will initially be recruited under the Mental Capacity Act, as patients will be unconscious when entered into the trial. Consent will be sought from patients who regain capacity. Support is required to include patients who die before consent can be sought. Confidential patient information will be disclosed to the University of Warwick. Individual level patient data will be disclosed to NHS Digital, PEDW and ICNARC for linkages to datasets these organisation hold, and a linked dataset returned to the University of Warwick.

The applicants noted that data linkage to Health Data Research UK (HDR UK) was planned. An amendment would be submitted before this was undertaken.

A recommendation for class 1, 2, 3, 4, 5 and 6 support were requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients aged 18 years and over who experience an in-hospital cardiac arrest, are attended by the hospital cardiac arrest team and who require resuscitation with advanced airway management. 4190 patients will be included.
Data sources	1. Participant NHS hospital Trusts 2. NCAA (National Cardiac Arrest Audit), held by Intensive Care National Audit and Research Centre (ICNARC) 3. Patient Episode Database for Wales (PEDW), held by NHS Wales Informatics Service (NWIS)
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode – district level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **The CAG request clarification on the Consent process. It was queried at what point consent was sought and whether consent was sought for only those who survived the cardiac arrest. Clarification on the consent process needs to be provided as follows:**

    a. **Clarify when consent would be sought and whether consent was sought for only those who survived the cardiac arrest.**

    The applicants advised that consent for follow-up would be sought from surviving patients, who had not registered a National Data Opt-Out, once they left intensive care. Consent would not sought from patients who did not survive to this point.

    b. **Confirmation that, should a patient who is approached for consent refuse, then their confidential patient information will be deleted.**

    All confidential patient information will be deleted if a person approached for consent refuses to participate in follow-up.

    The CAG noted the above information and raised no further queries.

2. **The poster needs to be revised to provide more information about the study.**

    The applicants provided a revised poster. The CAG reviewed this document and raised no further queries.

3. **Methods of promoting the study online need to be explored and feedback provided to the CAG.**

    A study website and a twitter account have been created, containing information about the study. Both were reviewed by the Patient and Public Trial Management Group member and Research and Audit Federation of Trainees Representative to ensure the information is suitable for patient viewing, and to provide trainees interested in the study with the correct information. A log will be kept of the feedback received. The CAG noted this information and raised no further queries.

4. **Methods of sign-posting those whose first language was not English to information about the study need to be explored and feedback provided to the CAG.**

The applicants are exploring ways of translating the poster provided at point 2 and other study information into the non-English languages spoken most often by the communities served by participating hospitals, including Welsh where appropriate, and will feed back to CAG as the study proceeds. The CAG noted this information and raised no further queries.

5. **Clarify whether the confidential patient information can be de-identified as the project is ongoing, or whether all confidential patient information will be held until 31 December 2026.**

The applicants confirmed that it will be possible to de-identify confidential patient information as the project proceeds, following data linkage and validation. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 22 July 2022**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital 21/22 DSPT review for**, Intensive Care National Audit and Research Centre (ICNARC)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13/09/2022)

   NHS Wales Informatics Service (NWIS) – CPIP in place

   The applicants confirmed that the University of the West of England would not process any confidential patient information under support, therefore a DSPT was not required for this organisation.

As the above conditions have been accepted and/or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information

Application maintenance

Annual review

Please note that this legal support is subject to submission of an annual review report, for the duration of support, to show that the minimal amount of patient information is being processed and support is still necessary, how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

The next annual review should be provided no later than **31 October 2023** and preferably 4 weeks before this date. Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support. Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing. Please ensure you review the HRA website to ensure you are completing the most up to date 'section 251' annual review form as these may change.

For an annual review to be valid, there must also be evidence that the relevant DSPT submission(s) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Register of Approved Applications

All supported applications to process confidential patient information without consent are listed in the published 'Register of Approved Applications'. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website. It contains applicant contact details, a summary of the research and other pertinent points.

This Register is used by controllers to check whether support is in place.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. Changes to processors will require evidence of satisfactory DSPT submission. The amendment form can be found in the Confidentiality Advisory Group pages on the Health Research Authority website.

Support for any submitted amendment would not come into effect until a positive outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new and signed CAG application form and supporting documentation to support the application amendment. This is necessary to ensure that the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application, and that the legal support in place is related to the correct legal entity.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process timings.

Further information and relevant forms to amend the support is available on the HRA website.

Reviewed documents

The documents reviewed at the meeting are as follows.

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG_Form_ReadyForSubmission]		
Other [14CAG1030 HRA PS Final Approval Letter]		30 December 2014
Other [A3 data flow map_04Aug22V1.0 (Data Flow Diagram) CN (CAG) 27-08-22]	1	27 August 2022
Other [AIRWAYS-3 PPI Supporting Statement 12-04-22]		12 April 2022
Other [Data protection impact assessment]		15 June 2022
REC favourable opinion letter and all correspondence [314379 22 WA 0156 further information favourable opinion 22072022]		22 July 2022
Research protocol or project proposal [AIRWAYS-3 Protocol V1.1 09052022]	1.1	09 May 2022
Written recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [00003311 - Letter of Support AIRWAYS3 signed (2)]		07 July 2022
22-CAG-0112 (AIRWAYS-3) A4Poster_v2.0 (03-10-22)	2.0	03 October 2022
22-CAG-0112 (AIRWAYS-3) CAG Feedback (Response)		
22-CAG-0112 (AIRWAYS-3) Online Presence Report PPI-RAFT		
CAG_Form_AIRWAYS-3_27102022_removal of HDRUK		27 October 2022

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

With the Group's best wishes for the success of this project.

Yours sincerely

Kathleen Cassidy
Confidentiality Advisor

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Included: List of members who considered application
Standard conditions of support

Copy to:

Confidentiality Advisory Group meeting attendance
8 September 2022

Members present:

Name	
Professor William Bernal	CAG alternative vice-chair
Dr Sandra Duggan	CAG member
Mr David Evans	CAG member
Dr Rachel Knowles	CAG member
Ms Rose Payne	CAG member
Mr Dan Roulstone	CAG member
Mr Umar Sabat	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr William Lyse	Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

NHS
Health Research Authority

Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Health Research Authority, is subject to compliance with the following standard conditions of support.

The applicant and those processing the information under the terms of the support will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.

4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities and are acting in compliance with the application detail.

6. Activities must be compliant with the General Data Protection Regulation and relevant Data Protection Act 2018.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken/to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.