



Health Research Authority

2 Redman Place
Stratford
London
E20 1JQ

Email: cag@hra.nhs.uk

20 May 2025

Ms Yomi Adegbaaju
NHS Blood and Transplant
500, North Bristol Park
Filton
Bristol
BS34 7QH

Dear Ms Adegbaaju,

Application title:	A Multi-Centre Randomised Controlled Trial of the Clinical and Cost Effectiveness of Pre-Hospital Whole Blood Administration versus Standard Care for Traumatic Haemorrhage
CAG reference:	22/CAG/0050
IRAS project ID:	300414
REC reference:	22/SC/0072

Thank you for your amendment request to the above research application, submitted for support under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Supported applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

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 an application should be supported, and if so, any relevant conditions.

Health Research Authority decision

The Health Research Authority, having considered the advice from the Confidentiality Advice Team (CAT) as set out below, has determined the following:

1. The amendment, to remove TARN as a data source and data processor, and include instead the National Major Trauma Registry (NMTR) as a data source, with NHS England as the data processor, and to increase the sample size to 900 from 848, is supported, subject to compliance with the standard conditions of support.

Amendment request

This application aims to determine whether pre-hospital leukocyte-depleted whole blood transfusion is better than standard care in reducing the proportion of participants who experience death or massive transfusion. 's251' support is currently in place to allow the

research team at participating NHS trusts to access patient records to check for evidence of existing dissent to use of their data in research, the disclosure of confidential patient information from the NHS trusts to NHS Blood and Transplant (NHSBT) Clinical Trials Unit and the onward disclosure to Trauma Audit and Research Network (TARN) and Intensive Care National Audit and Research Centre (ICNARC) for data linkage, and the return of a linked, pseudonymised dataset to NHSBT.

This amendment seeks to remove TARN as a data source and data processor. This data source is now held by NHS England, and is called the National Major Trauma Registry (NMTR). The only change is administrative as trauma injury data is now managed by NHS England. Therefore NMTR replaces TARN as a data source, and NHS England replace TARN as the data processor.

The amendment also seeks 's251' support to increase the sample size to 900 from 848.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

The NHS England 23/24 DSPT reviews for **NHS England (regarding the National Major Trauma Registry), NHS Blood and Transplant, and ICNARC** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 13 March 2025)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
Confirmed 19 May 2025

Reviewed documents

<i>Document</i>	<i>Version</i>	<i>Date</i>
CAG Amendment form		27 February 2025
22.SC.0072.AM11 300414_Favourable_opinion_of_a_substantial_amendment		19 May 2025

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.

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

Enclosures: Standard conditions of Support

cc. oxfordc.rec@hra.nhs.uk

Standard conditions of support

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

The applicant and those processing the information 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.
6. Activities remain consistent with the General Data Protection Regulation and 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 supported 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.