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23 August 2022

Dear Dr Green

Initial Assessment Letter

Study 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
IRAS project ID:	300414
EudraCT number:	2021-006876-18
Protocol number:	v1.0
REC reference:	22/SC/0072
Sponsor	NHS Blood and Transplant

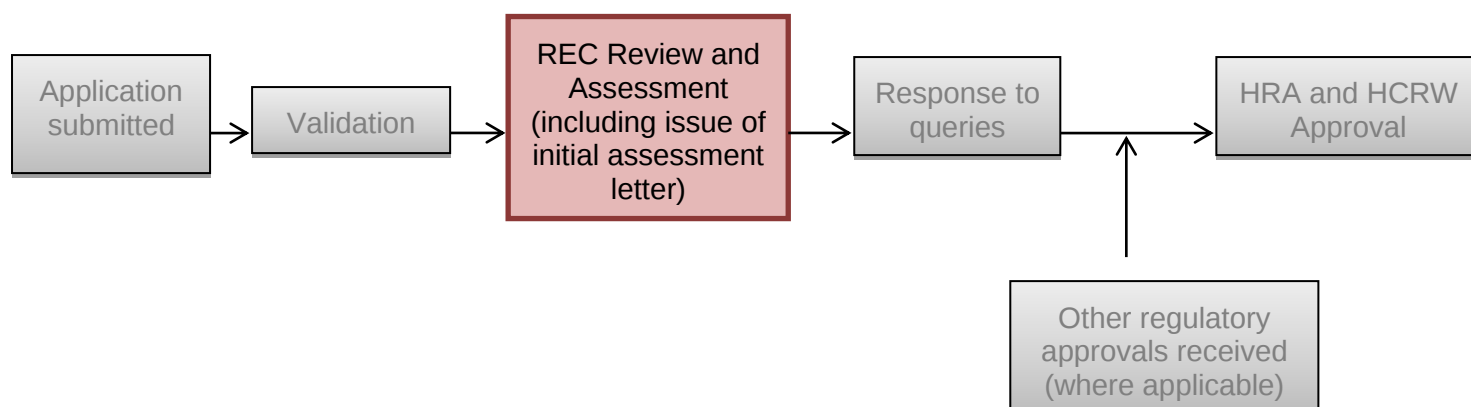
Thank you for your application for [HRA and Health and Care Research Wales \(HCRW\) Approval](#). I am writing to confirm that you are now able to share the Local Information Pack with participating NHS organisations in England and Wales in order to invite them to arrange of capacity and capability to deliver your study. Please note that **the research should not begin** at any participating NHS organisations in England or Wales until HRA and HCRW Approval is issued.

To share the Local Information Pack with participating NHS organisations in England and Wales please use the template email available on the [IRAS website](#).

Once the Local Information Pack has been shared, please work with participating NHS organisations to arrange capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

What happens next with my application for HRA and HCRW Approval?

Your application is progressing. Please find below an indication of where you are in the process (indicated by the red box).



I am undertaking the assessment of the application and you will receive any queries following the REC meeting.

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 in Northern Ireland and Scotland.

If you indicated in your IRAS form that you have participating organisations in Northern Ireland and/or Scotland, the national coordinating function of each participating nation has been informed and provided with the initial document set. The relevant national coordinating function/s will contact you as appropriate. We will provide them the final document set and study wide governance report when available.

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.

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 **300414**. Please quote this on all correspondence.

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Yours sincerely,

Maeve Groot Bluemink
Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: Ms Joanne Lucas, NHS Blood and Transplant

Information to support study set up

The below provides all parties with information to support the arranging 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. As part of the application process, details may change prior to a Letter of HRA and HCRW Approval being issued.

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
• Site Type 2 (Transfusion Laboratory) • Site Type 3 (Receiving Hospital) • Site Type 4 (Transfusion Laboratory and Receiving Hospital)	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.	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The agreement is unmodified.	External funding has been secured from NHS Blood and Transplant, Air Ambulance Charities and the Ministry of Defence. Funding will be provided to site as detailed in the OID and agreement.	Principal Investigators (PIs) are expected.	For Main Protocol research activities (all site types): 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 an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement

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					checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance.
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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 intend to apply for inclusion on the NIHR CRN Portfolio.
- **Site Type 1 (Air Ambulance) & Interview/Focus Groups:** Some activity will take place outside the NHS. HRA & HCRW Approval does not cover activity outside the NHS. Before undertaking activity outside the NHS the research team must follow the procedures and governance arrangements of responsible organisations.