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Email: approvals@hra.nhs.uk
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10 May 2021

Dear Dr Inwald

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**PRESSURE: PRotocolised Evaluation of permiSSive blood pressure targets versus Usual caRE. Evaluating the clinical and cost effectiveness of using a permissive blood pressure target to guide titration of vasoactive drugs in critically ill children with hypotension.**
IRAS project ID:	**289545**
Protocol number:	**A095842**
REC reference:	**21/EE/0084**
Sponsor	**Cambridge University Hospital NHS Foundation Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

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 within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

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.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or 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 **289545**. Please quote this on all correspondence.

Yours sincerely,

Michael Pate
Approvals specialist

Email: approvals@hra.nhs.uk

Copy to: *Ms Alanna Brown, ICNARC*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [PRESSURE_CTSA_V1.0_26-02-2021]		26 February 2021
Copies of materials calling attention of potential participants to the research [PRESSURE Participant Information Leaflet (Parents or Guardians)]	1.1	19 April 2021
Copies of materials calling attention of potential participants to the research [PRESSURE Family Room Poster]	1.0	10 February 2021
Covering letter on headed paper [PRESSURE_IRAS 289545_Ethics re-submission cover letter_05 May 2021]		05 May 2021
IRAS Application Form [IRAS_Form_08032021]		08 March 2021
Letter from funder [NIHR128895 PRESSURE Grant Award Letter_03 December 2019]		03 December 2019
Letters of invitation to participant [Enrolment Covering Letter]	1.0	10 February 2021
Letters of invitation to participant [Enrolment Follow-Up Covering Letter (2)]	1.0	10 February 2021
Letters of invitation to participant [Bereaved-Enrolment Covering Letter (1)]	1.0	10 February 2021
Letters of invitation to participant [Bereaved-Enrolment Follow-Up Covering Letter (2)]	1.0	10 February 2021
Organisation Information Document [Organisation Information Document_Non-Commercial_PRESSURE - sponsor signed 24 February 2021]	1.0	13 January 2021
Other [Follow-Up Email for questionnaire]	1.0	10 November 2020
Other [Follow-Up Letter for questionnaire]	1.0	10 November 2020
Other [Newsletter (Parents or Legal Guardians)]	1.0	10 February 2021
Participant consent form [PRESSURE Consent Form (Parent or Guardian)]	1.0	10 February 2021
Participant consent form [PRESSURE Bereaved Consent Form (Parent or Guardian)]	1.0	10 February 2021
Participant consent form [PRESSURE Assent form]	1.0	10 February 2021
Participant information sheet (PIS) [PRESSURE PIS less than 8 years]	1.0	09 February 2021
Participant information sheet (PIS) [PRESSURE PIS 8-10 years]	1.0	09 February 2021
Participant information sheet (PIS) [PRESSURE PIS 11+ years]	1.0	09 February 2021
Participant information sheet (PIS) [PRESSURE Bereaved-Participant Information Sheet (Parents or Guardians)]	1.1	28 April 2021
Participant information sheet (PIS) [Participant Information Sheet (Parents or Guardians) Clean]	1.1	28 April 2021
Referee's report or other scientific critique report [PRESSURE letter response to board]		12 November 2019
Research protocol or project proposal [PRESSURE Protocol]	2.0	28 April 2021
Schedule of Events or SoECAT [PRESSURE SoECAT 121119 signed MTOK]	V1.0	12 November 2019
Summary CV for Chief Investigator (CI) [David Inwald CV Oct 20]		01 October 2020
Summary, synopsis or diagram (flowchart) of protocol in non technical language [PRESSURE Trial Flow_V1.0_06-11-2020]	1.0	09 November 2020
Validated questionnaire [CHU-9D-Questionnaire]		
Validated questionnaire [PedsQL-Infant(1-12Months)_AU1.0_eng-GB1]		

Validated questionnaire [PedsQL-Infant(13-24Months)_AU1.0_eng-GB1]		
Validated questionnaire [PedsQL-4.0-Core-PT_AU4.0_eng-GB2 (age 2-4)]		
Validated questionnaire [PedsQL-4.0-Core-PYC_AU4.0_eng-GB2_(age 5-7)]		
Validated questionnaire [PedsQL-4.0-Core-PC_AU4.0_eng-GB2 (age 8-12)]		
Validated questionnaire [PedsQL-4.0-Core-PA_AU4.0_eng-GB2 (age 13-18)]		

IRAS project ID	289545

Information to support study set up

The below provides all parties with information to support the arranging and confirming 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.

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
Multicentre study with the same site type.	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.	Funded by National Institute of Health Research (NIHR).	A PI is expected at each participating organisation.	All study activities will be undertaken by local staff employed by the NHS organisation. Therefore, no honorary research contracts or letters of access are expected for this study.

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.