TRIC-BLOCK

Evaluating the prevalence and practice of neuromuscular blockade by infusion within UK Intensive Care Units

Study Protocol

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Version 1.0 | 19.01.2026

TRICNetwork PICSTAR

The Faculty of Intensive Care Medicine

Intensive Care Society

PCCS Paediatric Critical Care Society

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1 Project overview

Title of study	TRIC-BLOCK: Evaluating the practice of neuromuscular blockade by infusion within UK Intensive Care Units
Design	Prospective multi-centre service evaluation
Study aims	Evaluate current practice in prescribing, maintenance, monitoring and cessation of neuromuscular blockade infusions in critically ill patients in UK adult and paediatric Intensive Care Units.
Target population	All patients commenced on invasive mechanical ventilation during the study period
Interventions	None
Study duration	Two-week screening window with one-week data collection for each participating patient

2 Background

2.1 Current usage of continuous neuromuscular blockade

Neuromuscular blocking drug (NMBD) use is commonplace in intensive care for several indications beyond bolus dosing in advanced airway management. Many units use NMBD intravenous infusions to manage severe acute respiratory distress syndrome (ARDS), traumatic brain injury, status asthmaticus, intraabdominal hypertension and to reduce overt shivering in therapeutic hypothermia. However, the supporting evidence base remains limited. Despite existing randomised trial data for NMBD use in moderate-severe ARDS (1–5), current consensus guidelines provide only a 'weak recommendation' for any of the other indications listed above (6,7). Furthermore, the two largest randomised controlled trials supporting the use of NMBD in ARDS only studied cisatracurium and vecuronium (1–5). It is also currently unclear whether NMBD should be used with fixed-rate high doses or titrated to paralytic effect (8). Recent professional society guidelines acknowledge the need for further research in this area (8).

During the COVID-19 pandemic, due to a shortage of cisatracurium, the UK ICM Anaesthesia COVID-19 collaboration recommended the administration of rocuronium by continuous infusion as an alternative agent, a practice which has continued since (9). Whilst such a recommendation was entirely justifiable at the time, there is no research confirming the effectiveness of rocuronium as a continuous NMBD infusion or evaluating best practice in its administration. Moreover, the benefits of cisatracurium may include a specific ability to decrease the inflammatory response in patients with ARDS (10). By substituting cisatracurium for rocuronium outside of clinical trials, treating teams may be reducing NMBD effectiveness. This issue is recognised internationally (8).

2.2 Potential harms

Whilst the benefits of NMBD infusions are recognised, they are not without risk of harm. There is evidence to suggest that prolonged use of NMBD in critical illness is associated with increased rates of Intensive Care Unit (ICU) acquired weakness and increased all-cause mortality (11,12). Monitoring studies demonstrate prolonged neuromuscular blockade with aminosteroid NMBD (such as rocuronium) in patients with renal and hepatic impairment due to impaired drug clearance. This contrasts with use of benzylisoquinolinium agents (atracurium / cisatracurium) which are largely degraded in the plasma in an organ-independent fashion (6,13). Prolonged neuromuscular blockade can have a direct impact on patient care - a 2022 New Zealand observational study of 51 patients found significant residual neuromuscular blockade present in up to one third of patients prior to planned extubation (both post-operative and non-postoperative). The authors concluded residual neuromuscular blockade may be an under-recognised problem in ICU practice. The risk of prolonged blockade was higher with rocuronium than atracurium (14).

2.3 Monitoring of patients receiving neuromuscular blockade

One method used in the recognition and management of prolonged neuromuscular blockade is use of a peripheral nerve stimulator (PNS) to monitor a 'train-of-four' count (TOF). The use of PNS in anaesthesia is a recommended standard of NMBD monitoring (15). This standard does not apply to intensive care practice. The aforementioned New Zealand observational study found 63% of ICUs rarely test neuromuscular function before attempting tracheal extubation and 37% never do (14). Current consensus guidelines recommend against using PNS and TOF *alone* but accept they are useful tools if incorporated into a general assessment of the patient (weak recommendation, based on very low-quality evidence) (7). The guideline authors cite a lack of healthcare-professional familiarity, training and availability as barriers to routine PNS use.

Concerns about patient awareness whilst receiving NMBD mean that patients receiving NMBD are normally deeply sedated. The use of encephalogram-derived parameters may reduce the incidence of awareness in patients under anaesthesia by monitoring the depth of sedation (16). Whilst these monitors are sometimes used in intensive care for patients receiving NMBD by continuous infusion, their use has not been validated in this setting, and practice is variable (7). Despite uncertainty about the utility of PNS and quantitative depth of sedation monitoring, the use of both was recommended by the UK ICM Anaesthesia COVID-19 collaboration for patients receiving continuous rocuronium infusions during the pandemic (9). It is unclear whether these recommendations were enacted or continued as adopted standards during NMBD infusion use after the pandemic.

2.4 Use of continuous neuromuscular blockade in paediatric patients

Like adult patients, neuromuscular blocking drugs (NMBDs) are administered to critically ill children for the management of severe hypoxaemic respiratory failure and as a neuroprotection strategy when there is raised intracranial pressure. However, unlike adults, NMBDs in children may also be used to prevent unintended extubation or device removal.

There is wide interpatient variability in the choice and dosing of NMBDs for critically ill children (17). Consensus guidelines published in 2022 recommended the following (18):

- Use of train-of-four (TOF) monitoring in conjunction with clinical assessment to determine depth of neuromuscular blockade
- Administration of the lowest effective dose of NMBD to achieve desired clinical effects and manage breakthrough movement
- Use of EEG-based monitoring to assess sedation depth
- Ensuring adequate sedation and analgesia to prevent awareness

As in adult practice, the quality of available evidence to produce these guidelines was low.

2.5 Why this service evaluation is needed

The use of NMBD in both paediatric and adult intensive care patients is relatively commonplace, but the evidence base to support and guide this practice is limited. There is uncertainty regarding the choice of NMBD as well as the dosing, duration and monitoring of effect. Given such uncertainty, the likelihood of practice variation in UK intensive care units is high. Evaluating the current state of UK practice will provide a transparent and valuable statement of baseline practice to inform future research, implementation studies and future guidelines.

3 Aims

- To evaluate current practice of prescribing, maintenance, monitoring and cessation of NMBD by continuous infusion in critically ill patients in UK adult and paediatric ICUs.

4 Objectives

- To undertake a two-week service evaluation in adult and paediatric ICUs to capture national variation in practice and to evaluate the following aspects over a follow-up period of 7 days for each included patient:
    - Prevalence of continuous intravenous NMBD use for invasively ventilated patients
    - NMBD agents used and indications
    - Dosing regimen and duration of use during follow-up, overall and in the context of BMI, lean body weight, renal / liver function
    - Use of bolus dosing before and during continuous infusion
    - Assessment/monitoring for depth of neuromuscular blockade
    - Assessment/monitoring for depth of sedation in patients receiving NMBD infusion
    - NMBD discontinuation practice, including use of emergency reversal agents
    - Adverse events and incidents associated with continuous NMBD use including allergic reaction, accidental awareness, inadvertent discontinuation or extravasation of NMBD, failed or accidental extubation, unintended line or device removal and need for physical restraint
- To collate local continuous NMBD guidance from participating UK ICUs to develop a descriptive comparison of current UK practice recommendations

5 TRIC-BLOCK organisational structure

5.1 Overview

TRIC-BLOCK is a collaborative service evaluation led by the Trainee Research in Intensive Care (TRIC) network in collaboration with the Paediatric Critical Care Society Trainees Audit and Research (PICSTAR) network. The project is supported by a central committee responsible for study design and oversight and is delivered through a network of Regional and Site Leads who facilitate local engagement and data collection across participating hospitals.

5.2 Roles and responsibilities

5.2.1 Regional Leads

Regional Leads champion TRIC-BLOCK across their region by identifying and supporting participating hospitals and trainees. A Regional Lead:

- Recruits and coordinates Site Leads within regional hospitals
- Maintains regular communication with Site Leads to ensure timely and consistent data collection

5.2.2 Site Leads

Site leads operationalise TRIC-BLOCK locally, ensuring governance compliance and accurate data collection. A Site Lead:

- Registers the service evaluation with local governance bodies and provides confirmation of approval to the Regional Lead and TRIC-BLOCK committee.
- Identifies local contributors to participate in data collection.
- Arranges research server (REDCap) access for local contributors via the central TRIC-BLOCK committee
- Selects a two-week screening window for patients to participate in the service evaluation (within the designated study period)
- Coordinates and oversees data collection at their site by:
    - Identifying patients who meet the inclusion criteria during the chosen two-week screening window
    - Leads the accurate collection of data for each participating patient using the electronic case report form (hosted on REDCap) for up to 7 days after inclusion
    - Promptly escalating any queries or concerns to the TRIC-BLOCK committee
- Confirms completion of data collection to both the Regional Lead and TRIC-BLOCK committee

6 Methods

6.1 Overview

The study will be conducted as a prospective evaluation of current NMBD practice conducted across UK ICUs in both adult and paediatric patients. We will gather routinely collected data through review of medical records, prescribing documentation and daily ICU nursing charts.

All patients initiated on invasive ventilation who are admitted to a participating ICU during the 2-week study period, will be eligible for inclusion.

Once a patient is included in the service evaluation they will be followed up for 7 days.

6.2 Study approval

In accordance with the UK Health Research Authority guidelines (HRA decision tool) the project is classified as a service evaluation (not research). As such, ethical approval will not be required.

See *Appendix 2: HRA Research Decision Tool* and *Appendix 3: HRA Research Ethics Committee decision tool*).

Site Leads will be required to apply for permission from local audit / clinical governance teams.

Further details of what data will be collected can be found in section 6.4.

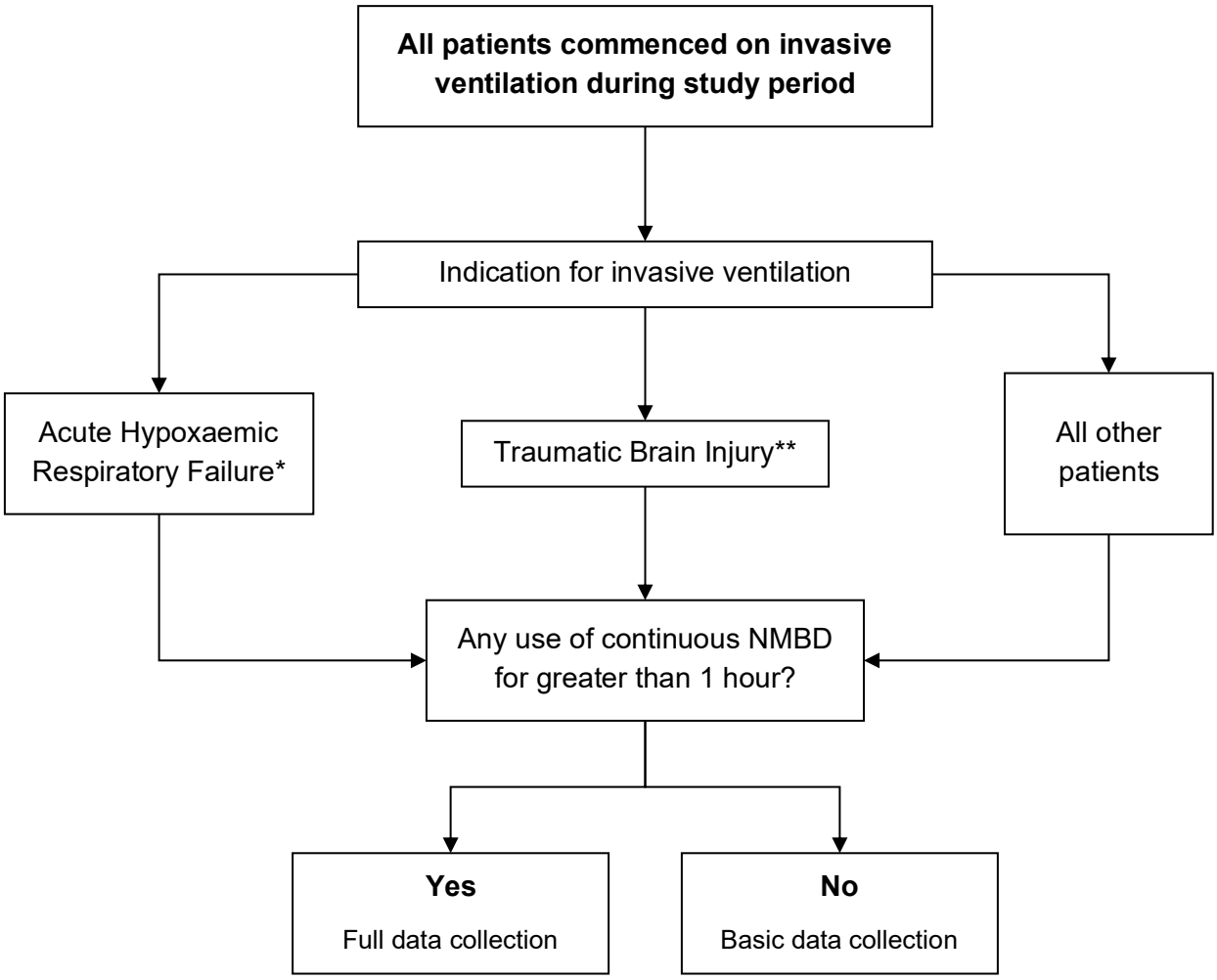
6.3 Collation of local guidelines

Upon registering to participate in TRIC-BLOCK, Site Leads will be invited to share their local guidelines or practice documents regarding NMBD infusion.

6.4 Data collection

6.4.1 Overview

Data collection will be conducted as detailed in Figure 1 below.



** Of any cause, including cases of probable / possible ARDS*

*** 'Traumatic Brain Injury' includes traumatic cerebral injury of any type including focal / diffuse / haemorrhagic. NOTE - spontaneous intracerebral haemorrhage will be included in 'All other patients'*

Figure 1: Data collection overview

6.4.2 Inclusion criteria

All patients newly admitted to a participating site and commenced on invasive mechanical ventilation during a site's selected 2-week study period will be included in the service evaluation.

Patients intubated prior to ICU admission (e.g. in the emergency department, pre-hospital setting, or theatre) and subsequently admitted to intensive care within the same 24-hour period will be included.

Patients transferred from another location (e.g. another hospital) who have been invasively ventilated for more than 24 hours prior to ICU admission will be excluded.

6.4.3 Data collection

Data will be entered into an electronic case report form via a secure, password-protected, data entry web portal, 'Research Electronic Data Capture' (REDCap, www.project-redcap.org), hosted by Warwick University.

Once a patient meets the inclusion criteria, their baseline demographics will be entered into REDCap, generating an anonymous study ID. Site leads must retain a secure record of this study ID to enable linkage to the patient being evaluated. This linkage document must not be shared outside the individual site under any circumstances and must be securely destroyed at the end of the study period. Patient data will be pseudonymised to the direct clinical care team but anonymised to the central team who will receive no identifiable information and no method of linking identifiable information to the study ID.

Data collection teams will subsequently complete all appropriate elements of the case report forms on REDCap throughout the 7-day follow-up period for each patient.

6.4.4 Subgroup rationale

Three subgroups will be identified:

1. Patients with acute hypoxaemic respiratory failure (AHRF)
2. Patients with traumatic brain injury (TBI)
3. All other patients (General ICU population; not AHRF or TBI)

Groups 1 and 2 have been selected because they represent the most common indications for continuous neuromuscular blockade with existing national guidelines and recommendations.

'Traumatic Brain Injury' includes traumatic cerebral injury of any type including focal, diffuse and/or haemorrhagic injury. Importantly however, *spontaneous* intracerebral haemorrhage will be included in 'All other patients'.

Potential indications for continuous NMBD in patients in group 3 may include (but are not limited to): hypercapnic respiratory failure, impaired airway protection (not TBI), intracranial pathology (not TBI), cardiac or respiratory arrest, shock, metabolic acidosis, postoperative, neuromuscular disorders, trauma and use in the prevention of unintended device removal in paediatric patients. These indications have a less well-established evidence base, and most are not supported in consensus guidelines.

6.4.5 Data collected for all patients

Demographic and physiological information will be obtained from routinely documented clinical records.

Demographic data will include sex assigned at birth, age bracket, height and weight.

Severity of illness will be described using the Sequential Organ Failure Assessment (SOFA) score in adults and the Paediatric Index of Mortality, version 3 (PIM3) in children, based on standard ICU documentation.

6.4.6 Patients who receive continuous neuromuscular blockade

These patients will undergo further data collection of the 7-day follow-up period to ascertain:

- Which NMB drugs were administered
- Dosing regimens, delivery methods and duration of use
- Use of bolus dosing before and during continuous infusion
- Dosing in context of BMI, lean body weight and renal / liver function
- Methods used in monitoring of depth of neuromuscular blockade
- Methods used in monitoring depth of sedation
- Discontinuation practice, including emergency reversal agent use
- Adverse events or incidents associated with continuous NMBD use including allergic reaction, accidental awareness, inadvertent discontinuation or extravasation of NMBD, failed or accidental extubation, unintended line or device removal and need for physical restraint
- Patient outcome at the end of the study period (remains in ICU, deceased, discharged to ward, discharged home, transferred to another hospital)

6.4.7 Patients who do not receive continuous neuromuscular blockade

A more streamlined data set will be recorded including patient outcome, rates of failed extubation and the need for bolus doses of NMBD for ventilator dyssynchrony.

6.5 Dissemination plan

- Results will be presented as a descriptive analysis of current practice and areas of practice variation.
- Upon completion of data collection and analysis, findings will be disseminated through the following channels:
    - Peer-reviewed academic publications
    - Conference presentations and papers
    - An executive summary will be provided to each participating site

6.6 Further work

- The findings from this study will underpin a future structured expert consensus process (such as a Delphi methodology) with the aim of developing national guidance.
- Recommendations will be disseminated through relevant professional societies and colleges.
- The study will identify key areas for future research to inform future audit development and clinical benchmarking.

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8 Appendix 1: Clinical governance submission guidance

The tables below can be used to guide completing your own local research and innovation registration forms. Please send any queries to the TRIC-BLOCK committee.

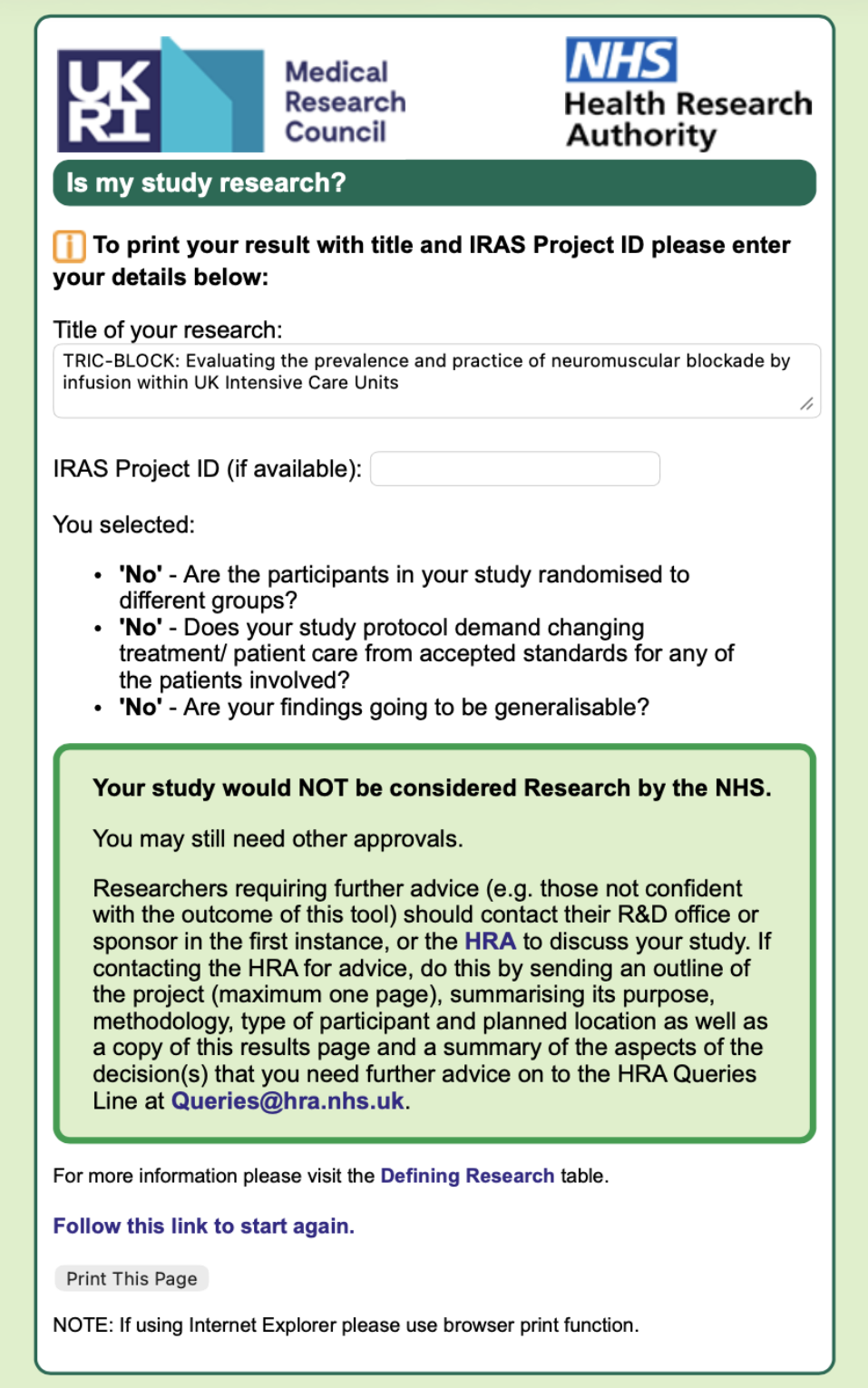
Field	**Example answers** *(Advisory notes in italics)*
Project title	**TRIC-BLOCK: Evaluating the prevalence and practice of neuromuscular blockade by infusion within UK Intensive Care Units**
Proposed start date	**02/03/2026**
Proposed end date	**15/04/2026**
Site	**Hospital X, Hospital Y, Hospital Z** *Insert your hospital name. If your trust has intensive care units across multiple sites, list them all.*
Department or division	**Intensive Care** *Your local department or division may have a different name*
Departmental audit/clinical governance lead	**Dr X (Consultant in Intensive Care Medicine)** *This will be the consultant within your unit who has overall responsibility for audit/clinical governance*
Audit/project supervisor	**Dr X (Consultant in Intensive Care Medicine)** *Most hospitals will require a named consultant supervisor*
Project lead	**Your name**
Other project team members	**Other names** *Include names of other collaborators for data collection*
Type of project	**National Service Evaluation** *Select the answer closest to this. Remember this project is **NOT research** (see below).*

Please also review the table on the following page.

Field *(Advisory notes in italics)*	**Example answers**
Is the required data/information already routinely collected e.g., within clinical systems or notes or existing databases and registries?	**Yes**
Will any new data/information about patients need to be collected (e.g. survey completion)?	**No**
Is the project considered to be research? ***See Appendix 2: HRA Research Decision* Tool**	**No**
Will a Participant Information Sheet and Informed Consent Form be used? ***The study is not research and therefore this is not required.***	**No**
Will external staff be consenting patients?	**N/A**
Will patient data be fully anonymised (i.e. all links between the patient's data and their identity have been completely broken and the data cannot be relinked)?	**No**
Will patient data be pseudonymised (i.e. all identifiable data will be removed, but with the use of a separately held code, so that data could be relinked if necessary)? ***It is <u>vital</u> to specify that any linkage codes will not be shared outside your individual site under any circumstances. You should clearly state that all linkage codes will be securely destroyed at the conclusion of the study period (and ensure this is done). <u>Only</u> the anonymised data will be shared with the TRIC-BLOCK committee. You should state how patient data will be pseudonymised to the direct clinical care team but anonymised to the central team who will receive no identifiable information and no method of linking identifiable information to the study ID.***	**Yes**
Will the patient data be identifiable (because it cannot be fully anonymised/pseudonymised)?	**No**
Will the data be anonymised or pseudonymised by staff in the patients' direct care team?	**Yes**
Will external staff be accessing patient medical records?	**No**
Will the data be shared with researchers outside the organisation for analysis?	**Yes**
Will the results/outputs of the project be shared more widely e.g., through publication or presentation?	**Yes**
Does this project have Research Ethics Committee (REC) approval? ***See*** ***Appendix 3: HRA Research Ethics Committee* decision tool**	**N/A**

9 Appendix 2: HRA Research Decision Tool

This document can be submitted to clinical governance teams as evidence that TRIC-BLOCK is not considered research.



Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

TRIC-BLOCK: Evaluating the prevalence and practice of neuromuscular blockade by infusion within UK Intensive Care Units

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the **HRA** to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at **Queries@hra.nhs.uk**.

For more information please visit the **Defining Research** table.

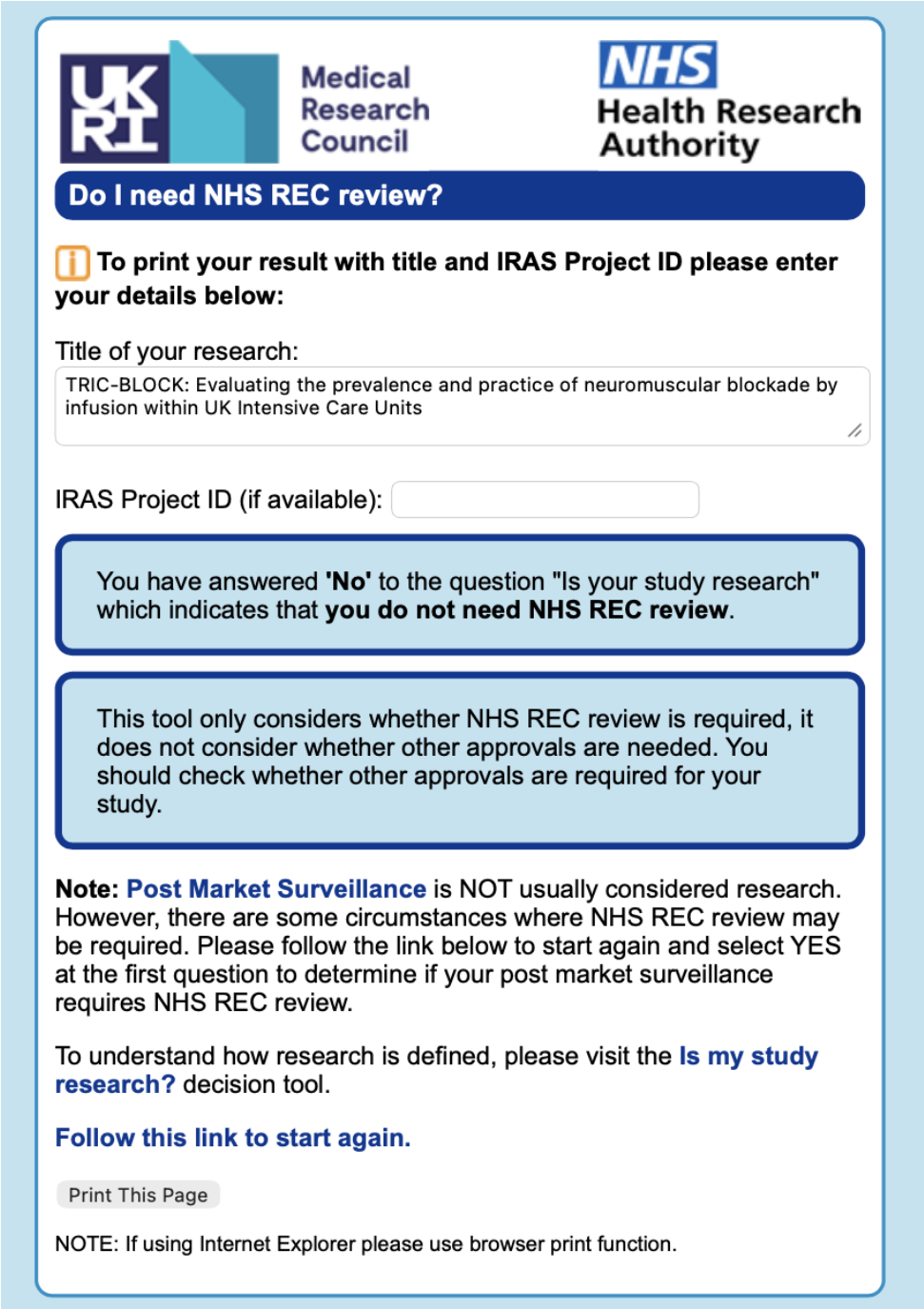
Follow this link to start again.

Print This Page

NOTE: If using Internet Explorer please use browser print function.

10 Appendix 3: HRA Research Ethics Committee decision tool

This document can be submitted to clinical governance teams as evidence that TRIC-BLOCK does not require research ethics committee review.



Medical Research Council

NHS Health Research Authority

Do I need NHS REC review?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

TRIC-BLOCK: Evaluating the prevalence and practice of neuromuscular blockade by infusion within UK Intensive Care Units

IRAS Project ID (if available):

You have answered **'No'** to the question "Is your study research" which indicates that **you do not need NHS REC review**.

This tool only considers whether NHS REC review is required, it does not consider whether other approvals are needed. You should check whether other approvals are required for your study.

Note: Post Market Surveillance is NOT usually considered research. However, there are some circumstances where NHS REC review may be required. Please follow the link below to start again and select YES at the first question to determine if your post market surveillance requires NHS REC review.

To understand how research is defined, please visit the **Is my study research?** decision tool.

Follow this link to start again.

Print This Page

NOTE: If using Internet Explorer please use browser print function.

11 Appendix 4: Definitions

Acute Hypoxaemic Respiratory Failure (AHRF)

A form of respiratory failure characterised by inadequate arterial oxygenation despite supplemental oxygen, typically defined by a reduced PaO_2/FiO_2 ratio. AHRF includes cases of probable or possible ARDS but is not limited to them.

Acute Respiratory Distress Syndrome (ARDS)

A subtype of AHRF defined by rapid onset, bilateral pulmonary infiltrates not fully explained by cardiac failure or fluid overload, and a PaO_2/FiO_2 ratio ≤300 mmHg with ≥5 cmH_2O PEEP. Severity is classified as mild, moderate, or severe based on oxygenation indices.

Paediatric Acute Respiratory Distress Syndrome (PARDS)

A form of acute respiratory failure in children characterised by new-onset parenchymal lung disease with hypoxaemia not fully explained by cardiac failure or fluid overload. PARDS is defined using the Paediatric Acute Lung Injury Consensus Conference (PALICC) criteria, which incorporate age-appropriate oxygenation indices (including Oxygenation Index and Oxygen Saturation Index), allow diagnosis in the presence of chronic lung disease or cyanotic heart disease, and do not require bilateral infiltrates. Severity is stratified as mild, moderate, or severe based on oxygenation thresholds.

Adverse Event (AE)

Any unintended or unfavourable clinical occurrence in a patient receiving care, including events temporally associated with NMBD infusion such as allergic reactions, accidental awareness, extravasation, or unintended device removal.

Aminosteroid Neuromuscular Blocking Drugs

A class of NMBDs (e.g., rocuronium, vecuronium) primarily metabolised by hepatic and renal pathways.

Baseline Severity Scores

- SOFA (Sequential Organ Failure Assessment): A composite score used in adults to quantify organ dysfunction and illness severity.

- PIM3 (Paediatric Index of Mortality, version 3): A validated mortality risk score used in paediatric intensive care.

Benzylisoquinolinium Neuromuscular Blocking Drugs

A class of NMBDs (e.g., atracurium, cisatracurium) that undergo organ-independent degradation via Hofmann elimination and ester hydrolysis, reducing the risk of accumulation in hepatic or renal impairment.

Bispectral Index (BIS)

A processed EEG-derived parameter used to estimate depth of sedation. Although validated in anaesthesia, its use in ICU practice is variable and not formally endorsed by consensus guidelines.

Body Mass Index (BMI)

A measure of body habitus calculated as weight (kg) divided by height (m^2). Used to contextualise NMBD dosing and evaluate potential for drug accumulation.

Bolus Dose

A single, discrete dose of an NMBD administered to initiate paralysis or supplement a continuous infusion.

Continuous Neuromuscular Blockade

The administration of NMBDs via continuous intravenous infusion to maintain sustained neuromuscular paralysis.

Cranial Decompression

A neurosurgical intervention involving removal of part of the skull to relieve intracranial pressure, often used in severe traumatic brain injury.

Emergency Reversal Agent

A medication used to reverse neuromuscular blockade in cases of prolonged paralysis or adverse events.

Extravasation

Leakage of intravenous medication into surrounding tissues, potentially causing local injury or systemic effects.

Failed Extubation

An unsuccessful attempt to discontinue mechanical ventilation, requiring reintubation or escalation of respiratory support. Failed extubation is defined as the need for reintubation within 48 hours of planned removal of the endotracheal tube.

Inclusion Window (Screening Window)

The two-week period selected by each site during which all newly invasively ventilated patients are screened for eligibility.

Invasive Mechanical Ventilation

Ventilatory support delivered via an endotracheal tube or tracheostomy. All patients newly commenced on invasive ventilation during the screening window are included.

Lean Body Weight (LBW)

An estimate of body mass excluding adipose tissue, used to guide weight-based dosing of NMBDs in patients with obesity or altered body composition.

Neuromuscular Blocking Drugs (NMBDs)

Medications that inhibit neuromuscular transmission, resulting in skeletal muscle paralysis.

Paediatric Patient

For the purposes of TRIC-BLOCK, any patient admitted to a paediatric intensive care unit (PICU), typically under 16 years of age, in accordance with local definitions.

Peripheral Nerve Stimulator (PNS)

A device used to assess neuromuscular function by delivering electrical stimuli to a peripheral nerve. Commonly used to generate a Train-of-Four count.

Pseudonymisation

The removal of identifiable patient information and replacement with a study ID, with linkage retained only locally. Linkage codes must not be shared outside the site and must be destroyed at study completion.

Sedation Depth Monitoring

Any method used to assess the adequacy of sedation in patients receiving NMBDs, including clinical assessment, sedation scales, or EEG-derived indices.

Traumatic Brain Injury (TBI)

Any traumatic cerebral injury, including focal, diffuse, or haemorrhagic lesions. Spontaneous intracerebral haemorrhage is not included and is categorised under “All other patients”.

Train-of-Four (TOF)

A neuromuscular monitoring technique involving four electrical stimuli delivered in rapid succession. The number of detectable muscle twitches reflects the degree of neuromuscular blockade.

Unintended Device Removal

Any accidental removal of an endotracheal tube, vascular access device, feeding tube, or other critical equipment, whether due to patient movement or external factors.