

Paediatric

Emergency

Research in the United Kingdom & Ireland

(PERUKI)

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| ***V9.0, PERUKI Executive Committee***  ***March 2024*** |

*Operational Policy*

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# Vision, Goals and Ambitions

## Vision

To improve emergency care for children and young people through rigorous multi-centre research.

## Goals

1. To strengthen PEM research in the UK & Ireland by facilitating collaboration and coordinating research activities of participating institutions
2. To develop and sustain a consensus-derived and well informed research agenda used to guide the network activities and produce high-quality studies in PEM
3. To encourage the translation of network research findings into practice
4. To create a community that promotes cohesion and sharing of expertise between centres within the UK & Ireland, and the rest of the world
5. To provide opportunities for bidirectional education and exchange of ideas and information between clinical and academic communities
6. To mentor new investigators to improve research skills and develop research projects

## Ambitions

1. To be the de facto academic organisation for paediatric emergency research in the UK & Ireland
2. To deliver independent research studies in collaboration with clinical trials units
3. To create a “Route to Research” pathway to develop academic and research capacity in our membership
4. For all PERUKI publications to be available open access
5. To be income generating

# Background and aims

## Introduction

Paediatric Emergency Research in the United Kingdom & Ireland (PERUKI) was established in August 2012 to foster collaborative multi-centre research in the UK & Ireland. This clinical studies group brings together a network of individuals and sites to overcome the challenges inherent in performing research with children in Emergency Departments including:

1. Rarity of serious outcomes and adverse events
2. Potentially limited applicability of data across different types of sites
3. Obtaining informed consent in the emergency setting
4. Tracking participants from the pre-hospital to the in-hospital setting
5. Potential low quality data from the emergency setting
6. Limited funding for PEM research
7. Restrictions on information and data sharing between institutions
8. Local and system obstacles in disseminating research findings and translating them into practice

The structure and operational policy of PERUKI is based on other national PEM research networks – the Pediatric Emergency Care Applied Research Network of the US (PECARN), the Pediatric Emergency Research of Canada network (PERC), and the Paediatric Research in Emergency Departments International Collaborative of Australia and New Zealand (PREDICT). Drawing several PEM networks together, Pediatric Emergency Research Networks (PERN; <https://pern-global.com/> and @PERNnetwork) is a global initiative which facilitates collaboration between national PEM research networks. PERUKI is a member network of PERN, and continues to build on previous collaborations with other networks.

Since its formation PERUKI has contributed significantly to the evidence base in PEM through the enthusiasm and engagement of all members. Studies have resulted in a number of publications, and nationally funded PERUKI studies have been successfully delivered, to time and target; further studies continue to be developed, and members throughout the network continue to give freely of their time to contribute to this, through study review, surveys, and data collection studies. The intercollegiate guidelines on standards for children in emergency care settings (2018) recommended all emergency departments treating children have a nominated lead for paediatric emergency research with PERUKI membership.

This document outlines the function, structure and processes of PERUKI; its contents should be referred to in order to sustain successful growth and collaboration in all PERUKI studies and governance issues.

We acknowledge the start-up help, advice, and support of individuals affiliated with the aforementioned established PEM research networks – PECARN (Nate Kuppermann), PERC (Martin Osmond) and PREDICT (Franz Babl). We also acknowledge the assistance received from APEM (Kath Berry) in the creation of this collaborative.

# Membership and structure

## Membership

Membership is open to any physician, nurse, paramedic, allied health professional, or researcher in the UK & Ireland involved in PEM clinical care or research. Individual membership is free, but members must abide by the PERUKI operational policy. A current membership list with contact details is maintained by the Executive Committee, confirmed annually, and operated in compliance with GDPR regulations.

Institutions can apply for membership and will be admitted after acceptance by the Executive Committee. Participating institutions must have an ED paediatric annual census and research infrastructure which allows meaningful participation. In general this will be in the range of 16,000 paediatric (aged <16 years) attendances per annum. However, sites will not be excluded from PERUKIsolely due to their census and sites seeing fewer than this are welcome to apply for membership – admittance to PERUKIwill be dependent on demonstrating the ability to participate meaningfully inPERUKIstudies. Site performance metrics are monitored by the Executive Committee in conjunction with feedback from study Chief Investigators and PERUKI interactions. The executive committee may review membership with a view to supporting sites, suggesting temporary dormancy, or in rare circumstances, revocation of membership.

Members must abide by the PERUKICode of Ethical Behaviour for multi-centre clinical trials, and the Guidelines for Authorship and Publications. They must also comply with all national and local institutional regulations pertaining to the performance of research.

PERUKI face-to-face member meetings are organised at least once per year to update on ongoing and completed studies, discuss potential new studies, share research-related process updates, and share the forward view. The Executive Committee draws up the agenda with input from PERUKImembers. Informal meetings may also be arranged in association with any major conference that is relevant to PEM. Other communications will occur regularly through teleconferences, email, and the PERUKIwebsite.

Membership forms are available on the website <https://www.peruki.org/>

## Executive Committee

The Executive Committee consists of the following positions:

1. Chair
2. Vice Chair
3. Invited Past Chair
4. Secretary
5. Treasurer
6. Knowledge Translation Officer
7. Trainee member(s)
8. Nursing member
9. Representative for England\*
10. Representative for the Republic of Ireland\*
11. Representative for Northern Ireland\*
12. Representative for Scotland\*
13. Representative for Wales\*

*\*The executive committee should aim to represent the entirety of the UK and Ireland. The representatives for England, Wales, Scotland, Northern Ireland and the Republic Ireland will be sought only when there is a lack of representation from that region within the executive committee roles 1-6 above.*

Members of the Executive Committee are elected from standing members of the Research Steering Committee (RSC), or those who have made contributions to PERUKI business such as study review and delivery. Election is by majority vote through secret ballot of the RSC. Executive Committee members can be removed from office by a vote in favour of removal by two-thirds of the RSC.

An election for Vice Chair is held every three years. The Immediate Past Chair will solicit nominations from members at least one month in advance of elections. Nominations must come with support from two PERUKImembers in good standing. Once elected they will serve as Vice Chair for three years progressing to Chair if willing and if no objections from the executive committee. Where significant objections exist the outgoing Chair can (at their discretion) re-open nominations for the incoming Chair. The outgoing Chair will solicit nominations from members at least one month in advance of elections. Nominations must come with support from two PERUKImembers in good standing. Where there are significant alterations in progression (for example, if the Vice Chair or Chair step down from the committee prematurely) then the tenure of each of the remaining posts will be adjusted at the discretion of the Executive Committee.

Elections for the positions of Secretary, Treasurer, Knowledge Translation Officer and Regional Representatives (as required) follow the same process and will be held every three years by secret ballot. Any PERUKImember in good standing may nominate another PERUKImember (with their consent) for these positions, and self nomination is encouraged. PERUKI is committed to encouraged equality and diversity.

The Trainee Member(s) serves a maximum term of two years. At a relevant PEM national trainee meeting, all trainees in attendance convene and elect their representative.

Executive Committee meetings are held at least monthly in and otherwise as often as needed to conduct business in person, by teleconference, or by electronic means.

The Executive Committee are responsible for:

1. Keeping accurate minutes of Executive Committee meetings and presenting these (on request) to the Research Steering Committee
2. Developing PERUKIregulations and guidelines
3. Administering funds that come into PERUKIand providing an annual financial report
4. Setting meeting agendas
5. Communication with members
6. Maintaining up-to-date membership contact lists
7. Reviewing new and ongoing PERUKIstudies and addressing issues

The Executive Committee may establish topic-specific working groups comprised of Research Steering Committee members, general members and non-members with expertise as the need arises.

### Ex-officio members

Ex-officio members of the Executive Committee can be appointed at the discretion of the Executive Committee. They do not have voting rights but can attend all Executive Meetings relevant to their role. If required (at the discretion of the executive committee) these individuals will be appointed through open recruitment processes, either internal or external to the general PERUKI membership.

Current ex-officio members include:

1. Invited Past Chair

Other ex-officio members can be created at the discretion of the executive committee Individuals with specific roles (for example, administrative support, website development, social media interaction) will work closely with the Executive Committee in a non-voting capacity where deemed appropriate.

Representative Groups may include

1. RCEM Representative
2. RCPCH Representative
3. IAEM Representative

## Research Steering Committee

The Research Steering Committee (RSC) is the primary governing body of PERUKI. It consists of the site representatives (or their proxies). It has the right to co-opt members onto the Committee, and may invite members appropriate for the business of the meeting.

The RSC quorum consists of at least half of all RSC members (or their proxies), and on voting matters a majority of those voting will see the matter approved. It will as required by teleconference, and in person at the Annual Meeting.

The RSC is responsible for:

1. Selection of Executive Committee members
2. Determining regulations and guidelines
3. Reviewing and approving the general research agenda of PERUKI
4. Determining which studies to conduct as PERUKIadoptedstudies
5. Determining if topic-specific working groups or sub-committees should be formed

### Site representative

Participating member institutions will select their site representative to the PERUKI RSC. This site representative (or their proxy) will be the primary liaison between participating sites and the PERUKIRSC and will represent the site at RSC meetings. Sites may change the individual acting as site representative as they see fit; when changes are made, or when the site representative is unavailable for a period of time (for example, parental leave), the site should notify the PERUKI secretary with details of the new site representative or proxy.

Site representatives need not serve as the Site Principal Investigator for every PERUKIproject, but are welcome to identify which of their colleagues are interested in this role. It is optimal that a range of staff participate in PERUKIstudies. Similarly, while it is expected that someone from every site should review research proposals, this need not necessarily always be the site representative – rather, this should be delegated to someone else at the local site if appropriate.

All contributions, including meeting attendance, proposal review, study participation, and consultation, will be recognised with electronic certificates.

## Mentorship of Novice Investigators

PERUKIwill play a supportive role in the development of projects by junior or novice researchers via the “Route to Research” strategy. If requested, members of the PERUKI Research Steering Committee and other identified members of PERUKI provide mentorship in study design, protocol development, and applications for funding and manuscript preparation. In doing so, we hope to support the growth of research throughout all PERUKI regions, and enable meaningful increases in those leading on research projects and contributions to the evidence base.

# Guidelines for the Review of Studies

## New studies

### General Principles

Where possible the Chief Investigator should propose the study at an early stage of development and provide updates as funding is sought. Proposals will be reviewed at PERUKI Executive Committee meetings and an initial decision to either reject, support with adoption or send to the RSC will be made. Following RSC review a final decision can be made to either reject the study, support without adoption or adopt. The Executive Committee have the discretion (in exceptional circumstances) to provisionally support proposals if timely RSC review is not possible; however a final review and decision must be sought from the RSC prior to full adoption.

Weighting may be given to studies likely to attract funding, or meeting the questions raised in the PERUKI research prioritisation project.

A PERUKIstudy must involve more than one centre. However, as few as two centres working collaboratively constitute a PERUKIstudy. PERUKImay advise researchers or centres on how to progress to a multi-centre investigation.

The Research Steering Committee reviews study proposals to ensure they are deliverable, relevant to PEM, and do not compete with existing studies. If conflict is identified the Chief Investigators of both studies are notified, and asked to explore whether conflicts can be overcome. A nominated member of the Executive Committee (or Research Steering Committee where appropriate) should also be involved in this discussion. The Chief Investigators submit a written report to the Research Steering Committee outlining how potential conflicts might be resolved, and how potential synergies might facilitate enrolment into each other’s study.

In choosing participating sites, PERUKIsupports the principals of inclusiveness, openness, creating linkages and the promotion and fostering of research collaborations and excellence across all PERUKIsites. Studies approved by the Research Steering Committee are sent to all site representatives who determine if their sites can participate and who from each site will act as Principal Investigator. To ensure that standards of research and conduct expected for PERUKI studies are maintained, at least one member of the Executive Committee must be included in the study team on all PERUKI studies, and they will act as the internal PERUKI sponsor. This contribution should be recognised, and if significant, they should be included as a byline author on relevant outputs. This should be agreed prior to study commencement, and specified in relation to published outputs and applications for funding.

Publication plans should be developed early in the life of a PERUKI study, and should be available on request. This should be a living document, updated by the study team as required. The PERUKIname and/or logo should appear in presentations and manuscripts that result from PERUKIcollaborations. Contribution should be recognised on any published outputs by including PERUKI as a byline author (for example, “In collaboration with PERUKI”); on conference abstracts this may not be possible, and the study title should for example end with “a PERUKI study”. Recognising this contribution provides assurance to readers that the study has been subject to the rigours of PERUKI processes, and is also important in continuing to demonstrate the track record of PERUKI in delivering successful high quality research.

# Guidelines for Authorship and Publications

## Authorship

Prior to the start of any PERUKIstudy the Chief Investigator and Executive Committee should agree upon the contribution of each member to the study and the implications for authorship. Participation in PERUKIstudies does not guarantee authorship. All publications arising as a result of collaboration in PERUKI should however be written “in collaboration with PERUKI”.

In order to ensure that standards of research governance, conduct, and written content expected for PERUKI studies are maintained, at least one member of the Executive Committee is included in the study team on all studies as the internal PERUKI sponsor. This contribution should be recognised, and if significant, they should be included as a byline author on relevant outputs. This should be agreed prior to study commencement, and specified in relation to published outputs and applications for funding.

Chief Investigators should adhere to “Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals” (available at [www.icmje.org](http://www.icmje.org), accessed 1st February 2024).

## Publications

All final drafts of publications should be reviewed by the PERUKI Executive Committee member named on the study.

Because of the short lead times for abstracts submitted to scientific meetings it is not expected that abstracts will be reviewed prior to submission. However, members should submit material for review prior to the actual presentation.

Acknowledgement of PERUKIis required in all publications and presentations of PERUKI adopted studies.

# Interactions with other International Paediatric Emergency Medicine Research Networks

PERUKI collaborates continuously with other like-minded individuals and bodies. Close relationships with other international PEM research networks are therefore encouraged and fostered. These groups include

1. UK & Ireland based organisations such as TARN (the Trauma Audit & Research Network) and GAPRUKI (General Adolescent and Paediatric Research in the UK & Ireland).
2. International organisations which include the Pediatric Emergency Research Canada (PERC), Pediatric Emergency Care Applied Research Network (PECARN), Pediatric Emergency Medicine Collaborative Research Committee (PEMCRC), Paediatric Research in Emergency Departments International Collaborative (PRECICT), the Spanish Pediatric Emergency Research Group (RISeuP/SPERG), the Latin American Pediatric Emergency Group (RIDEPLA), and Research in European Paediatric Emergency Medicine (REPEM).

PERUKI is a member of Pediatric Emergency Research Networks (PERN), a global collaborative of PEM research networks which aims to answer globally relevant PEM questions. Two positions on the PERN Executive Committee are filled by the PERUKI Chair and Immediate Past Chair.

As a member network, PERUKI is committed to delivering PERN studies, which will already have undergone scientific scrutiny by all member networks making up the PERN Executive Committee. A study adopted by PERN will be adopted by PERUKI unless the PERUKI Executive Committee feel this is inappropriate. In this situation the RSC would be asked to review the PERN study, and if rejected PERUKI would not participate in that particular PERN study.

A PERUKI lead(s) is sought from the Research Steering Committee (though a non-committee member may fill this role if no representative from the Research Steering Committee can be identified). It will not always be essential for all sites to take part, but PERN studies which do require this approach will be highlighted. The PERUKI lead for each PERN study undertakes all necessary legal and ethical processes, and may consider applying for funding. Updates of PERN and other collaborative studies are provided at each Research Steering Committee meeting.

# Code of Ethical Behaviour for Multicentre Clinical Trials

## Principles

Ours is a collaborative network of investigators who share their intellectual property and resources for the common goal of undertaking PEM research. Collaborative research can only flourish in an atmosphere of openness and trust, and to promote free flow of ideas among PERUKImembers, there is an expectation of good ethical behaviour. Each PERUKImember agrees to follow this Code of Ethical Behaviour for Multicentre Clinical Trials. This expectation extends to interactions with industry and other funding partners.

## Ethical Behaviour among Investigators

The "intellectual property" of a PERUKIprotocol belongs primarily to the Chief Investigator(s) and secondarily to the Principal Investigators. When a protocol is introduced to PERUKIby a Chief Investigator, other PERUKImembers should declare any real or potential conflicts of interest and offer to absent themselves from further discussions. Such conflicts include, but are not limited to, developing or implementing, or intending to develop or implement, a similar protocol with the same or other funding agency. Once a PERUKImember has agreed to participate in a particular study, the member should not undertake any conflicting study that could interfere with the capability to perform the PERUKIstudy.

In the event that a PERUKIstudy does not come to fruition, a participating member should not undertake a similar study without prior discussion with the Executive Committee to determine whether the study impinges on the intellectual property of the PERUKIstudy. This applies to studies with the same or other funding agencies.

It is good practice prior to beginning a study that rules of interaction should be established between investigators. These should govern the performance of supplementary studies, additional use of clinical material derived from the study, and use of the data for presentation and publication.

Research proposal review materials and meeting discussions are privileged communications prepared only for use by PERUKIResearch Steering Committee members.

## Ethical Behaviour in interactions with Industry Partners

When an industry-generated protocol is presented to PERUKIfor consideration, the protocol remains the intellectual property of the industry participant and confidentiality must be maintained. The protocol should not be modified or used by PERUKIinvestigators without the permission of the industry partner. For industry studies it is the sponsor’s responsibility to create any documentation related to Intellectual property.

When an investigator-generated protocol is submitted to industry for consideration, it remains the intellectual property of PERUKIand confidentiality should be maintained. The protocol should not be modified or used by industry without the permission of PERUKI. PERUKIexpects that industry partners who choose not to fund a PERUKIstudy will not undertake the same or similar studies with a PERUKI member without the approval of PERUKI. An agreement should be made at the study set-up stage that PERUKI will be credited in authorship of future publications and study outputs.

## Breaches of Ethics by PERUKI Members or by Industry Representatives

Good communication and policy adherence are likely to prevent ethical or research governance issues.

Allegations of breaches of ethical behaviour by PERUKI members should be brought to the attention of the PERUKIExecutive Committee who will serve as the review committee of PERUKI. This process will be strictly confidential.

After an investigation into the circumstances of the alleged incident, including written testimony by involved parties where deemed necessary, the PERUKIExecutive Committee will make a judgement. The complainant and the alleged offender will be informed of the decision in writing.

Sanctions available for breaches of ethical behaviour by a PERUKImember will include a written warning, suspension, or expulsion. Notice of the decision will also be sent to the appropriate individual responsible for the member's academic performance. Sanctions available for breaches of ethical behaviour by industry will include, but not be limited to, a written warning, and suspension of interactions (research and other) by PERUKImembers with the offending party.

Appeals of Executive Committee decisions can be made to an appeals committee comprised of one member representative of each PERUKIaffiliate institution.

*(adapted from PERC, PREDICT)*

## Revision of PERUKI governing principles and code of ethical behaviour

Any member of the Executive Committee may propose revisions to the PERUKIgoverning principles, operational policy, and/or code of ethical behaviour. Any proposed revisions, once approved by the Executive Committee, must be submitted to the PERUKIResearch Steering Committee for ratification. A majority of those voting will constitute ratification.