



Paediatric
Emergency
Research in the
United Kingdom &
Ireland
(PERUKI)

Operational Policy

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 Paediatric Emergency Medicine in the UK & Ireland. This clinical studies group was formed to create a network of individuals and sites to overcome the challenges inherent in performing research with children in Emergency Departments including:

1. Serious outcomes and adverse events are rare.
2. Data collected in tertiary institutions are not necessarily applicable to other settings.
3. Informed consent is difficult to obtain in the emergency setting.
4. Patients are difficult to track from the pre-hospital to the in-hospital setting.
5. Data quality from the emergency setting can be poor.
6. Funding for research is limited.
7. Sharing of information between institutions is often restricted.
8. Difficulty in disseminating findings and translation of science into practice.

The structure and governance 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) 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 going forward.

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 the first nationally funded PERUKI studies are due to commence recruitment, moving the collaboration into the next stage. This document outlines the function, structure and processes of PERUKI and its contents should be referred to in order to continue 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, PERC and PREDICT. We also acknowledge the assistance received from APEM in the creation of this collaborative.



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 establish a robust operational infrastructure to develop and conduct clinical trials and observational studies using robust study designs and methodologies.
4. To provide opportunities for bidirectional education and exchange of ideas and information between clinical and academic communities, and encourage the translation of network research findings into practice.
5. To create a framework that promotes cohesion and sharing of expertise between centres within the UK & Ireland, and the rest of the world.
6. To mentor new investigators to improve research skills and develop research projects.



Membership and structure

Membership

Membership is open to any physician, nurse, paramedic, allied health professional or researcher in the UK & Ireland involved in PEM delivery or research. Individual membership is free, but is dependent on abiding by PERUKI terms and conditions. A current membership list with email addresses will be maintained by the Executive Committee and confirmed annually.

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 PERUKI solely due to their census and sites seeing fewer than this are welcome to apply for membership – admittance to PERUKI will be dependent on demonstrating the ability to participate meaningfully in PERUKI studies. Site performance metrics will be monitored by the Executive Committee in conjunction with feedback from study Chief Investigators and PERUKI interactions.

Members must abide by the PERUKI [Code 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 members will meet in person at least once per year to be updated on ongoing and completed studies, and to discuss potential new studies. The Executive Committee will draw up the agenda with input from PERUKI members. 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 PERUKI website.

Executive Committee

The Executive Committee consists of the following positions:

1. Chair
2. Vice Chair
3. Immediate Past Chair
4. Secretary
5. Treasurer
6. Trainee representative

Members of the Executive Committee will be elected from and by the members of the Research Steering Committee by majority vote through secret ballot. Executive Committee members can be removed from office by a vote in favour of removal of two-thirds of the Research Steering Committee.

An election for Vice Chair will be held every two years by secret ballot. The Immediate Past Chair will solicit nominations from members at least one month in advance of elections. Any two PERUKI members in good standing may nominate another PERUKI Research Steering Committee member



(with their consent) for Vice Chair. Once elected they will serve as Vice Chair for two years, progress to Chair for a two-year term, and subsequently Past Chair for a two-year term. At the end of this term the member may stand for election to a position on the Executive Committee immediately.

Elections for the positions of Secretary and Treasurer will be held every two years by secret ballot. The Immediate Past Chair will solicit nominations from members at least one month in advance of elections. Any PERUKI member in good standing may nominate another PERUKI member (with their consent) for either position.

The Royal College of Emergency Medicine and Royal College of Paediatrics and Child Health will be invited to provide a representative to the Executive Committee. They will be offered the option of serving a fixed term of two years, or provide an ad hoc presence dependent on the nature of PERUKI research activities.

The Trainee Representative will serve a term of one year. Each year at the PEM national trainee annual meeting, all trainees in attendance will convene and elect their representative.

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

The Executive Committee will be responsible for:

1. Keeping accurate minutes of Executive Committee and Research Steering Committee meetings and presenting these to the Research Steering Committee.
2. Developing PERUKI regulations and guidelines.
3. Administering funds that come into PERUKI and provide an annual financial report.
4. Setting the agenda of meetings of the Research Steering Group.
5. Communication with members.
6. Maintaining up-to-date membership email lists.
7. Reviewing new and ongoing PERUKI studies 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.



Research Steering Committee

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

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

The Research Steering Committee will be responsible for:

1. Selection of Executive Committee members by majority vote.
2. Determining regulations and guidelines by majority vote.
3. Reviewing and approving the general research agenda of PERUKI.
4. Determining which studies to conduct as PERUKI studies by majority vote.
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 Research Steering Committee. This site representative (or their proxy) will be the primary liaison between participating sites and the PERUKI Research Steering Committee and will represent the site at Research Steering Committee meetings.

Site representatives should attend and promote formal PERUKI meetings, and regularly attend PERUKI teleconferences.

Site representatives should not serve as the Site Principal Investigator for every PERUKI project, but should identify which of their ED colleagues are interested in this role. It is optimal that a range of staff participate in PERUKI studies. 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 can 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 Junior Investigators

PERUKI will play a supportive role in the development of projects by junior or novice researchers. If requested, members of the PERUKI Research Steering Committee and other identified members of PERUKI could function as mentors in the areas of study design, protocol development, and applications for funding and manuscript preparation.



Guidelines for the Review of Studies

New studies

General Principles

The ideal way to review new studies is for Chief Investigators (or their proxy) to propose their research protocols at a face-to-face PERUKI meeting and have their study become a “PERUKI study”. However, we realise that deadlines for grant applications do not always permit this to take place. Where possible the Chief Investigator should propose the study at an early stage of development and provide updates as funding is sought. Where this is not possible the Research Steering Committee will review protocols electronically and/or by teleconference. The overall goal of these guidelines is therefore to maximise the chance that Chief Investigators will receive constructive and informative feedback. Any PERUKI member may bring forward a study to the PERUKI Research Steering Committee for consideration as a PERUKI study.

Some weighting may be given to studies that are likely to attract funding, or meet the questions raised in the PERUKI research prioritisation project (available at <http://emj.bmj.com/content/early/2015/02/12/emered-2014-204484.abstract?sid=a502de30-1013-440e-8fdb-15f25f60b66e>).

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

It is the responsibility of the Chief Investigator to develop the research question and write up the study proposal. To be considered for presentation, a completed study proposal must be submitted prior to the designated PERUKI meeting. The template for this is available on the website.

The Research Steering Committee will review the study proposal to ensure it is not competing with any existing studies, and that the study is relevant to PEM. If the Research Steering Committee identifies a potential conflict with an existing PERUKI study, they will notify the Chief Investigators of both the proposed new study and the existing study with which there is a potential conflict. The Research Steering Committee will ask the two Chief Investigators to discuss potential conflicts and synergies to identify ways that the proposed and existing studies can be conducted and how they might enhance each other’s enrolment. Once their discussions are complete, the two Chief Investigators will submit a written report to the Research Steering Committee outlining all potential conflicts and how these might be resolved to allow for parallel conducting of both studies, and any potential synergies that might facilitate enrolment into each other’s study.

If an agreement on how to conduct both a new and existing study in parallel cannot be achieved, either of the Chief Investigators can ask the Research Steering Committee to mediate.

In choosing participating sites, PERUKI supports the principals of inclusiveness, openness, creating linkages and the promotion and fostering of research collaborations and excellence across all PERUKI sites. Therefore once reviewed and approved by the Research Steering Committee studies may be sent to all site representatives who will determine if their sites can participate and who from each



site will act as Principal Investigator. Chief Investigators may identify and liaise with proposed collaborating sites without the assistance of the Research Steering Committee or the Executive Committee.

The PERUKI name and/or logo should appear in presentations and manuscripts that result from PERUKI collaborations.

Pre-Meeting Study Proposal Guidelines

We require that we receive by email no later than 4 weeks before the designated PERUKI meeting:

1. A study proposal on the specified template.
2. A single page list of issues on which the presenter would like feedback from PERUKI members.

The study proposal and question list will be pre-circulated to Research Steering Committee members if it is received by the Secretary. It is best that these be submitted by email.

Research Steering Committee members are expected to read all study proposals that are pre-circulated, and to balance the discussion of background issues with those of design and execution.

The list of questions and issues should help focus the PERUKI members to discussion of issues that would be most helpful to the presenter.

Guidelines for Presenting

The following are not proscriptive, and the final format will depend on the content of the meeting.

Fully developed studies

There will be 45 minutes allotted for new studies. It is recommended to use no more than 15-20 minutes for presenting your study. Allow 25 minutes for group discussion and feedback on your pre-circulated questions and issues. The presenter and PERUKI members together must ensure that there is adequate time for group input around methodology and feasibility. The template for presentations is on the website.

Begin with a structured abstract, including the clinical question it addresses, the basic design features, and the population, intervention and outcomes of interest. Give a brief presentation of previous work in this area ensuring that study designs, sample sizes, results and conclusions are clear.

Spend most time on the methods of your study. Focus primarily on the study design issues that are most difficult, debatable, and/or those for which you would most appreciate feedback. While any issue on any protocol may be reasonable fodder for discussion, it is primarily your (i.e., the presenter's) responsibility to ensure that issues of greatest importance to you are discussed.

Report tentative plans for your study over the next 6-12 months, and identify the goals you hope to achieve before the next Research Steering Committee meeting. This should include:



1. Systematic reviews.
2. Protocol revisions.
3. Background work such as feasibility studies.
4. Requests for collaboration.
5. Potential grant submissions.

Partially developed studies

This may be a novel idea with the ultimate intention of developing a fully-fledged multicentre protocol, or a completed single centre trial presented with the intention of developing a multi-centre trial. These types of studies will only be considered if the Chief Investigator has the ultimate intention of developing a PERUKI multi-centre trial.

Presentations of partially developed studies will be allotted 20 minutes. You should use no more than 10 minutes for presenting your study proposal, leaving 10 minutes for group discussion.

Present a brief background, the core study idea or question, and as much of the methods as possible. The more developed your proposal is, the better feedback you will receive.

Present a plan for further developing your study idea in as much detail as is possible.

Post Presentation Guidelines

Following each presentation, the Research Steering Committee will discuss the project and the Chair will verbally summarize the issues discussed and the suggestions for the project.

Approval as a PERUKI study will be decided by consensus of the Research Steering Committee.

Alternatively the Chief Investigator will be advised what remains to be done prior to submitting for review and obtaining a letter of support from the PERUKI Research Steering Committee.

The PERUKI Secretary will summarise the foregoing in written format, which will be sent to each presenter after the meeting.

Ongoing studies

The Chief Investigator is expected to present an update about ongoing PERUKI studies at the Research Steering Committee meetings in person or through a member of the Research Steering Committee.

A one page update of all ongoing PERUKI studies should be supplied by the Chief Investigator to the Research Steering Committee by email 4 weeks prior to the designated PERUKI meeting. This should address enrolment, and any other important issues. The Chief Investigator of all ongoing studies will also provide a verbal update at the Annual Meeting.

If investigators of on-going trials have new study issues about which they would like general feedback, they may ask to give a longer formal presentation of 20 minutes that includes slides.



Completed studies

Investigators who have completed a PERUKI trial will be allotted 15 minutes to present their results (10 minutes for presentation and 5 minutes for discussion).

Present your study in the same format that you would use for an oral presentation at a medical conference.

Begin with the study title and authors, a brief summary of why this issue is important and previously published work. Clearly state the study question.

Present your methods in sufficient detail to provide listeners with a clear understanding of your study design.

Succinctly present your study results focusing on the primary and secondary outcomes of interest.

In addition to reporting your study's results, you should also discuss their implications, and what further follow-up studies might be pursued.

Prior to the meeting, the investigator should submit an abstract of their study's objectives, methods, results, and discussion.

(adapted from PERC, PREDICT)

Topic-specific Workstreams

It is expected that there will be a number of studies on a similar topic running at any one time. This is particularly so for some of the more important or common conditions we see. Each topic-specific workstream will be appointed a lead. As opposed to individual studies which may be proposed by any PERUKI member, each workstream lead should be a member of the Research Steering Committee in order to ensure a higher level of integration and feedback is achieved for the workstreams. Workstream leads will be selected by the committee following expressions of interest addressed to the Executive Committee.



Guidelines for Authorship and Publications

Authorship

Prior to the start of any PERUKI study the Chief Investigator and Site Principal Investigators should agree upon the contribution of each member to the study and the implications this has on authorship. Participation in PERUKI studies does not guarantee authorship. All publications arising as a result of collaboration in PERUKI should however be written “on behalf of PERUKI”.

Chief Investigators should adhere to “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical considerations in the conduct and reporting of research: Authorship and contributorship” (published by the International Committee of Medical Journal Editors, available at www.icmje.org, accessed 1st February 2013) as follows:

Byline authors

An “author” is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications. *An author must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors’ ability and integrity.* In the past, readers were rarely provided with information about contributions to studies from persons listed as authors and in Acknowledgments. Some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole.

While contributorship and guarantorship policies obviously remove much of the ambiguity surrounding contributions, they leave unresolved the question of the quantity and quality of contribution that qualify for authorship. The ICJME has recommended the following criteria for authorship; these criteria are still appropriate for journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multi-centre group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments. The NLM (National Library of Medicine) indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.



- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Some journals now also request that one or more authors, referred to as “guarantors,” be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

Increasingly, authorship of multicenter trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship/contributorship.

The group should jointly make decisions about contributors/authors before submitting the manuscript for publication. The corresponding author/guarantor should be prepared to explain the presence and order of these individuals. It is not the role of editors to make authorship/contributorship decisions or to arbitrate conflicts related to authorship.

Contributors Listed in Acknowledgments

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chairperson who provided only general support. Editors should ask corresponding authors to declare whether they had assistance with study design, data collection, data analysis, or manuscript preparation. If such assistance was available, the authors should disclose the identity of the individuals who provided this assistance and the entity that supported it in the published article. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under such headings as “clinical investigators” or “participating investigators,” and their function or contribution should be described—for example, “served as scientific advisors,” “critically reviewed the study proposal,” “collected data,” or “provided and cared for study patients.” Because readers may infer their endorsement of the data and conclusions, these persons must give written permission to be acknowledged.



Publications

All PERUKI members may propose publications or presentations related to PERUKI projects. Members are required to submit topics in advance, and the topic must be approved by the lead study team. The Executive Committee will share the topic with all Research Steering Committee members and relevant Site Principal Investigators to determine the writing team. The writing team will present a plan for the publication or presentation with content, proposed writing team and timeline to the Executive Committee for approval. The writing team should reflect study participation and the role of the Chief Investigator. Any trial data accessed in this way by PERUKI members who are not on the main study team is shared with the understanding that it will be treated confidentially pending the publication of any resulting articles.

Material submitted to the Executive Committee for review will be circulated to all Research Steering Committee members and Site Principal Investigators. Following group discussion in person or by electronic means the Executive Committee will recommend approval, approval with modification or disapproval and communicate this to the lead author.

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 PERUKI is required in all publications and presentations.

(adapted from PERC, PECARN, PREDICT)



Interactions with other International Paediatric Emergency Medicine Research Networks

PERUKI aims to collaborate with other like minded individuals and bodies. Close relationships with other international PEM research networks are therefore encouraged and fostered. These groups include 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), and Research in European Paediatric Emergency Medicine (REPEM).

PERUKI is a formal member network 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 will be filled by the PERUKI Chair and Immediate Past Chair.

As a formal member network, PERUKI is committed to delivering studies which have been approved as PERN studies. A PERUKI lead will be sought from the Research Steering Committee (though a member may fill this role only 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 will undertake all necessary legal and ethical processes, and may consider applying for funding.

Updates of PERN and other collaborative studies will be 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 research in PEM. In order to promote free flow of ideas among PERUKI members, there must be an expectation of ethical behaviour among participants. Collaborative research can only flourish in an atmosphere of openness and trust. With PERUKI membership each individual must agree to follow this Code of Ethical Behaviour for Multicentre Clinical Trials. This expectation of ethical behaviour extends to interactions with industry and other funding partners.

Ethical Behaviour among Investigators

The "intellectual property" of a PERUKI protocol belongs primarily to the Chief Investigator(s) and secondarily to the Principal Investigators. When a protocol is introduced to PERUKI by a Chief Investigator, other PERUKI members should declare any real or potential conflicts of interest and absent themselves from further discussions of the protocol. 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 outside of the PERUKI framework. Once a PERUKI member 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 PERUKI study.

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

Prior to beginning a study, rules of interaction should be established between investigators. These "rules" 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 PERUKI Research Steering Committee members.

Ethical Behaviour in the Interactions with Industry Partners

When an industry-generated protocol is presented to PERUKI for 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 PERUKI investigators without the permission of the industry partner.

When an investigator-generated protocol is submitted to industry for consideration, it remains the intellectual property of PERUKI and confidentiality should be maintained. The protocol should not be modified or used by industry without the permission of PERUKI. PERUKI expects that industry



partners who choose not to fund a PERUKI study will not undertake the same or similar studies with a PERUKI member without the approval of PERUKI.

Breaches of Ethics by PERUKI Members or by Industry Representatives

Allegations of breaches of ethical behaviour by PERUKI members will be brought to the attention of the PERUKI Executive 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, the PERUKI Executive 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 PERUKI member 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 PERUKI members with the offending party.

Appeals of Executive Committee decisions can be made to an appeals committee comprised of one member representative of each PERUKI affiliate 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 PERUKI governing principles and/or code of ethical behaviour. Any proposed revisions, once approved by the entire Executive Committee, must be submitted to the PERUKI Research Steering Committee for ratification. A majority of those voting will constitute ratification.

