

Paediatric

Emergency

Research in the United Kingdom & Ireland

(PERUKI)

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| ***V8.1, PERUKI Executive Committee******April 2021*** |

*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 develop a set of evidence based clinical operational standards that PERUKI members aspire to.
3. To deliver independent research studies in collaboration with clinical trials units
4. To create a “Route to Research” pathway to develop academic and research capacity in our membership
5. For all PERUKI publications to be available open access
6. 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 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 by these links: Individual and Site

## 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 member

Members of the Executive Committee are elected from members of the Research Steering Committee (RSC) or those who have made contributions to PERUKI business such as study review and delivery 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 RSC.

An election for Vice Chair is held every three years by secret ballot. The Immediate Past Chair will solicit nominations from members at least one month in advance of elections. Nominations must come with support from any two PERUKImembers in good standing. Once elected they will serve as Vice Chair for three years. While the initial committee was structure was designed with a view to keeping progression to Chair for a three-year term, and subsequently Immediate Past Chair for a three-year term it may not be possible for a person to commit to this longer term role. Therefore the Vice Chair should stand for re-election at the end of their term to the Chair role and applications for Chair from the RSC (not wider membership are possible). 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 and Treasurer follow the same process and will be held every three years by secret ballot. The Immediate Past Chair will solicit nominations from members at least one month in advance of elections. Any PERUKImember in good standing may nominate another PERUKImember (with their consent) for either position. PERUKI is committed to encouraged equality and diversity.

The Trainee Member serves a 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 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 are responsible for:

1. Keeping accurate minutes of Executive Committee and Research Steering Committee meetings and presenting these to the Research Steering Committee (with copies available on the website)
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. Website and Social Media Secretary

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

The Royal College of Emergency Medicine and Royal College of Paediatrics and Child Health could 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.

## Research Steering Committee

The Research Steering Committee (RSC) 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 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 meet regularly 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 PERUKIstudies
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 should attend and promote formal PERUKI meetings, and regularly attend PERUKIteleconferences. If a site representative (or proxy) misses three consecutive meetings either in face or teleconference the site will be contacted about their ongoing involvement in PERUKI. Further absence may result (at the discretion of the executive committee) in the termination of site membership.

Site representatives should not serve as the Site Principal Investigator for every PERUKIproject, but should 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. The ideal for new study review is for Chief Investigators (or their proxy) to propose their research prior to a face-to-face PERUKI meeting (where it should be formally presented) and have their study adopted as a “PERUKIstudy”. However deadlines for grant applications do not always permit this to take place; where this is not possible the Research Steering Committee will review proposals electronically and/or by teleconference. We aim to maximise the chance that Chief Investigators will receive constructive and informative feedback. Any PERUKImember may bring forward a study to the PERUKIResearch Steering Committee for consideration. The Executive Committee have the discretion 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 (available at https://goo.gl/8VesY2).

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 Chief Investigator should develop the research question and the study proposal. To be considered for presentation at PERUKI meeting, a completed study proposal must be submitted no later than 6 weeks prior to the designated PERUKI meeting. The template for this is available on the [website](http://www.peruki.org).

The Research Steering Committee reviews study proposals to ensure they do not compete with existing studies, and that they are deliverable, and relevant to PEM. 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 member 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. Chief Investigators may identify and liaise with proposed collaborating sites without the assistance of the Research Steering Committee or the Executive Committee.

The PERUKIname and/or logo should appear in presentations and manuscripts that result from PERUKIcollaborations.

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. 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.

All PERUKI studies should take a “modified open access” approach to the data collected. Clinical report forms will be available for review, and PERUKI members may submit original questions and a potential publication plan to the study team. If the data are available these will be provided and the member who raised the question may lead on developing the output in collaboration with the study team who should be included as byline authors as per authorship guidance.

Data should not be used by contributing sites unless this has been specifically agreed with the study team in order to avoid any conflict of interest.

### Pre-Meeting Study Proposal Guidelines

We suggest that we receive by email no later than 6 weeks before the designated PERUKImeeting:

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

The study proposal and question list is circulated to the Research Steering Committee, who will balance the discussion of background issues with those of design and execution. A list of questions and issues contained in the study proposal will help focus a discussion of issues 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 PERUKImembers together must ensure that there is adequate time for group input around methodology and feasibility.

Begin with a structured abstract including the clinical question, the design, the population, intervention, and outcomes of interest. Briefly present previous work in this area ensuring that relevant information such as 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 PERUKImulti-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 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. Adoption of a PERUKIstudy 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 PERUKIResearch Steering Committee. The PERUKISecretary, or nominated deputy, will summarise the foregoing in written format, which will be sent to each presenter after the meeting.

## Ongoing studies

The Chief Investigator should present updates about ongoing PERUKIstudies at Research Steering Committee meetings, either in person or through a member of the Research Steering Committee.

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

If investigators of ongoing 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 PERUKIstudies 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 – this is often a good opportunity to explore what questions will likely be asked, and will almost always inform and improve the content of any written outputs.

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 summary of their study’s objectives, methods, results, and discussion in a format suitable for publication on the PERUKI website

*(adapted from PERC, PREDICT)*

# Guidelines for Authorship and Publications

## Authorship

Prior to the start of any PERUKIstudy the Chief Investigator and Executive Committee should have agreed upon the contribution of each member to the study and the implications this has on authorship. Participation in PERUKIstudies does not guarantee authorship. All publications arising as a result of collaboration in PERUKI should however be written “on behalf of 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 PERUKI studies. 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 “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](http://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.

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 meeting all the following conditions:
	+ substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
	+ drafting the article or revising it critically for important intellectual content
	+ final approval of the version to be published
* 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 may 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 do 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.

Increasingly, authorship of multi-centre 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 where possible should give written permission to be acknowledged.

## Publications

All final drafts of publications which utilise reference PERUKI must be seen by the PERUKI Executive Committee member who is sponsor for that particular study. They will ensure the final version of the output is in accordance with PERUKI values and if site leads are named in the manuscript that they are happy to be named.

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.

*(adapted from PERC, PECARN, PREDICT)*

# 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 or GAPRUKI.
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 studies which have been approved as PERN studies. A PERUKI lead(s) is sought from the Research Steering Committee (though a non-committee 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 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.

PERN studies are peer reviewed by organisations within PERN. A study adopted by PERN will automatically be adopted by PERUKI unless the PERUKI PERN representatives do not feel this is appropriate. In this situation the RSC would be asked to review the PERN study. This may mean that the study is rejected by PERUKI and this would mean that PERUKI would not participate in that particular PERN study

# 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 PERUKImembers, there is an expectation of ethical behaviour among participants. Collaborative research can only flourish in an atmosphere of openness and trust. With PERUKImembership each individual agrees 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 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 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. 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 the 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.