



General and Adolescent Paediatric Research in the United Kingdom & Ireland (GAPRUKI)

*V1.1, GAPRUKI Executive Committee
October 2020*

Operational Policy

Contents

| | |
|---|----|
| Vision, Goals and Ambitions | 3 |
| Vision..... | 3 |
| Goals | 3 |
| Ambitions..... | 3 |
| Membership and structure | 4 |
| Membership..... | 4 |
| Executive Committee | 5 |
| Research Steering Committee | 6 |
| Guidelines for the Review of Studies | 7 |
| New studies..... | 7 |
| General Principles | 7 |
| Pre-Meeting Study Proposal Guidelines | 8 |
| Ongoing studies | 8 |
| Guidelines for Authorship and Publications | 9 |
| Authorship | 9 |
| Byline authors | 9 |
| Contributors Listed in Acknowledgments..... | 10 |
| Publications..... | 11 |
| Interactions with other International Paediatric Emergency Medicine Research Networks | 12 |
| Code of Ethical Behaviour for Multicentre Clinical Trials | 13 |
| Principles..... | 13 |
| Ethical Behaviour among Investigators | 13 |
| Ethical Behaviour in the Interactions with Industry Partners..... | 13 |
| Breaches of Ethics by GAPRUKI Members or by Industry Representatives..... | 14 |
| Revision of GAPRUKI governing principles and code of ethical behaviour..... | 14 |

Vision, Goals and Ambitions

Vision

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

Goals

1. To strengthen general paediatric 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 general paediatric research
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
7. To work collaboratively with other networks and groups including community paediatrics and emergency networks
8. To support the participation of children, young people and their families in the development of research projects and to work in collaboration where appropriate

Ambitions

1. To be a leading academic organisation for general paediatric research in the UK & Ireland
2. To raise the profile of general paediatrics as a thriving academic speciality in its own right including developing the skills of the next generation of paediatricians
3. To deliver independent research studies in collaboration with clinical trials units
4. To develop academic and research capacity in our membership
5. For all GAPRUKI publications to be available open access
6. To improve collaborative research working between primary, community, secondary and tertiary care

Membership and structure

Membership

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

Active membership is encouraged for the benefit of the organisation and its members. Membership will be monitored by the Executive Committee in conjunction with feedback from study Chief Investigators and GAPRUKI interactions. Members who have not responded to GAPRUKI communication for 2 years may be removed from the mailing list. The executive committee may review membership with a view to supporting sites, suggesting temporary suspension, or in rare circumstances, revocation of membership.

Members must abide by the GAPRUKI 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.

GAPRUKI member meetings (face-to-face or virtual) are organised to update members on ongoing and completed studies, discuss potential new studies, share research-related process updates, and share the forward view. The Executive Committee will draw up the agenda with input from GAPRUKI members. Informal meetings may also be arranged in association with any major conference that is relevant to general paediatrics. Other communications will occur regularly through teleconferences, email, and the GAPRUKI website.

Membership forms are available on the website.

GAPRUKI members should not serve as the Site Principal Investigator for every GAPRUKI project, but should identify which of their colleagues are interested in this role. It is optimal that a range of staff participate in GAPRUKI studies. Similarly, while it is expected that all members should complete GAPRUKI surveys, this can be delegated to someone else at the members site if appropriate.

All contributions to studies, will be recognised, where this is possible, via electronic certificate.

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
7. Website and social media representative
8. Parent/carer organisation representative (PPI/lay member)

Members of the Executive Committee are elected from GAPRUKI members or those who have made contributions to GAPRUKI business such as study review and delivery by majority vote through ballot. Executive Committee members can be removed from office by a vote in favour of removal of two-thirds of the membership.

An election for Vice Chair is held every three years by 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 GAPRUKI members in good standing. Once elected they will serve as Vice Chair for three years, with a view to keeping progression to Chair for a three-year term, and subsequently Immediate Past Chair for a three-year term. Where this described progression is not possible (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 and website and social media representative follow the same process and will be held every three years by ballot. The Immediate Past Chair will solicit nominations from members at least one month in advance of elections. Any GAPRUKI member in good standing may nominate another GAPRUKI member (with their consent) for either position. GAPRUKI is committed to encouraging equality and diversity.

The Trainee Member can be nominated by any GAPRUKI member and approved by the executive committee. The trainee member will usually serve a 3 year term, or may step down if these leave the training programme or take up a consultant post.

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. Developing GAPRUKI regulations and guidelines
2. Keeping accurate minutes of Executive Committee meetings
3. Administering funds that come into GAPRUKI and providing an annual financial report
4. Setting meeting agendas

5. Communication with members
6. Maintaining up-to-date membership contact lists
7. Reviewing and approving the general research agenda of GAPRUKI alongside the Research Steering Committee (RSC)
8. Reviewing new and ongoing GAPRUKI studies and addressing issues
9. Communicating regularly with RSC chair

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 (RSC) is the body who will review submitted studies and surveys and provide feedback to the executive committee and recommendations on which studies should be supported by GAPRUKI. It consists of 8-10 members (selected by self-nomination, with 1 supporting GAPRUKI member) from the GAPRUKI membership ideally including a representative from each of England, Ireland, Scotland, Wales and Northern Ireland. 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, and on voting matters a majority of those voting will see the matter approved. It will meet regularly by teleconference or video conference, and in person at least once a year (if circumstances allow).

The RSC is responsible for:

1. Reviewing and approving the general research agenda of GAPRUKI alongside the Executive Committee
2. Reviewing study proposal from members
3. Determining which studies to conduct as GAPRUKI studies
4. Determining if topic-specific working groups or sub-committees should be formed
5. Managing the process of application of sites to participate in GAPRUKI studies
6. Reviewing the GAPRUKI research priorities on a regular basis

There are several benefits to researchers of submitting a proposal to the GAPRUKI research steering committee (RSC). First, the committee will provide friendly and honest peer review. Second, the final funding application of a project may be strengthened by a statement that the project has the approval of the RSC. Third, the applicant may establish a network of potential recruitment centres through the GAPRUKI (in addition to the pre-existing NIHR networks).

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. Chief Investigators (or their proxy) should propose their research via the study submission form for discussion at the next Research Steering Committee meeting. A decision will then be made as to whether the study will be adopted as a “GAPRUKI study”. The Research Steering Committee will review proposals electronically and/or by teleconference as required if needed between meetings. The Research Steering Committee will provide constructive and informative feedback to Chief Investigators. Any GAPRUKI member may submit a study to the GAPRUKI Research Steering Committee for consideration.

Weighting may be given to studies meeting the questions raised in the GAPRUKI research prioritisation process (currently being prepared for publication) and likely to attract funding.

A GAPRUKI study must involve more than one centre. However, as few as two centres working collaboratively may constitute a GAPRUKI study. GAPRUKI may 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 discussion at a GAPRUKI Research Steering Committee meeting, a completed study proposal must be submitted no later than 6 weeks prior to the meeting. The template for study proposals is available on the GAPRUKI website.

The Research Steering Committee reviews study proposals to ensure they do not compete with existing studies, and that they are deliverable, and relevant to general paediatrics. 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, GAPRUKI supports the principals of inclusiveness, openness, creating linkages and the promotion and fostering of research collaborations and excellence across all GAPRUKI sites. Studies approved by the Research Steering Committee are sent to appropriate members 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.

Pre-Meeting Study Proposal Guidelines

The Research Steering Committee need to receive by email (no later than 6 weeks before the next meeting) a study proposal on the specified template (see website) ensuring that all sections are completed, in particular the section 'specific areas in which you would like input from the group'.

The study proposal will be 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 proposer.

Ongoing studies

The Chief Investigator should submit updates about ongoing GAPRUKI studies to the Research Steering Committee on a 6 monthly basis and liaise regularly with their link committee member. They could also send copies of report that are required for the CLRN. Ongoing GAPRUKI studies will be reviewed by the RSC at least twice a year.

Guidelines for Authorship and Publications

Authorship

Publication plans should be developed early in the life of a GAPRUKI study, and should be available on request. This should be a living document, updated by the study team as required.

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

Prior to the start of any GAPRUKI study the Chief Investigator, Executive Committee and Research Steering Committee should have agreed upon the contribution of each member to the study and the implications this has on authorship. Participation in GAPRUKI studies does not guarantee authorship. All publications arising as a result of collaboration in GAPRUKI should however be written “on behalf of GAPRUKI”.

In order to ensure that standards of research governance, conduct, and written content expected for GAPRUKI studies are maintained, at least one member of the Executive Committee or RSC must be included in the study team on all GAPRUKI 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.

All GAPRUKI studies should take a “modified open access” approach to the data collected. Clinical report forms will be available for review, and GAPRUKI 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.

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.

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 reference GAPRUKI must be seen by the GAPRUKI Executive Committee or RSC member who is the link for that particular study. They will ensure the final version of the output is in accordance with GAPRUKI 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 GAPRUKI is required in all publications and presentations.

(adapted from PERUKI, PERC, PECARN, PREDICT)

Interactions with other International Paediatric Emergency Medicine Research Networks

GAPUKI collaborates continuously with other like-minded individuals and bodies. Close relationships with other national paediatric research networks (such as PERUKI) and international general paediatric research networks (such as Australian and Canadian) are therefore encouraged and fostered. These groups include

- i) UK & Ireland based organisations such as PERUKI.
- ii) International organisations which include the Australian and Canadian networks.

Code of Ethical Behaviour for Multicentre Clinical Trials

Principles

GAPRUKI is a collaborative network of investigators who share their intellectual property and resources for the common goal of undertaking research in general paediatrics. In order to promote free flow of ideas among GAPRUKI members, there is an expectation of ethical behaviour among participants. Collaborative research can only flourish in an atmosphere of openness and trust. With GAPRUKI membership 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 GAPRUKI protocol belongs primarily to the Chief Investigator(s) and secondarily to the Principal Investigators. When a protocol is introduced to GAPRUKI by a Chief Investigator, other GAPRUKI members 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 GAPRUKI 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 GAPRUKI study.

In the event that a GAPRUKI study 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 GAPRUKI study. 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 GAPRUKI Research Steering Committee and Executive Committee members.

Ethical Behaviour in the Interactions with Industry Partners

When an industry-generated protocol is presented to GAPRUKI 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 GAPRUKI investigators 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 GAPRUKI and confidentiality should be maintained. The protocol should not be modified or used by industry without the permission of GAPRUKI. GAPRUKI expects that industry partners

who choose not to fund a GAPRUKI study will not undertake the same or similar studies with a GAPRUKI member without the approval of GAPRUKI. An agreement should be made at the study set-up stage that GAPRUKI will be credited in authorship of future publications and study outputs.

Breaches of Ethics by GAPRUKI 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 GAPRUKI members should be brought to the attention of the GAPRUKI Executive Committee who will serve as the review committee of GAPRUKI. 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 GAPRUKI 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 GAPRUKI 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 GAPRUKI members with the offending party.

Appeals of Executive Committee decisions can be made to the RSC. Appeals to decisions made by the RSC can be made to the executive committee.

(adapted from PERUKI, PERC, PREDICT)

Revision of GAPRUKI governing principles and code of ethical behaviour

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