



Patient and Public Involvement & Engagement (PPIE) in Experimental Medicine and Early Phase Studies in Children & Young People(CYP)

**NIHR ALDER HEY CLINICAL RESEARCH
FACILITY (AHCRF) PPIE STRATEGY 2017-2022**

1. AHCRF Vision

The National Institute for Health Research (NIHR) Alder Hey Clinical Research Facility (AHCRF) will improve the health and well-being of children by providing a world-class centre of expertise that is internationally competitive in driving the development of better, safer medicines and other therapies for babies, children and young people (CYP)

2. Introduction

The NIHR AHCRF aims to deliver a seamless, high quality environment across the age groups for experimental medicine research, delivering meaningful involvement and engagement of babies, CYP, and their families.

Patient, family and public involvement and engagement (PPIE) is a central element to the work of the AHCRF and this document sets out our approach to PPIE, the vision, background, strategic priorities for 2017-2022, and an implementation plan.

We will align our work to National NIHR Strategies (Going the Extra Mile¹; UK Clinical Research Facility PPIE Strategy, and continue to work with leaders in the field to ensure our program of work complies with National Standards² for PPIE.

3. Our Vision

We will use transparent processes for working with patients, families and members of the public, thus ensuring that experimental medicine and early phase study development in the AHCRF can flourish in an informed and inclusive environment.

4. Background

PPIE in experimental medicine and early phase studies in CYP has underpinned every aspect of the AHCRF to date. During the first funding round from 2012-2017

¹ NIHR Going the Extra Mile: <https://www.nihr.ac.uk/news/going-the-extra-mile-a-strategic-review-of-public-involvement-in-the-national-institute-for-health-research/2739>

² <http://www.invo.org.uk/current-work/standards/>

extensive PPIE activities had been carried out informed by a PPIE strategy and implementation plan³. This was achieved through national leadership and expertise, driving forward in partnership with GenerationR Young Person's Advisory Groups (YPAGs), working co-creatively with: the James Lind Initiative; One NIHR (Going the Extra Mile); European Medicines Agency Network of Paediatric Research Networks (EnprEMA); and establishing International collaborations (e.g. International Children's Advisory Network (iCAN) and the European Young Person's Advisory Group Network (eYPAGnet) in PPIE amongst CYP.

This strategy builds upon the 2012-2017 PPIE strategy and has been developed in collaboration with patients and families, and is aligned to the delivery and overall strategic aims of the AHCRF.

5. Strategic Priorities

We will achieve this by the following five strategic priorities:

Strategic Priority 1: Work in partnership with CYP, families, members of the public and researchers in the design and delivery of experimental and early phase research

Strategic Priority 2: Continuous improvement through patient experience and public awareness

Strategic Priority 3: Widen participation and involvement of CYP and families in AHCRF activities

Strategic Priority 4: Grow the evidence base of the impact of CYP and family involvement and engagement in the design and delivery of experimental and early phase research.

Strategic Priority 5: Engage, inform, educate and stimulate thinking about the work of the AHCRF among the citizens of today and tomorrow in Liverpool, nationally and Internationally

³ <http://generationr.org.uk/wp-content/uploads/2017/10/CRF-PPI-Strategy-2012-2017.pdf>

6. Implementation Plan (2017-2022)

Key objectives in these five areas are listed below. This encompasses PPIE actions at whole organisation/AHCRF and in collaboration with our partners in the Royal Liverpool & Broadgreen Hospital University Trust (RLBHUT) Clinical Research Unit (CRU), UK Clinical Research Facility Network (UKCRFN), and within individual research projects and themes.

Strategic Priority 1: Work in partnership with children, young people, families, members of the public and researchers in the design and delivery of experimental and early phase research

To achieve this, the AHCRF will:

1.1	Equip researchers with the necessary skills to undertake effective PPIE activities by promoting PPIE to all Theme (Infection, Musculoskeletal, Oncology, and Neurosciences) Leads and others.
1.2	Increase the quality of experimental medicine studies by embedding CYP and family involvement in the earliest stages of research design, including patient-led input into the prioritisation and management of experimental and early phase studies.
1.3	Continue to build effective partnerships to deliver training and support for researchers about the importance of involving young people and families in early phase research design and delivery, examples include: development of an online toolkit to involve young people http://ypag.grip-network.org
1.4	Continue to partner with key stakeholders (Regulators; Industry, Charities, Academia) to co-develop innovative projects that empowers CYP and their families to participate in experimental and early phase research (Projects such as the NIHR HS&DR TRECA Study – an innovative project to assist young people and their parents to decide whether to participate in a clinical trial using multimedia information resources)
1.5	Work with the Core Outcome Measures in Effectiveness Trials (COMET)

	Initiative to co-produce with CYP lay summaries to explain patient outcome measures
1.6	Pilot a model of how to engage with CYP and families in the development of Paediatric Investigation Plans (PIPs) for experimental and early phase studies in CYP in collaboration with the European Medicines Agency, European Paediatric Formulations Initiative, and European Young Person's Advisory Group Network (eYPAGnet).
1.7	Continue to partner with the Health Research Authority, and European Medicines Agency to ensure the informed assent/consent/risk v benefits of participating in clinical trials is explained to CYP in formats that they understand and want.
1.8	Continue partnerships with the Paediatric Medicines Research Unit (PMRU) to develop paediatric formulations and devices that are safe and effective and age-appropriate.

Strategic Priority 2: Continuous Improvement through patient experience and public awareness

To achieve this, the AHCRF will:

2.1	Systematically undertake patient experience surveys with CYP and families who use the CRF, using CYP age-appropriate and co-produced questionnaire. Results will inform ways of working within the CRF and results will be published and shared
2.2	Continuously improve how we communicate research to patients and the public by disseminating and collecting research awareness surveys that inform the AHCRF, RLBHUT and UKCRFN communication strategies.
2.3	Share learning both locally and nationally via the UKCRFN and wider NIHR (e.g. I Am Research Campaign; International Clinical Trials Day etc.)

Strategic Priority 3: Widen participation and involvement in AHCRF activities

To achieve this, the AHCRF will:

3.1	Lead on strategies to widen participation by developing outreach activities and publicising opportunities for involvement and engagement amongst CYP and families.
3.2	Build on strategic partnerships with Industry, Charities, Regulators, and Academia) and continue to set up joint projects to promote effectiveness of our PPIE strategy.
3.3	Continue to coordinate, share and support the active involvement of CYP and families locally, nationally and across the Globe, through forums such as: GenerationR Alliance; eYPAGnet, and iCAN.
3.4	Develop the role of Young Patient Research Ambassadors in collaboration with the NIHR Clinical Research Network Patient Research Ambassador Initiative to ensure CYP and their families are aware of research and view research as part of their care package.

Strategic Priority 4: Grow the evidence base of the impact of CYP and family involvement and engagement in the design and delivery of experimental and early phase clinical trials.

To achieve this, the CRF will:

4.1	All PPIE activities will be developed with specific objectives, methods, outputs and indicators for impact and aligned with existing methodological research such as: <ul style="list-style-type: none">➤ Public Involvement Impact Assessment Framework➤ Evidence Base for Public Involvement in Trials➤ Collaborations with the MRC Hub for Trials Methodology Research patient perspectives theme (Patient Centred Trials) –
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	Methodological (link) study, a Liverpool led MRC HTMR funded project to identify priorities of key PPI stakeholders for methodology research to resolve uncertainties about PPI in clinical trials, as well as to help coordinate and improve the design of future PPI work.
4.2	Develop specific objective, methods, outputs and indicators of CYP and family involvement activities
4.3	Develop specific objectives, methods to assess the impact of knowledge on CYP and families involved
4.2	Continue to share good practice, knowledge, skills and resources through our dedicated 'GenerationR', AHCRF and Royal Liverpool, UKCRF websites
4.3	Take forward recommendations highlighted in the James Lind Initiative, Impact Report co-authored by the PPIE Manager
4.4	Join the NIHR Senior PPIE Team Impact Working Group to ensure our impact assessments are in line with the whole of the NIHR and wider.
4.5	Build in PPIE into AHCRF Quality Assurance Processes and Reporting to systematically collect and monitor data on PPIE activities.

Strategic Priority 5: Engage, inform, educate and stimulate thinking about the work of the AHCRF among the citizens of today and tomorrow in Liverpool, Nationally and Internationally

To achieve this, the CRF will:

5.1	Engender greater understanding and awareness of medical research amongst children, young people, their families and members of the public through AHCRF Research, Education, Awareness, Program (REAP). The objectives of REAP are to: (1) to consult actively and meaningfully (i.e. through two-way dialogue); (2) to raise awareness of biomedical and medical technology research amongst patients, families and members of the public; and (3) to
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	<p>create a unique, sustainable cohort of children and families who are available to participate in and contribute to research for CYP.</p> <p>We will expand our engagement with young people locally and nationally through our school's outreach program and continue via STEMNET to promote scientific careers and engage young people with CRF activities to include:</p> <ul style="list-style-type: none"> ● Holding regular hands-on workshops, including laboratory- based activities, with patients and school pupils introducing them to cutting edge biomedical research (Lupus Day; Jasmine's Visit, etc.); ● Developing curriculum and continuing professional development re- sources for teachers, to ensure that teaching practices reflect contemporary biomedical research (in partnership with the James Lind Initiative); ● Collaborating with the National Citizen Service Program in the North West to incorporate learning about medical research; ● Undertaking attitudinal research, surveys and focus groups and workshops with patients and members of the public on issues such as, undertaking research in children, practical challenges, risk versus benefits, adverse drug reactions, what are clinical trials, views of children's biobanks and taking samples from healthy children, development of a 'Consent 4 Consent' programme (based on CRU's established, successful approach).
5.2	<p>Develop the role of Young Patient Research Ambassadors - We will promote active involvement and engagement of Young Patient Research Ambassadors via the NIHR Patient Research Ambassador Initiative, which embeds a patient-centred research culture in the NHS by engaging patients, the public and NHS care staff in research more effectively. We will specifically lead on and develop the role of Young Patient Research Ambassadors who are ideally placed to raise the profile and awareness of research undertaken at AHCRF. This will include developing partnerships with the British Society for Antimicrobial</p>

	Resistance and Antibiotic Action to establish and support a national group of Young Antibiotic Ambassadors.
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7. Partners and Collaborations

We will continue to partner with key stakeholders (Regulators; Industry, Charities, Academia) to co-develop innovative projects that empowers CYP and their families to participate in experimental and early phase research. We will also continue to work with relevant PPIE activities in other programmes, such as: UKCRF Network, INVOLVE, One NIHR, EUPATI, MRC HTMR, EUPFI, Life Sciences Strategy and so on.

We will also continue to work with eYPAGnet, iCAN and other relevant initiatives including the Paediatric Clinical Research Infrastructure Network (PEDCRIN), and the European Joint Programme for Rare Diseases.

This will ensure that the CRF is in a prime position to benefit from ongoing activity and maximise resources for new involvement/engagement activities

8. Leadership and Governance

Leadership is provided by the AHCRF PPIE Manager. The PPIE work stream program of work is reported to the AHCRF Steering Committee via the AHCRF Senior Management Team. The NIHR AHCRF reports annually to the NIHR. A summary of PPIE activities and their impact forms part of this report. The PPIE Manager is responsible for collating and summarising this information.

9. Resources

Named PPIE Work Stream Lead: Jenny Preston. Youth Participation and Family Support Officer: Sammy Ainsworth. Budget allocated for PPIE activities awarded in April 2017 to cover GenerationR Liverpool YPAG meetings; Parent & Carers Forum; Design and on-going costs for GenerationR website and regular meetings and teleconferences with GenerationR YPAG facilitators across the country.

10. Monitoring, Reporting and Review Arrangements

Delivery of the PPIE Work stream objectives is reviewed and monitored at AHCRF Operational and Senior Management Team meetings. Work stream outputs and impact are reported annually to NIHR and at UKCRF Network Annual Conference.

11. Communication and Dissemination

We will develop an effective communications/social media strategy and implementation plan with young people and families to 'reach-out' to as many stakeholders as possible about CRF work. The strategy will include the continuation and support of national awareness raising campaigns such as NIHR 'IAmResearch' and International Clinical Trials Day; educating CYP about medical research through the media, and via public engagement events to share cutting edge research with the public, for example 'Meet the Scientist' – a series of family- friendly weekend events, in partnership with the World Museum.