NHS
National Institute for Health Research

GenerationR
young people improving Research

GenerationR Liverpool YPAG Annual Report

2016-2017

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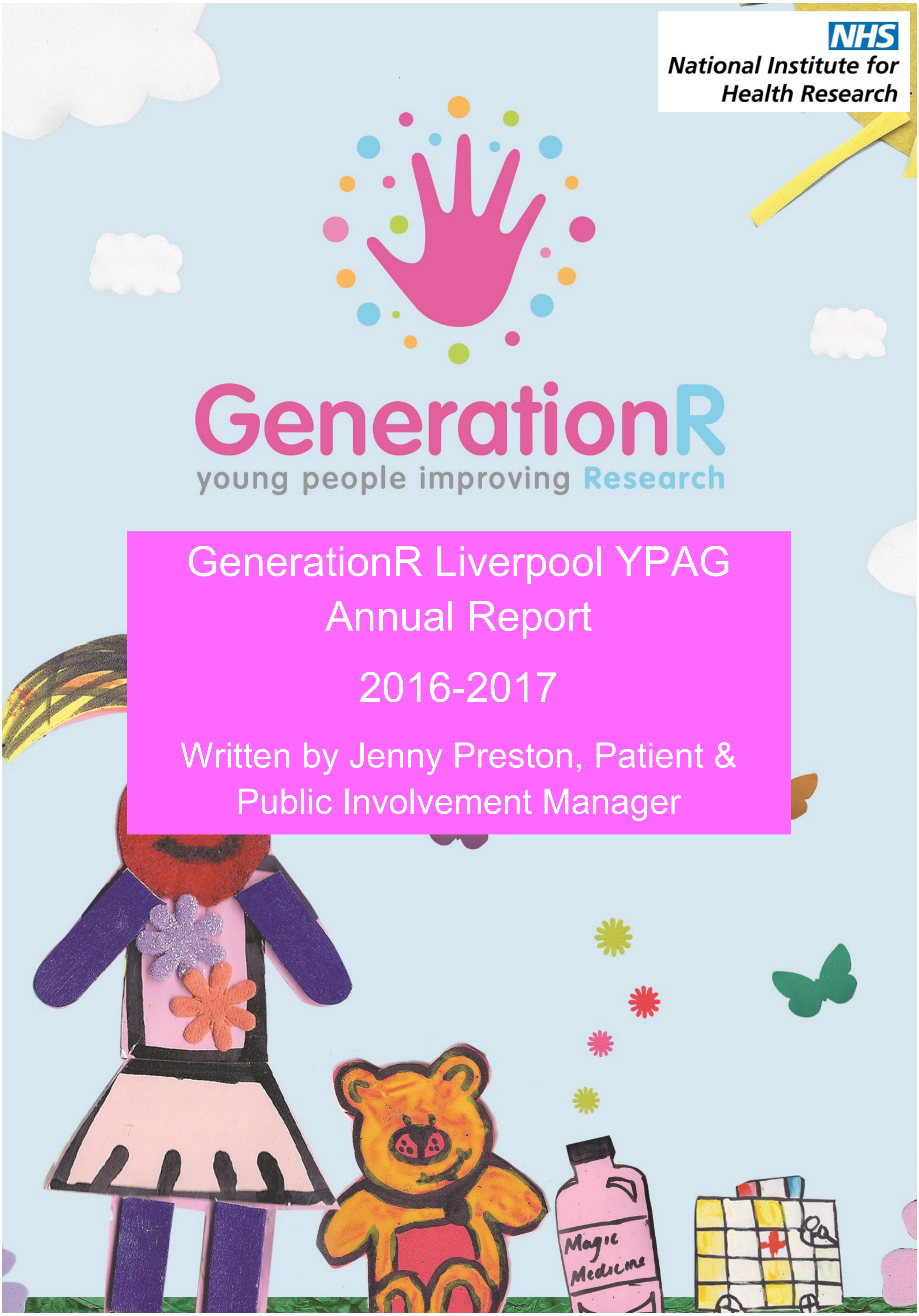

Introduction & Background:

GenerationR is a National Young Persons' Advisory Group made up of local young people's groups across the UK. Groups are funded by the National Institute for Health Research and/or other National Health Service organisations, through various channels.

The GenerationR Liverpool Young Person's Advisory Group (YPAG) was set up in 2006 and currently has around 14 young people aged between 13-19yrs old. Some members have experience of taking part in health research, some have experience of living with a condition or disability, and some wish to pursue a career in medicine/research/science. The Liverpool YPAG meets approximately every six weeks at the Institute in the Park at Alder Hey Children's NHS Foundation Trust.

Until the 1st April 2015 the group was funded by the National Institute for Health Research (NIHR) Clinical Research Network: Children. The group is now funded by NIHR Alder Hey Children's NHS Foundation Trust Clinical Research Facility (CRF). The group supports the key objectives of the CRF PPIE strategy providing a Local, National and International forum for advice to researchers working on paediatric research.

Planning & Processes of accessing the YPAG:

If a researcher or research team wishes to access the group a discussion takes place with the PPIE Manager and a study details form (Appendix 1) is completed to address questions such as study details (e.g. type of study, stage of study etc.); type of PPI activity (e.g. review of protocol, review of patient information sheet, outcome measures etc.); expected outcomes from the activity and evaluation methods.

Once a decision has been made as to the type of activity required, the researcher will be then asked to sign a Researcher Agreement Form, (Appendix 2) which sets out very clearly what to expect from the group and what the group expects in return. We strongly encourage researchers to attend YPAG meetings face to face so that effective dialogue can be achieved but this isn't always possible so the PPIE Manager is happy to undertake the activity specified.

Several weeks after the consultation has taken place the facilitator will contact the researcher to gain some feedback (Appendix 3) as to what happened as a result of the young people's input, for example, did anything change to the protocol or patient information sheet as a result of the group's comments and did this go through ethics without any problems? This is really important as it demonstrates the impact of young people's role in the design and delivery of paediatric research. See the feedback and impact section below.

One-Stop Support Service for Researchers:

In total eight YPAG meetings were held in the reporting period between April 2016 - March 2017. A total of 22 projects incorporating clinical research, and quality improvement projects have been presented at YPAG meetings. The diversity of projects and range of specialities, and organisations represented is evidenced in the list below:

Date	**Title Presentation**	**Project**
April 2016	**YPAG meeting:** Study in children & teenagers with Type 1 diabetes to test a new insulin called insulin-glargine - U300 (Sanofi): Patient Information Sheet Review	Research

	GRASP study - effect of closed loop on progression of Type 1 diabetes from onset in youth (Wellcome Trust - MRC funded project): Patient Information Sheet Review	Research
May 2016	**YPAG meeting:**	
	Major Depressive Disorder Study: Patient Information Sheet Review	Research
	A Randomised, Active-Controlled, Open-Label, Flexible-Dose Study to Assess the Safety and Tolerability of Topiramate as Monotherapy compared with Levetiracetam as Monotherapy in Paediatric Participants with New or Recent - Onset Epilepsy. (Janssen-Cilag International NV): Patient Information Sheet Review	Research
June 2016	**YPAG meeting:**	
	Day and night closed loop in young people with Type 1 diabetes (Wellcome Trust - MRC funded project): Patient Information Sheet Review	Research
	Study on Valasertib for the treatment of acute myeloid leukemia in children (Boehringer Ingelheim): Patient Information Sheet Review	Research
September 2016	**YPAG Meeting:**	
	Lilly Script & Storyboard - Being in a Research	Research

	Study	
November 2016	Clinical Research Facility Patient Questionnaires (Senior Research Nurse, CRF)	Quality Improvement
December 2016	**YPAG meeting:**	
	Development of a Paediatric ICF Template. (GW Pharma). Poster abstract accepted for conference (link)	Research
	Clinical Nutrition Acceptability Study (Vitaflo): Patient Information Sheet Review	Research
	Voices Study: interview questions advice	Research
	A randomised, double-blind, multicentre, placebo-controlled study to evaluate the safety and efficacy of methoxyflurane (PENTHROX®) for the treatment of acute pain in children and adolescents from 6 to less than 18 years of age presenting to an emergency department with minor trauma (Quintiles): Patient Information Sheet Review	Research
	A Treatment of Juvenile psoriatic arthritis (JPsA) and enthesitis-related arthritis (ERA) (types of Juvenile Idiopathic Arthritis) (Novartis): Patient Information Sheet Review	Research

January 2017	**YPAG Meeting:**	
	CAM-Pain study - child and adolescent musculoskeletal pain in primary care: Patient Information Sheet Review, recruitment discussions; outcome measures important to young people	Research
	Voices Project - Qualitative Study. Discussion on young people's views on outcome measures and ways to disseminate findings	Research
	100,000 Genomics Project - Patient Information Sheet Review	Research
	The TRECA study: TRials Engagement in Children and Adolescents. Patient Information Sheet Review	Research
	Open Label Evolocumab Study in Patients Aged 10-17yrs with HeFH & HoFH (Amgen): Patient Information Sheet Review	Research
	Evaluation of faecal volatile organic compounds in the diagnosis of paediatric inflammatory bowel disease: Patient Information Sheet Review	Research
	What helps children bounce back from having a major physical injury. Patient Information Sheet Review	Research
March 2017	**YPAG meeting:**	

	Young people's views of delivering intravenous antibiotics at home for children with severe bacterial infections: Early stage study review	Research
	Elbow study - patient information sheet and logo review	Research

Feedback & Impact:

Feedback from researchers were received for most of the above activities (some are still being collated). Several researchers also provided thank you letters to the group to be kept for their portfolio of activities. Below are just a few examples of thanks and recognition they receive as a result of their input:

" We have developed a more user friendly study information booklet, and created multiple versions that are age appropriate. All patient facing material was reviewed by the YPAG and we have made numerous changes and additions to improve readability following feedback. The YPAG suggested we broaden our correspondence options with potential participants to include electronic platforms, and we have now included email contact details. We have expanded the range of options for where the interviews can take place to include participant's home or local GP at a time that suits the participant. The group also provided a number of useful suggestions beyond the scope of this current study, for example the use of a monetary "gift voucher" for participation; this is something that we will consider in the development of future studies.This is just a summary of the recommendations we have acted upon, and we feel the design and methods of the study have been improved substantially by your help and advice. We are also more than happy to feedback on the key results of our study in due course". (Dr Paul Campbell: Principal

Investigator CAM-Pain Study)

"I would like to show my appreciation for the opportunity to gain invaluable feedback on many aspects of my research project. The help and guidance that I received was useful and all members of the team were helpful and very professional". (Elbow study: Principal Investigator)

"I would like to thank you immensely for your review of the patient information sheets and informed consent forms (PIS,ICFs) for our study. With your help we now have received Ethics Committee approval for our study and the patient documents. This means that in 2017 we will be helping to find a new treatment for paediatric patients with heart failure in the UK & globally and furthering the research in this condition….The Ethics Committee were happy with your review. They read this with interest and were really pleased with your recommendations.. This was the first time I had heard about GenerationR.. The work you do is invaluable to research in the UK" (Katie Smith: Clinical Project Manager, Novartis)

Assessing the impact of young people's involvement

A project, commissioned by the James Lind Initiative, and led by the PPIE Manager and independent research consultant (Dr Louca-Mai Brady) looked at young people's involvement in the design and delivery of research studies adopted by National Institute for Health Research (NIHR) Clinical Research Network: Children (CRN Children). The project explored what information was available on how and when young people are involved in health research, and what difference this involvement makes to research and to the young people involved.

We looked at the information CRN Children and the GenerationR Young People's Advisory Groups collect on when and how young people are involved in research, and then talked to professionals who work in public involvement. We found that:

- Most of the information collected is about the stages of research in which people have been involved, but there is hardly any information on who was involved and how;

- There is currently no way of finding out which young people were involved in CRN Children studies, whether studies had involved young people rather than their parents, or what difference any involvement may have made.

The report, available to download: http://generationr.org.uk/wp-content/uploads/2017/05/Impact-of-CYPs-involvement_JLI__GenR2.pdf) makes recommendations about how NIHR could find out more who is involved in research and how, as well as what difference this involvement makes to research and to the young people involved.

Engagement, Involvement and Promotional Activities

Engaging, informing, educating and stimulating thinking about clinical research is achieved through our Research, Education, Awareness, Program (REAP) (Appendix 4) The Liverpool YPAG and Patient Research Ambassadors are committed to engaging with a variety of audiences including young people, clinical staff, patients, and members of the public. Here are some of the activities the group, and families have undertaken this year:

July 2016 - Poster for the International Children's Advisory Network (iCAN) Summit 2016

- Members of the YPAG developed a poster about GenerationR for the International Children's Advisory Network Summit 2016 the poster can be found at: http://generationr.org.uk/wp-content/uploads/2017/05/ican-poster-final.jpg

July 2016 - GenerationR attendance at the iCAN Summit 2016

- Five members of the GenerationR Liverpool Group attended the iCAN Summit in Barcelona. iCAN is a Global consortium of Youth Advisory Groups (YPAGs) working together to provide a voice for children and families in paediatric medicine through synergy, communication and collaboration. A blog of the Summit produced by a member of the group can be found at: https://www.linkedin.com/pulse/ican-summit-2016-simon-stones

October 2016 - European Medicines Agency (EMA) meeting

- "Better medicines for children". 10-11th October. Participation in a panel discussion on "How can Children, carers and families contribute to drug development?". Sophie Ainsworth (Founder of RAiISE: Raising `Awareness of Invisible Illnesses in Schools and Education,GenR and Young Ambassador) attended the meeting to present about the work of GenerationR and how she got involved via her personal experience of being diagnosed with Lupus. Presentation slides can be found here: http://generationr.org.uk/liverpool/

18th March 2017 - RAiISE Meeting

- Sophie Ainsworth (Young Lupus Patient from Alder Hey CRF) held a focus group meeting with parents, young people and teachers to develop resources for the information pack for schools to help young people cope with living with an invisible illness. Sophie's latest blog can be found here: http://generationr.org.uk/living-with-an-invisible-illness-part-5/

March 2017 - Patient & Family led Charity event to raise awareness of research

- Patients and families held a Charity Concert to raise awareness of research undertaken at Alder Hey Children's Hospital. Over 450 people attended the concert and raised over £5000. For a video of the event click here:

http://www.clitheroeadvertiser.co.uk/news/crowds-enjoy-hey-clitheroe-music-extravaganza-1-8423965

March 2017 - NIHR ‘I Am Research’ Campaign

- Members of the YPAG contributed to the naming of the campaign, artwork and content for information leaflets. Further information can be found here: https://www.nihr.ac.uk/news-and-events/support-our-campaigns/i-am-research/

April 2017 - Statement of aspiration: improving research by involving children and young people published

- A number of key life-sciences industry representatives have signed up to a *statement of aspiration* which highlights the importance of active collaboration with children and young people and their parents to improve research. It acknowledges the role of Young Persons’ Advisory Groups in facilitating this kind of involvement in the UK and stresses the need to find secure funding for these groups. The statement was an outcome of a meeting hosted by the Nuffield Council on 22 April 2016 which brought together young people (members of GenerationR), industry representatives and staff from the National Institute of Health Research (NIHR). So far, signatories include: The Association of the British Pharmaceutical Industry (ABPI); AstraZeneca; The Ethical Medicines Industry Group (EMIG); GenerationR; GSK; The Health Research Authority (HRA); The National Institute for Health Research (NIHR); Proveca; Quintiles; Roche and UCB. The ‘Statement of Aspiration” can be found here: http://nuffieldbioethics.org/wp-content/uploads/Statement-of-aspiration-involving-CYP-in-research.pdf

4-5 May 2017 - European Patients Forum

- Jenny Preston delivered a training session to the European Patients Forum (EPF) Youth Group on Ethics and Conflicts of Interest in Research. 8 young people were present at the meeting and represented several countries and various medical conditions. Slides can be found here: http://generationr.org.uk/liverpool/

North West Coast Awards

- Young Patient Research Ambassador wins award at the NIHR North West Coast Award for 'Outstanding contributions to patient and public involvement'. Find out more here: https://www.youtube.com/watch?v=n1Nrz0D-6fU&feature=youtu.be

11th April 2017 - Lupus Awareness Raising Event

- Sophie Ainsworth (Lupus Patient), parents and staff held a research information stand at Alder Hey Children's Hospital to highlight research into Lupus and research in general. They distributed questionnaires to patients, families and staff about their understanding and awareness of research.

Patient Focused Medicine Development (PFMD) Initiative

- Patient Focused Medicines Development (PFMD) aims to transform the way in which we understand, engage, and partner with patients globally in the design and development of research and medicines by focusing on unmet patient needs. PFMD are bringing together and synergizing disparate but complementary efforts that integrate the voice of the PATIENT across the lifecycle of medicine. PFMD was established in October 2015 as an open, independent global coalition of health stakeholders. GenerationR included in the searchable tool to promote and highlight the model for engaging and involving young people in health research. Find out more here: https://involvement-mapping.patientfocusedmedicine.org/initiatives/generation-r?from=search

Conclusion

The GenerationR Liverpool YPAG and Patient Research Ambassador's continue to bring insight, intelligence, enthusiasm and compassion to discussions with researchers and other key stakeholders. The group have achieved a considerable amount over the year and continue to be an invaluable resource for researchers across the Globe. Looking ahead for 2017-18 brings exciting new projects as well as maintaining a high standard of support for researchers. The group will be involved in the development of educational tools and curriculum to teach more young people about key issues in clinical research, work alongside life science partners throughout the lifecycle of a study and be instrumental in the establishment and development of a European Young Person's Advisory Group Network (eYPAGnet).

(Appendix 1) - Study data capturing form

Study data	Field required
Date approached	
PPI lead	Jenny Preston
Name of researcher/investigator	
Contact details	
Name of study	
Protocol Number (If Industry Study)	
Type of study	
Stage of study	
Where did you hear about GenerationR Young Persons' Advisory Group?	
PPI Activity	
Type of activity (review of protocol, patient information sheet design etc.)	
Background to Study	
Deadline for activities to take place	
Can the researcher attend the next young person's meeting?	
Outcome of activity **(To be completed by PPI Manager)**	
Month activity actually took place	
Is this a one off consultation or on-going?	
What was the main outcome of the activity?	
Evaluation of the activity **(To be completed by PPI Manager)**	
Did you evaluate the activity?	
After activity has taken place	
Have you received feedback from the researcher	

Appendix 2 (Researcher Agreement)

Agreement between researchers and GenerationR Young Person's Advisory Group (YPAG)

We are **GenerationR Young Person's Advisory Group (YPAG)**; our aim is to improve the way research is done with children and young people. We have lots of experience in aiding researchers.

What we will do for you

- Give our opinions on the study from a young person's perspective
- Help you make the study more child/young person friendly by giving you our opinions
- Review or write patient information leaflets and any other related documents
- We are happy to spend a reasonable amount of time on each task
- We will take part in and conduct focus groups
- Help with your funding and ethics applications

Although we are happy to help with your research, there are a few things we expect in return for helping you with your study.

- We would appreciate a thank you letter for our portfolios in recognition of our efforts
- We would like an update on any changes you have made to the protocol/ information leaflet, successful funding and ethics applications
- We would be happy to receive any feedback/constructive criticism you may have about our input into your study and about our group by completion of a researcher evaluation form

Please sign this agreement to confirm that you are happy with these terms.

On behalf of GeneratiionR YPAG

Researcher..
....

Appendix 3 - Researcher Feedback Form

GeneratiomR Liverpool Young Person's Advisory Group

Involvement Feedback form for Researchers

Please tick and provide more details as necessary.

1. How did you hear about the young person's advisory group?

Please specify

2. What was the main purpose of accessing the young person's advisory group?

Exploring a possible research question – early stages of protocol development	
Ethical approval	
Consultation to research funding application (for example, RfPB)	
RCT – Protocol review or study design	
Diary design	
Questionnaire design	
Patient Information Leaflets	
Other	

Please specify

3. How much time did you allow for consultation prior to an ethics submission or funding submission (if applicable)?

Less than 1 month	
Less than 2 months	
Less than 3 months	
3-6 months	
6-12 months	
12 months +	

4. How satisfied were you with the process of engaging with the young person's advisory group:

Please specify 1 being the lowest level of satisfaction 10 being the highest

Information provided in advance of the young person's meeting	
Organisation of meeting with the group	
Outcome from the meeting	

5. Did the responses from the group have an impact on your research?

Yes		No	

If yes, please specify

6. Did you feel you got everything that you needed from the group?

Yes		No	

If no, what more could have been done?

7. Would you recommend the young persons' group to other colleagues?

Yes		No	

Please add any other comments you have

Thank you for completing this form.