



BPSU Study guidance – Patient and Public Involvement (PPI) for BPSU studies

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Paediatric Surveillance Unit

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BPSU parent bodies:



with support from:



Purpose

The intention of this guidance is to brief applicants about PPI so that they can engage with appropriate individuals and organisations in order to write clear and concise submissions which have a high probability of success when submitted to the BPSU Scientific Advisory Committee for endorsement.

Introduction

The term 'patient and public involvement' (PPI) is used to describe the active involvement of both patients and/or members of the public as collaborators in research. In recent years PPI has become an important part of all health research with major funders (<https://www.nihr.ac.uk/patients-and-public/>) considering it an essential criterion for success.

BPSU clinical studies are unique in that there is no individual patient consent process, all the data being collected by paediatricians from medical records, so it is essential to involve either patients, who bring their lived experience to the research process, or members of the public, particularly where there are potential wider public health implications resulting from the research.

Why PPI is important

Overall the purpose is to improve the development, design, conduct, dissemination and action throughout BPSU research studies. Good PPI keeps the research centred on the benefits for patient whether direct or indirect, in both the short or long term. This patient centeredness helps to keep all stakeholder interests aligned and has a value in itself as has been shown to improve research outcomes, create new hypotheses, better guidelines and more relevant public health policy.

Of particular importance is to:

- ensure the study produces information that is of value to patients and their families.
- ensure study development and design are focused on value for public benefit.
- ensure openness, transparency and accountability to the public for the use of personal information.
- overcome ethical concerns that individuals with rare conditions may be identified, even when the data has been anonymised.
- reassure ethics committees that patients/the public are supportive of your research.
- improve communication with members of the public when studies are of a controversial or of a sensitive nature.
- enable appropriate media coverage and policy advocacy by groups representing either patients or the public when taking action based on research findings.

Who you should consult, when and how

Completing PPI is a bespoke process individual to each application because it is determined by the nature of the study and the ease and availability of interested individuals or organisations. However, making early approaches enhances mutual respect between the research group and PPI and

facilitates sincere, meaningful and continuing involvement throughout the research process.

Finding appropriate individuals, groups or organisations that represent the interests of patients or the public covering the areas of your research, can, on occasions, be challenging. However, there is considerable expertise in this area including:

- BPSU Scientific Committee PPI representatives.
- PPI representatives on local Research Design Services (RDS).
- Relevant charities and support organisations, whose remit may or may not be disease or condition specific.
- Social media sites.
- Consulting the People in Research website.

Before you approach anyone, it is important to have an early succinct/concise/clear description of the proposed research where PPI involvement would become beneficial:

- your research -including clear objectives and methods,
- your expectations of PPI involvement -why and how you wish to involve people, what you would like from them and how much time this will take,
- how you will support people and if you are able to pay for their time.

There is no one single right way conduct PPI. The options can include any of the following:

- Consulting individuals via email or by phone.
- Meeting informally with patients, members of the public or patient group representatives.
- Inviting a patient, member of the public or patient representative to be on your project steering/advisory group.
- Consulting with people more formally through focus or discussion groups.
- Holding workshops for larger groups of people - possibly also involving other stakeholders.

The stages of PPI consultation.

It is essential to have patient and public involvement throughout the development, design, delivery and dissemination of the research project.

1. **Development.** This is the most important stage-since being clear about what is being studied, why and the development of clear research objectives are all vital for successful study design. Patients bring a user perspective, compared to those of the clinician, just as public involvement might focus on the burden of the condition to society.
2. **Design.** Well-resourced patient support organisations often have a wealth of information about the condition, what other research is being undertaken and the priorities for their members. They may be

able to contribute financially, to questionnaire design, provide case studies and help interpret results.

3. **Delivery.** The public information leaflet is the primary method of communication between researchers, patients, families and the public about the background to the study. PPI ensures that information is appropriate and easily understood by patients and the public.
4. **Dissemination.** Dissemination of results is often overlooked by researchers, but significant findings need to be communicated to the world if action or improvement is expected. PPI organisations may have significant media and advocacy experience to help disseminate the results and implications of BPSU study findings. In particular they may
 - make reports more accessible and relevant to a wide range of audiences
 - make messages more powerful
 - contribute patient stories/experiences that can bring the results to life
 - advocate report findings to policymakers and other health service stakeholders
 - ensuring results are made available to patients
 - ensure research findings are acted upon.

BPSU Scientific Committee expectations.

As a minimum, the BPSU expects to see involvement in:

- the study designs.
- producing the lay summary for the BPSU study.
- producing the Public Information Leaflet (PIL).
- the interpretation of the findings.
- producing a lay summary of the findings for dissemination.

At the P1 stage BPSU expects documented evidence of:

- who you have involved and how.
- the outcome of this involvement.
- and whether PPI has been considered and how PPI has influenced you so far.

At the P2 stage the expectation is that there will be clear evidence of

- support from PPI organisations for the research
- their subsequent involvement during and after the study
- whether PPI has been budgeted for

Appendix

Advice on writing lay summaries.

The BPSU SC often receives patient leaflets that are poorly written with long and complex sentences which is surprising as many patient/public oriented social media sites, relaying health information, are excellent examples of communication simply because they have involved either the public or patients in their development.

There are two essential features of a 'good' lay summary: that it contains the information that patients/the public want to hear about and is written in plain English i.e. content and language. Lay summaries will be needed when

- describing of your study when approaching PPI organisations,
- a lay summary of your proposed study, for the BPSU application form,
- a public information leaflet,
- a summary of the results.

Lay summary content

- why it is being undertaken
- who is funding the work
- what it is investigating
- where it is taking place
- time period
- how the information will be collected
- what are the possible risks and benefits?
- assurance of anonymity and confidentiality
- who should be contacted if there are any questions about the study

Lay summary Language and writing style

- Think about your audience.
- Talk directly to your reader.
- Use simple words and avoid scientific jargon and acronyms.
- Be positive and direct.
- Use active verbs rather than passive ones.
- Avoid long complicated sentences.
- If acronyms are unavoidable, include their meaning on first use.
- Don't turn verbs into nouns.
- Test your writing with patients and patient representatives/members of the public.

References

- 1) Patient and Public Involvement (PPI): Feedback from Researchers to PPI Contributors. The Centre for Research in Public Health and Community Care.
<https://www.herts.ac.uk/research/centres/cripacc/patient-experience-and-public-involvement>
- 2) BPSU. Patient and Public Involvement Guidance for Research Supported by the BPSU.
https://www.rcpch.ac.uk/sites/default/files/2018-04/bpsu_ppi_guidance4_0.pdf

NIHR. Patient and public involvement in health and social care research: A handbook for researchers.