National Institute for Health Research

NIHR Leeds Biomedical Research Centre (BRC) Patient and Public Involvement (PPI) Group

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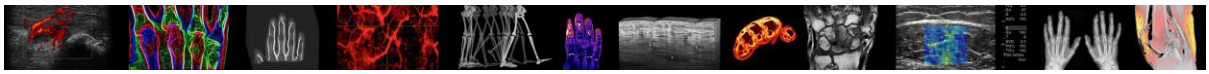

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List of Abbreviations

CI	**Chief investigator, overall responsibility for a study**
PI	**Principal Investigator, responsible for study at a site**
CRN	**Clinical Research Network**
GCP	**Good Clinical Practice**
INVOLVE	**The national advisory group that supports public involvement in the NHS, public health, social care and research.**
BRC	**Biomedical Research Centre**
MSK	**Musculoskeletal**
NIHR	**National Institute of Health Research**
PPI	**Patient and Public Involvement**
R&D	**Research & Development**
REC	**Research Ethics Committee**
RCT	**Randomised controlled clinical trial**

NIHR Leeds Biomedical Research Centre
Patient and Public Involvement Group

Background

The Leeds Biomedical Research Centre is funded through the National Institute of Health Research (NIHR). The aim of the unit is to be a world class leader in the diagnosis, management and prevention of musculoskeletal diseases. Integral to receiving NIHR funding, is that the BRC's research activities must be centred on research that will make a difference to patient treatment (known as translational research). The NIHR state that patients and the public must be actively involved in planning and reviewing research activities as:

> *"involving patients and members of the public in research can lead to better research, clearer outcomes, and faster uptake of new evidence".*

The NIHR encourages patients and the public to be actively involved in all NIHR-funded health and social care research, to:

- Set research priorities
- Identify the important questions that health and social care research needs to answer
- Give their views on research proposals alongside clinicians, methodologists, scientists, and public health and other professionals
- Help assess proposals for funding
- Be active partners in the research process for clinical trials and other health and social care research studies
- Publicise the results

Many people involved in PPI describe involvement in research as follows:

> *as research that is done **with** or **by** the public and not **to**, **about** or **for** them.*

The BRC Patient and Public Involvement Group was established in 2009, formalising the ad-hoc patient consultation that was being conducted across several different groups in Leeds for musculoskeletal research.

Mission statement/Purpose

'To create a successful partnership between PPI and research through oversight and review of the research activities of the BRC. This will ensure researchers engage effectively with the patients, public and carers, creating a successful partnership between PPI and research to ensure that research planning, conduct and communication of results is undertaken in accordance with the best interests of the patients.'

Requirements to achieve the aims of the BRC Patient and Public Involvement Group

The PPI group will work in partnership with researchers to identify, design, prioritise, conduct and disseminate patient focussed research that is relevant, ethical and will make a difference to patient care. Our values can be summarised:

1. In order to maximise PPI involvement in the research process, members need access to appropriate training, expertise and support being involved at the earliest stage possible
2. To be active partners in the research process, researchers must engage with us using language that is appropriate to provide clear meaning and context of any research activities
3. Furthermore, any patient or participant literature must be presented in a manner which encourages true informed consent
4. We support inclusion, diversity and equity for all patients
5. In order for true participation on behalf of the PPI group in the partnership, we require adequate time to review and comment on requests given by researchers.
6. Requirement for PPI representatives to be appropriately acknowledged in relevant documentation regarding grant applications and trial steering committees to ensure recognition of PPI involvement.
7. PPI members should be informed of the outcome of their involvement by the researcher/s at the agreed time points.

Our roles in research

We seek to be actively involved in all aspects of the research process, but our activities are particularly focussed on the following:

Engaging researchers: We wish to encourage researchers to view projects from the perspective of the patient, rather than it being driven by the objectives of the research process. In order to do this, we ask them to consider specifically patient commitment (in terms of number of visits, timing of appointments, etc.), additional risks (particularly above and beyond what the alternative treatment involves), potential side effects and what happens with regard to treatment at the end of the study.

Our aim is to encourage researchers to explain these concepts in plain English and in a context by which patients and members of the public can make a truly informed choice as to the nature of the research. Provision of a jargon buster or glossary may be required.

Reviewing Grants and Planning Research: PPI review is now considered essential for particular grant schemes and the BRC PPI group is actively involved in this process. For meaningful review, the PPI group request that the researcher provides a summary of the research (Appendix 2) and/or role description (Appendix 1) as appropriate at least two weeks prior to the grant deadline. PPI feedback on the grant application may be through a focus group with PPI representatives.

Reviewing Patient Literature: It is suggested that all patient or participant based information is reviewed by PPI representatives, for clarity, accuracy and appropriateness. The review will be via email with responses collated by the BRC to forward to the researcher. Hard copies can be provided to PPI representatives if requested. The PPI group can also help researchers provide summaries in clear and concise language so non-medical individuals can easily understand the outcome of research studies.

Communicating research to the public: While researchers are proficient at communicating the results of studies in an academic forum such as publishing in scientific journals and presenting at conferences, the PPI group want to ensure that all research (a) provides feedback to the participants of the study as to the outcome of the research; (b) presents updates to BRC meetings such as "Ask the Researcher"; and (c) presents the outcomes of the research to the general public, either through the local media, or the BRC website.

PPI representatives on steering committees: Once grants have been approved and studies are ongoing, the study will be overseen by a steering group. PPI representatives often participate in the steering group in order to provide a patient perspective to the management of the study. It is suggested that where PPI representation is required, two PPI representatives are members of the steering group. Requests for PPI representatives for steering committees should be via completion of the role description (Appendix 2).

PPI representatives participating in focus groups and steering committees will be asked to sign a Code of Conduct including confidentiality requirements (Appendix 5).

Other ways Volunteers Can Be Involved

- Attend 'Ask the Researcher' seminars and other PPI meetings
- Suggest innovative ideas for research from the patient perspective

Useful Resources

INVOLVE was established in 1996 and is part of, and funded by, the National Institute for Health Research, to support active public involvement in NHS, public health and social care research. As a national advisory group their role is to bring together expertise, insight and experience in the field of public involvement in research, with the aim of advancing it as an essential part of the process by which research is identified, prioritised, designed, conducted and disseminated.

As part of the NIHR family, the BRC works with INVOLVE (www.invo.org.uk) and is extremely grateful for the guidance and support that has been developed by the group. Of particular note, we are guided by the following documents:

- Briefing notes for researchers:

http://www.invo.org.uk/resource-centre/resource-for-researchers/

- Developing training and support for public involvement in research:

http://www.invo.org.uk/resource-centre/training-resource/

- Payment guidelines for involvement:

http://www.invo.org.uk/wp-content/uploads/2012/11/INVOLVEPayment-Guiderev2012.pdf

- Jargon buster to understand research:

http://www.invo.org.uk/resource-centre/jargon-buster/

As a group, we also use the following resources:

- Plain English guidance

http://www.plainenglish.co.uk/files/howto.pdf

- Guidance on participant information sheets

http://www.hra-decisiontools.org.uk/consent/index.html

- General information on patient involvement in clinical research:

http://www.nihr.ac.uk/patients-and-public/

BRC Specific Resources

The BRC PPI group have developed some specific guidance to help PPI volunteers review different elements of the research process. These include the following:

(i) ***Role description template:*** designed to provide a description of the activity that members of the PPI group are being asked to participate in, including time commitment, expertise and support (Appendix 1) – particularly useful for researchers planning PPI focus groups / PPI representation on steering committees

(ii) ***Guidelines for researchers applying for grants*:** A summary sheet which researchers are asked to complete at least two weeks prior to their deadline which will be reviewed by PPI volunteers (Appendix 2)

(iii) ***Prompt list for PPI Reviewers:*** A prompt sheet to guide PPI reviewers through the grant process and provide structured feedback and review to researchers (Appendix 3).

(iv) ***Review of Patient Information & Literature***: Guide for PPI reviewers to provide structured feedback and review to researchers (Appendix 4)

(v) ***Code of Conduct:*** To be signed by PPI volunteers participating in focus groups or steering committees, or in receipt of confidential information such as grant applications (Appendix 5)

BRC Contacts

The BRC PPI activities are managed by:

Gwynneth Cracknell BRC PPIE Manager, g.t.cracknell@leeds.ac.uk, (0113) 3924485

Kirste Mellish, BRC Director of Operations: k.j.mellish@leeds.ac.uk, (0113) 39 24398

Up to date information on PPI activities can be found on the BRC website: www.lmbru.ac.uk by following the Patient and Public Involvement Group link on the home page.

For non- musculoskeletal research patient and public involvement please contact:

Leeds Teaching Hospitals: Donna Johnstone, 0113 3920155, donnajohnstone@nhs.net

Yorkshire Clinical Research Network: comms.crnyorkshumber@nihr.ac.uk

Appendices

Appendix One - Role Description Template

Purpose of document

This document is to be completed by researchers to indicate what is the nature and commitment of the assistance they are requiring of the PPI Group. Members will be given this information in order for them to make an informed view on whether they wish to participate in the activities. To be used for activities such as participation in focus groups and membership of steering committees.

NIHR Leeds BRC Patient & Public Involvement Role Description

Background: User involvement, also sometimes known as Patient and Public Involvement, is the creation of a partnership between users and researchers to try to make the research process more effective. The BRC, a collaboration between Leeds Teaching Hospital Trust and the University of Leeds, is a Biomedical Research Centre funded by the NIHR (National Institute of Health Research) to develop musculoskeletal research into responsive patient care.

Role:

User representative on: **[specify study]**

Purpose:

[**For example:** To give the patients' perspective to the development of a study focussing on …]

Details of the study:

[For example: Post operative leg length inequality is one of the key factors in patient pain and discomfort following total hip replacement. Implant sizing and positioning are vital for joint replacement success and these are assessed using x-rays pre and post-operatively respectively. This study and grant application will look at the process of image scaling for conventional x-ray images and to produce a prototype device that can be used within a clinical radiography environment to improve both accuracy and repeatability.

The team will produce prototype positioning/calibration devices, use these clinically and would like to evaluate their use with public and patient involvement prior to a design optimization process and repeat of the procedure to ensure devices are fit for purpose.**]**

A panel of researchers, including **[list of named researchers]** will develop this study protocol and grant application. We need to make sure that the study takes into account the needs of patients.

Role Responsibilities:

[add / modify as appropriate for the role]

- To be a representative of the views and concerns of other patients and carers.
- To offer advice, where you think it appropriate, on the study design and commitment that is being ask of patients in this study

- Contribute to discussion and the preparation of the final document (checking language is accessible for the lay summary, etc.)
- To share your experiences and views about patient and public involvement
- To identify ways in which the study could be improved

Commitment:

[add / modify as appropriate for the role]

- There is a requirement to attend **[specify meeting(s) frequency and duration]**
- We would like you to read and review the study documents, offering advice on the aspects that you think are important. We would expect this to take no longer than **[specify expected duration]**
- The term of involvement we require is **[Specify duration]** days/weeks for this particular grant role; however if you are willing to be an advisor on future grant applications, the term of the role could be until **[specify duration]**

Qualities:

User representatives should have experience, knowledge or interest as any of the following:

- As a patient
- As a family member or carer of a patient
- As a member of an organisation that represents patients and public interests in issues relating to **[add as appropriate]**

Essential criteria:

- The ability to represent and express the views of other patients and carers is essential to the role.
- The ability to engage in discussion with other participants
- Understanding of the issues relating to **[add specific detail]**
- Be able to maintain confidentiality
- Have the time to attend meetings and read final documentation if required.

Desirable criteria:

- Knowledge or experience of **[add specific detail]** would be advantageous but not essential.
- Have an understanding of research processes and procedures
- Have access to a computer and e-mail

Support:

- We wish to recruit **[add number]** members of the group for each meeting to provide support and advice.
- Researcher contact details **[add details]**
- Gwynneth Cracknell is the main contact for the group and can be contacted through the department on g.t.cracknell@leeds.ac.uk
- Training and access to resources such as terminology glossaries will be arranged as appropriate
- Regular updates or feedback will be provided on a regular basis as we value your commitment and participation
- User representation is unpaid. However, travel reimbursement is available up to £50 per session. Refreshments will be provided where appropriate.
- Child and carers care cover is not available.

Considerations before applying for the role:

- You will also be asked not to disclose any confidential information and to sign a Code of Conduct before participating. If unsure over confidentiality issues, this should be discussed with Gwynneth Cracknell.
- Do you have the time to be involved?
- What do you wish to achieve by being involved?
- What support would you require?

Thank you for your support.

Appendix Two - Reviewing Grant Applications Guidelines for Researchers

Purpose of document

This document is a summary sheet that all researchers who are preparing any grant application for review by the PPI Group must complete.

NIHR Leeds BRC Patient and Public Involvement

Grant Application Summary

Instructions to researchers

This sheet provides a summary to our PPI representatives of your grant application. It should be written using the plain English guidelines and in a manner which is understandable to a lay audience explaining all acronyms if used. This is important as many parts of your grant will be necessarily written in a scientific and/or research language, so this will be used by our representatives as an overall guide to what you are doing. Before preparing this, it is assumed that you have read the Briefing Notes for Researchers from the INVOLVE website: http://www.invo.org.uk/resource-centre/resource-for-researchers/

This should be used in conjunction with the role description as appropriate

Be clear as to what you are asking the PPI group to do and ensure you include that you will provide feedback using plain English avoiding excessive medical terminology.

Please ensure you have included funding for PPI expenses including travel reimbursement costs.

Once completed contact Gwynneth Cracknell for details how to access the group.

Name of Grant

Applicant/s

Type of Grant

Funding body:

Grant Type:

Duration:

Aim of the Study

Background information and rationale as to why the study is needed

Brief overview of the study plan

Include a study schedule visit if available.

What will be the commitment of patients for this study?

How will you recruit patients?

What will happen to patients at the end of the study?

How will you communicate the outcomes of the study to patients who are involved?

How will you communicate your findings to the general public?

How will you feedback to the PPI group as to the outcome of the study?

What PPI Involvement is required in this study?

What funding have you included for PPI Involvement? Please include travel reimbursement costs.

Appendix Three - Reviewing Grant Applications Prompts for PPI Members

Purpose of document

This document is a prompt sheet or guide that has been designed to be used by PPI members to assist them in reviewing grant applications. The PPIE manager will provide this to members reviewing grant applications, along with the Application for Grant Review, prepared by the researcher (Appendix 2).

Name of Grant

General Aspects of the Study

	Yes	No	Unsure
Are the aims of the study clear?	☐	☐	☐
Is there a direct patient benefit to:			
(a) Patients undertaking this study?	☐	☐	☐
(b) Future patients?	☐	☐	☐
Is the study plan clear?	☐	☐	☐
Are the study scheduled visits appropriate?	☐	☐	☐
Do you have any concerns as to the commitment on behalf of the patients for this study?	☐	☐	☐
Is the recruitment plan going to work?	☐	☐	☐
Is adequate feedback to be provided?	☐	☐	☐

Comments (including any 'unsure' selections):

Patient Treatment

	Yes	No	Unsure
Do you have any concerns about patient care at the end of the study?	☐	☐	☐

Comments, including any 'unsure' selections:

PPI Involvement

	Yes	No	Unsure
Is the PPI involvement appropriate for this study?	☐	☐	☐
Are appropriate costs included?	☐	☐	☐

Comments including any 'unsure' selections:

Recommendation

Please indicate your appraisal of the study:

- ☐ This study is appropriate
- ☐ This study has merit but requires modifications
- ☐ This study has considerable flaws and needs considerable work.
- ☐ This study is not appropriate

General Comments, if any:

Appendix Four - Review of Patient Literature Prompt Sheet for PPI Members

Purpose of document

This document is a prompt sheet for PPI members to provide feedback to researchers for any patient based literature.

Instructions to PPI volunteers

Please appraise the literature provided and complete the review below, adding comments and excerpts as examples if required. If you prefer you can make the comments on the copy of the patient information for the researcher to review.

Name of document

General Overview of the literature

	Yes	No	Unsure
Is the information provided concise and clear?	☐	☐	☐
Is the language easy to understand?	☐	☐	☐
Is the format easy to read?	☐	☐	☐
Is there excessive use of acronyms and terminology?	☐	☐	☐
Are appropriate contact details provided?	☐	☐	☐

Comments including any 'unsure' selections:

Modifications suggested

1.

2.

3.

4.

Summary

Please indicate your appraisal of the literature:

- ☐ This literature is appropriate
- ☐ This literature requires minor modifications
- ☐ This literature requires major modifications

Comments and suggestions:

Appendix Five – Code of Conduct

Code of Conduct
NIHR Leeds BRC PPI Volunteers

In order to provide active and positive engagement between researchers and PPI representatives, the BRC PPI group have agreed a code of conduct when reviewing, advising and consulting with researchers. This document provides a Code of Conduct, which sets out the standards of behaviours expected by PPI members when consulting on research.

The code of conduct is to be signed by volunteers participating in PPI activities such as focus groups or reviewing confidential information such as grant applications. The purpose is to:

- **Give assurance to PPI volunteers**
- **Give credibility to the group and ensure a professional understanding of the confidential nature of the material to be discussed and reviewed**
- **Give assurance to researchers**

The mission statement of the PPI Group is

> *'To create a successful partnership between PPI and research through oversight and review of the research activities of the BRC. This will ensure researchers engage effectively with the patients, public and carers, creating a successful partnership between PPI and research to ensure that research planning, conduct and communication of results is undertaken in accordance with the best interests of the patients.'*

PPI members agree to work in partnership with researchers to identify, design, prioritise, conduct and disseminate patient focussed research that is relevant, ethical and will make a difference to patient care.

Equality and diversity

PPI members' behaviour and attitudes are consistent with the aims of the BRC PPI Group to support inclusion, diversity and equity for patients

Respect

PPI Members must treat each other, researchers and others they come into contact with when working in their role with respect and courtesy at all times.

Confidentiality

PPI members must respect the status of confidential issues they read and discuss. They are bound to maintain the status of this material and any discussions.

Integrity

Members are required to use their knowledge, expertise and experience to take the best decisions they can in the interests of patient involvement. Members should also promote and support the principles of good governance by leadership and example and should act in an individual capacity and not as a representative of any group, organisation or individual.

Commitment
Members must devote sufficient time preparing for and attending agreed meetings to ensure they add value to the PPI Groups

No personal benefit
Members must not benefit from their position beyond what is allowed by the law and what is in the interests of the PPI Group. PPI staff time and resources must be used prudently. Members should take decisions solely in terms of the values of patient and public. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends

Conflicts of interest
Members should identify and promptly declare any actual, potential or perceived conflicts affecting them. They must absent themselves from any discussion where there is any such conflict.

Probity
Members must comply with any rules agreed by the PPI Group including those relating to the acceptance of gifts and hospitality and the avoidance of activities which might compromise the PPI Group's neutrality.

Openness and accountability
Members must be open, responsive and accountable to each other, members of staff and other stakeholders about their decisions, actions and work, including their use of PPI group resources.

Statement of acceptance

I have read and understood the above Code of Conduct for PPI members. I agree to abide by the standards set in the code.

Signed: ……..

Name (please print) ……..

Date ……