Lay Advice on Diabetes & Endocrine Research (LADDER)
Academic Directorate of Diabetes & Endocrinology

Frequently Asked PPI Questions

This document has been prepared by Patient Lay Advisory Panel within the Academic Directorate of Diabetes & Endocrinology (LADDER) at Sheffield Teaching Hospital NHS Foundation Trust. The document is designed to highlight key questions researchers and patient panel members may ask each other, when discussing research.

The document is in two sections and in each section the questions are broken down into the different phases of research. The sections are as follows:

SECTION 1 - Standard PPI questions researchers can ask a patient panel:

SECTION 2 Standard PPI questions a patient panel can ask a researcher:

We hope you find this document useful and we thank Sheffield Hospitals Charity for their support with all Patient and Public Research initiatives at our hospital.

If you have any comments on this document we would love to hear from you, please contact Lydia Harris (lydia.harris@sth.nhs.uk) or phone 0114 2265911.

If you wish to find out more about our Patient and Public Research initiatives please visit

http://www.sheffieldclinicalresearch.org/for-patients-public/

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SECTION 1 - Standard PPI questions researchers can ask a patient panel:

Pre Funding

1. **Identify Clinically Related Problem**
    - Do you think patients perceive this to be a problem?
    - Do you think this problem is worth investigating?
    - Is the proposed idea seen as worthwhile to patients?

2. **Establish the Research Question**
    - Is the research question clear to patients?
    - Do you think that the project is worthwhile?
    - Do you think the project will benefit patients?
    - Do you support the research in principle?

3. **Research Design**
    - Is the reason for doing the study clear?
    - Is the purpose of the study understandable?
    - Did you understand what the project was about from the Lay Summary alone without looking up terminology?
    - Do you think Lay members of the grant review panel would understand the lay summary and consider it a 'plain English' description?
    - Do you think patients will agree to participate?
    - Would high risk patients want to participate?
    - Is the patient journey clearly set out?
    - Is the patient journey appropriate?
    - Is the frequency of visits acceptable?
    - Is the interval between proposed study visits appropriate?
    - Are the requirements of the study acceptable to the participants?
    - Is the researcher asking too much of the patient at each study visit?
    - Are the proposed visits too long/intensive?
    - What could be done to make the project more acceptable to patients/participants?
    - Do you have concerns about the tolerability of the procedures?
    - Do you think the chance of receiving placebo would put people off participating in the study?
    - Should patients be offered longer term use of the medication being trialled, if it proves effective?
    - Do you think patient benefit is enough to motivate patients to participate or should another incentive be offered? E.g. compensation for time, reimbursement of travel expenses is reimbursement an incentive? Travel should always be reimbursed.
    - Do you have any concerns over the use of the proposed medications?
    - Do you think patients are 'cared for' enough in this study? (Refreshments, etc)

- Should patients be thanked for taking part?
- How should we distribute the results of the study to the participants and/or their relatives?
- Should lay members who are part of the TMG or project steering group be co-authors on any publications?
- Should we researchers formally acknowledge the contribution of participants and PPI groups in our publications?
- Have we budgeted enough for PPI?
- What is a patient's view of taking an unlicensed drug?
- Do you think anything has been missed?
- Can you think of ways to improve the research?
- What will help you understand the project better?
- Do you have any suggestions to enhance recruitment and retention to the study?
- If funded, would the panel/individual patient agree to act as part of the project steering committee?

4. **Submit Proposal**
    - Are any of the panel members interested in being a co-applicant?
    - Will the panel be able to review a final version before submission?

<u>Post Funding</u>

5. **Approval and Ethics**
    - Are any of the panel members interested in writing or reviewing the lay summary?
    - Are any of the panel members interested in writing or reviewing the patient information sheets?
    - What terminologies should be used/avoided in patient information sheets/consent form?
    - Do you understand what the project is about from the patient information sheets/consent form?
    - Should we write a summary sheet of the study, in friendly informal terms, to go in front of the PIS?
    - Do you understand from the patient information sheets/consent form what the patient journey is?
    - Would you consent to take part in the study if asked or do you have any outstanding questions after reading the patient information sheets/consent form?
    - Would anyone like to accompany me to the Ethics Committee to demonstrate support?
    - Do you think we should have posters and leaflets advertising the study in clinics?
    - Should we use social media and message boards to disseminate information about the study?

6. **Deliver and Complete the Study**

- Can you suggest contact avenues for getting more subject participants?
- Are any of the panel members interested in being part of the project steering group?
- Are any of the panel members interested in representing service users on the Trial Management group?
- Will the panel be willing to receive reports on progress at key stages?

7. Dissemination of Research Findings

- Can you suggest ways of sharing the results/findings with the general and target population?
- Are Panel members interested in participating in dissemination events?
- Will the Panel be willing to design/review dissemination materials from a patient viewpoint?
- Should we disseminate research findings via posters in clinic?

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SECTION 2 Standard PPI questions a patient panel can ask a researcher:

Pre Funding

1. Research Design

- What is the benefit to patients of participating?
- What is expected of the participant during the study?
- What is the participant journey and is it appropriate (are the frequency of visits and procedures at each visit acceptable)?
- Will the study drug/device be made available to participants when the study finishes?
- Are the proposals for recruitment realistic?
- Is the proposed duration of the study adequate to address the research question?
- Are there sufficient research arms to test all the variables of interest to patients?
- Who is the target audience for the project (participants)?
- What are the inclusion and exclusion criteria?
- Will patients agree to participate?
- Will high risk patients want to participate?
- Will the chance of receiving placebo put people off participating in the study?
- Will patients be offered longer term use of the medication being trialled, if it proves effective?
- Will participants in the study who do not get the new drug/procedure be given it post study if it is found to be effective?
- Is the patient benefit enough to motivate patients to participate or should another incentive be offered? E.g. compensation for time, ~~reimbursement of travel expenses~~
- Will participants be reimbursed for travel, and offered refreshment?
- Are there any concerns over the use of the proposed medications?
- What is a patient's view of taking an unlicensed drug?
- Do you think anything has been missed?
- Are patients are 'cared for' enough in this study? (Refreshments, monitoring for tiredness etc)
- Will you thank patients for taking part?
- How will the results of the study be given to the participants and/or their relatives?
- Will lay members who are part of the TMG or project steering group be co-authors on any publications?
- Will researchers formally acknowledge the contribution of participants and PPI groups in their publications?
- Has enough been budgeted for PPI and what has been budgeted for?
- What follow-up is there to assess success/long term effects?
- What monitoring is there of side effects, late effects, and how will they be reported? (If appropriate)
- What are the stopping points at which the study will be terminated? (If appropriate)

- Will side effects and late effects all be submitted to the yellow card system? (If appropriate)
- For participants in trials of new and possibly dangerous drugs, will they be given a contact number in case of emergencies? (If appropriate)
- Is quality of life being measured, and how?
- If relevant and agreed - would you like a letter of support for your funders?
- If relevant and agreed - would you like a letter of support to Ethics?

Post Funding

2. **Deliver and Complete the Study**
    - What planning is being done if the study fails to recruit?
    - What, if any, support or interventions from the Panel will help successful delivery?
    - Would you like a lay rep to accompany you to Ethics?

3. **Dissemination of Research Findings**
    - How will the study results be shared with the participants and general /target population?
    - Can you suggest ways to disseminate results from this study?
    - Can you understand the patient focused dissemination materials
    - What, if any, help and support from Panel members might be needed in the dissemination phase?