



Appendix C: Project Plan Worksheet

Project Aim

Define the main purpose of your PPIE activity or project. Be clear about what change or improvement you hope to achieve through patient and public involvement. Guiding questions:

- What is the overall aim of this project?
- How will this PPIE activity make your research more inclusive, relevant, or impactful?
- What would success look like?

For example: The aim of this project is to establish a Public and Patient Involvement and Engagement (PPIE) group in a Clinical Trials Unit (CTU) at Ziauddin University in Karachi, Pakistan in order to support the patient-centred design, conduct and dissemination of clinical trials.)

[Draft your main project aim here]

Background

Explain the need for PPIE in your project or setting. Describe the research area, context, and communities you aim to engage with. Guiding questions:

- Why is PPIE important in this context?
- What gap or opportunity does this project address?
- Who are the main communities or groups affected by this research?
- What barriers might exist to participation or understanding?

For example: Patient and Public Involvement and Engagement (PPIE) groups bring together members of the public, patients and researchers to support the design, conduct and dissemination of high-quality patient-centred research. Ziauddin University has recently received accreditation for a clinical trials unit (CTU) and operationalised two large-scale international trials, Mega-ROX (Mega Randomized Registry Trial Comparing Conservative vs Liberal OXYgenation Targets) and REMAP-CAP (Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia). In view of the new CTU and current participation in international trials, this project proposes the establishment of a PPIE group within the Ziauddin University CTU to promote the patient-centred conduct of trials at our institution.

[Draft your background here]

Planned Work

Define the objectives of your work and for each objective, outline the specific methods for achieving that objective. Describe who will participate, what activities you will carry out, and how input from patient and public partners will be used. Below are example objectives and prompts to help you think through your own planned work. You can adapt, combine, or replace these objectives based on what fits your project. Your project plan is likely to change over time, especially as you receive input from patients and public partners, but it is worthwhile planning as much as possible ahead of time.

Objective 1: *Establish a PPIE group consisting of patients, family members and community representatives*

Guiding questions related to this example objective to draft the methods and planned work:

- Who will be involved (patients, families, youth, faith leaders, etc.) and how will you identify them?
- How will you invite them and support participation?
- How will diversity be ensured?
- How can participation be inclusive and accessible?

For example: We will identify and invite ICU survivors, caregivers, and representatives from local non-governmental organisations and faith communities to join the group. Recruitment will take place through posters, referrals, and social media posts. Meetings will be held quarterly to discuss trial materials and community engagement priorities. Efforts will be made to ensure diversity in gender, age, and background.

Objective 2: *To improve and co-develop the consent process for clinical trials*

Guiding questions related to this example objective to draft the methods and planned work:

- What materials or processes will you review?
- What activities will you organise (e.g. meetings, workshops, feedback sessions)?
- How will feedback from the group be incorporated into your research or materials?

For example: Group members will review consent forms and participant information sheets for ongoing trials (e.g., REMAP-CAP, Mega-ROX). Feedback will be collected through discussion and short surveys, focusing on clarity and cultural appropriateness. Revised versions will be shared back with the group for approval before use in the study.

Objective 3: *To share trial results with patients and the public in Karachi*

Guiding questions related to this example objective to draft the methods and planned work:

- How will you share findings or updates with participants and the public?
- How will you share results with your own group?
- What communication channels will you use?
- How will you make materials accessible and understandable?

For example: Once trial results are available, PPIE members will help develop plain-language summaries and advise on dissemination through community forums, newsletters, and local media. Materials will be translated into Urdu and shared via social media and hospital networks to reach wider audiences.

[Draft your planned work here]

Ethics

Describe the ethical considerations of the work you intend to carry out and how you plan to prevent, mitigate or address ethical issues. Guiding questions:

- How will patient and public partners be acknowledged (e.g. authorship, presentations) and compensated (e.g. reimbursement of expenses, honorariums) for their contribution?
- What personal information will be collected from PPIE group members (if any) and how will the confidentiality and security of this information be ensured?
- Will the names, photos or contact details of members be publicly available (e.g. website), and how will consent for this be sought?
- Are the planned PPIE activities going to involve patient or public partners having to recall adverse personal experiences? If so, how will any potential emotional distress be identified and managed?
- Will patients and public partners be asked to carry out research activities themselves (e.g. interviews), and if so, how will they be trained in Good Clinical Practice to ensure study participant safety?

For example: All PPIE members will be asked during onboarding about their preferences for having their name and photo included in promotional and public-facing materials, and all personal information will be stored on a secure password-protected electronic storage space only accessible by PPIE coordinators. Members can ask for their information to be deleted or modified at any time. Manuscripts and other academic outputs from the PPIE initiative will include all members as authors, and patient and public partners will be given opportunities to attend and present at events and training courses. Reimbursement is guided by the compensation & expenses policy.

[Draft your ethics section here]

Evaluation, Consolidation & Dissemination

Describe how you will assess the success of your PPIE activities, use what you learn, and share the results with others. Guiding questions:

- How will you measure success (e.g. attendance, diversity, quality of input, impact on materials)?
- How will lessons learned be applied or sustained?
- How will you share outcomes with participants and the wider community?

For example: We will evaluate success based on meeting attendance, participant feedback, and evidence of changes made to study materials. Lessons learned will be used to draft a PPIE guide for future projects. Findings will be shared at the National PPIE Summit, through internal newsletters, and via plain-language summaries distributed to all participants.

[Draft your evaluation, consolidation and dissemination section here]

Timeline

Provide a simple overview of when major activities will occur. Use months or quarters as appropriate.

Activity	Month/Quarter	Notes
<i>Recruit 10 PPIE members</i>	<i>Jan-Feb 2025</i>	<i>Posters, physician referrals</i>
<i>First group meeting</i>	<i>Mar 2025</i>	<i>Orientation & introductions</i>
<i>Review consent materials</i>	<i>Apr-Jun 2025</i>	<i>Two meetings</i>
<i>Incorporate feedback</i>	<i>Jul-Aug 2025</i>	<i>Revise study documents</i>
<i>Dissemination & evaluation</i>	<i>Sep-Nov 2025</i>	<i>Share outcome at PPIE Summit</i>

[Draft your timeline here]

Team

Outline your team members and responsibilities.

[Draft your team description here]

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