



Appendix E: Ethics Exemption Worksheet

Introduction

Establishing or running a PPIE group often involves working with patients, caregivers, or community members, but these activities are not research studies. They are part of developing institutional systems that make research more ethical, inclusive, and transparent.

Since the purpose of these activities is advisory and developmental, not to generate new or generalisable data, they typically fall outside the scope of ethics review for human subjects research. However, institutions and ethics committees may still request a formal exemption statement for clarity and accountability.

This worksheet therefore provides:

- A model exemption request example,
- Key points to emphasize when preparing an exemption submission, and
- A sample narrative that can be adapted for submission to an Ethics Review Committee (ERC) or Institutional Review Board (IRB).

When to Apply for Ethics Exemption

An ethics exemption is appropriate when involvement and engagement activities involve:

- Developing or running a PPIE or community advisory group, including recruiting members, co-creating terms of reference, or hosting orientation sessions.
- Training, dialogue, or consultation activities that seek input to improve research design, communication, or participant experience.
- Reviewing participant information sheets or study materials for clarity and accessibility.
- Co-developing standard operating procedures, frameworks or institutional policies for research engagement
- Evaluating internal processes for improvement, without collecting or analysing personal or health data.

In all such cases:

- No individual is recruited as a *research subject*.
- No data are collected for the purpose of drawing research conclusions.
- No clinical, behavioral, or experimental interventions are performed.
- The primary intent is institutional strengthening and partnership, not research

Ethics Exemption: Example Application Sections

Background

Explain why the PPIE group is being established and why ethics exemption is appropriate. Describe the broader research context and need for public involvement. Guiding questions:

- Why is PPIE needed in your setting or department?
- What are the key barriers or opportunities for involving patients and the public?
- How does this initiative fit within your institution's research activities?
- Is it part of broader research capacity-building efforts?

For example: Patient and Public Involvement and Engagement (PPIE) is increasingly recognized as essential for ensuring that health research is ethical, meaningful, and relevant. This initiative aims to develop a PPIE group within Ziauddin University to bring together patients, caregivers, and community representatives who will advise on study design, consent materials, and communication strategies. The activity does not involve collecting data from or about participants and therefore falls outside the scope of human subjects research.)

[Describe the background of your PPIE group here]

Rationale

Summarise why your team is applying for ethics exemption. Guiding questions:

- How does this initiative differ from a research study?
- What makes this activity advisory or developmental rather than experimental?
- Which national or international guidelines support the exemption?

For example: This is a capacity-building and systems-strengthening activity. It involves collaboration, discussion, and training to support ethical, inclusive research practices. No data will be collected for research purposes, and no interventions will be carried out. In line with Health Research Authority (HRA) and NIHR guidance, PPI activities do not require formal research ethics approval because they do not involve human subjects research.

[Describe the rationale for ethics exemption here]

Aim

Clearly define what the project intends to achieve. Guiding questions:

- What change or improvement do you hope to achieve through this initiative?
- How will it strengthen your institution's ability to engage patients and the public?

For example: This project aims to embed sustainable, meaningful PPIE practices within Ziauddin University's research ecosystem by establishing a formal PPIE group that supports ongoing clinical and public health studies.

[Describe the aim of the project here]

Objectives

Outline the main objectives of your initiative. Guiding questions:

- What are your primary goals?
- What capacity, processes, or tools will you develop?

Example Objectives:

1. *To build internal capacity through structured training on research fundamentals, ethics, and effective communication.*
2. *To strengthen operational frameworks, including updating the group's Terms of Reference and defining transparent policies on data privacy, recognition, and compensation.*
3. *To integrate PPIE into research processes by enabling meaningful contributions to the review of study documents and participant-facing materials.*
4. *To improve accessibility of research outputs by co-developing plain-language summaries and communication tools (e.g., videos) that explain research in lay terms.*
5. *To document and share learnings to support institutional knowledge around community engagement and inform future efforts.*

[Describe the objectives of the project here]

Recruitment

Guiding questions:

- Who will be eligible to join (patients, caregivers, community representatives)?
- How will recruitment occur (referrals, posters, social media)?
- What steps will ensure diversity and accessibility?
- What tool or form will you use to document interest and fit?

For example: The group will include 8–10 members representing diverse backgrounds, including patients, caregivers, and community representatives. Recruitment will occur through referrals and engagement in hospital or clinic settings. All members will participate voluntarily as advisors.

[Describe the recruitment process here]

Training

Guiding Questions:

- What orientation or training will be provided before engagement?
- How will you ensure members understand research and ethics basics?

For example: Introductory workshops on research ethics, informed consent, and participant rights will be offered in collaboration with [partner institution]. Training will be provided before members review study materials.

[Describe the training process here]

Compensation & Recognition

Guiding Questions:

- How will you compensate or reimburse members for their time and expenses?
- What institutional policy or standard will guide compensation?

For example: A transparent honorarium policy will ensure all contributors are compensated fairly for their time and travel in line with [institutional or funder] guidelines. Participation remains voluntary, but compensation ensures equitable involvement.

[Describe the compensation and recognition policy here]

Project Plan & Implementation

Guiding Questions:

- What key activities or outputs will be produced (e.g., Terms of Reference, SOPs, communication tools)?
- How will you manage logistics and documentation?

For example: The PPIE group will hold quarterly meetings. Processes will be documented for transparency, including meeting schedules, logistics, and follow-up actions. A Request for Input form will allow researchers to engage the group systematically.

[Describe the project plan and implementation here]

Ethical Considerations

Justify why the initiative qualifies for exemption. Guiding questions:

- How do you ensure ethical principles are maintained even without full ERC review?
- How will confidentiality, consent, and transparency be handled?

For example: The establishment and operation of this PPIE group fall outside the scope of ethics review because no data are collected for research. Participants are not research subjects and will not be recruited into studies through this process. Participation is voluntary, and all discussions will be documented and anonymized where appropriate. Any future evaluation involving data collection will undergo separate review.

[Describe the ethical considerations here]

Expected Outcomes & Impact

Describe what you hope to achieve and how the initiative will contribute to research culture. Guiding questions:

- What short- and long-term outcomes do you expect?
- How will this strengthen community trust and research quality?
- Will it produce materials or processes that others can use?

For example: Expected outcomes include strengthened capacity for public engagement, improved clarity of research materials, and a replicable model for embedding PPIE in other departments. In the long term, this initiative is expected to foster greater trust and relevance in research through ongoing dialogue between researchers and the public.

[Describe the expected outcomes and impact here]

References (Optional)

Include key supporting references or guidance documents used to justify exemption (e.g., HRA, NIHR, WHO, PCORI, or local ERC policy).

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