

Key Considerations to facilitate and sustain Public and Patient membership on Institutional Research Ethics Committees



The PPI Ignite Network promotes excellence and inspires innovation in public and patient involvement (PPI) in health and social care research in Ireland.

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Introduction

The PPI Ignite Network was established to promote excellence and inspire innovation in public and patient involvement (PPI) in health and social care research in Ireland. It aims to provide a shared voice for PPI and bring about change to research culture. The Network is based at seven universities with a national programme office in Galway, ten national partners and fifty-three local partners.

Work Package 3 (WP3) of the PPI Ignite Network, entitled 'Embedding PPI locally & nationally', aims to determine the extent to which PPI is currently embedded across Higher Education Institutions (HEIs) and strives to further embed best practice. It is co-led by University College Dublin (UCD) and RCSI University of Medicine and Health Sciences (RCSI). Part of the WP3 has focussed on identifying and understanding operational challenges to embedding PPI into research ethics committees (RECs) with a working group established to explore this.

The working group consisted of twelve members from: two PPI Ignite Network lead sites; three national partner organisations; one publicly funded organisation; one research ethics officer, and two PPI contributors. All members hold experience of current/previous REC membership and/or governance boards.

The group held four online meetings between 17th April – 4th July 2024. Outside of meetings, insights were gathered from other members of RECs (NREC, HSE RECs, institutional RECs) and published literature with findings brought back to the group for consideration. Some pivotal resources were used to springboard discussions and set the research ethics landscape including:

- Irish Health Research Forum Recommendations and Event Report 11th May 2023: Research ethics in Ireland: How do we strengthen and harmonise the system?
- HSE Roadmap for the Reform of Health and Social Care Research Ethics Committees. HSE Research & Development, January 2022

- HSE Standard Code of Governance & Management Required for HSE Reference Research Ethics Committees, HSE Research & Development, July 2022
- National Research Ethics Committees Operational Framework, National Office for Research Ethics Committees, Version 2, 13th September 2023
- Patient Engagement Open Forum (PEOF) Session Summary & Group Map report: Let's Talk Ethics: Ethics Committees and Patient Engagement 2nd April 2024

We are particularly grateful for input from:

- Tusla Child and Family Agency who have shared insights of the role of the Tusla Independent Research Ethics Committee and its application to both research and practice, and
- The National Office of Clinical Audit who have years of experience embedding PPI members on their Audit Committees and Governance Board.

Scope of document: This document aims to support institutional RECs to evaluate their own practice and assess their readiness to include PPI members on their committees. Acknowledging what barriers exist (including where and when they arise) forms an important step towards building an infrastructure for successful PPI membership on a REC. The document is framed as four stages of the Transtheoretical Model of Change: Contemplation; Preparation; Action; and Maintenance. [1]

What this document is not: It is not a protocol nor an absolute list of barriers to PPI membership. Whilst all RECs have common goals to uphold ethical standards and integrity of research, each local REC will operate within the context of their institution/organisational structures and thus this document primarily supports reflection of practice and motivation for change.

Readiness for Change



Contemplation

Why include PPI members?

Prior to introducing PPI members, existing members of the REC must firstly have a solid understanding of what PPI is and is not particularly in the context of REC membership and reviewing REC applications. This will assist with understanding the rationale for including PPI members on the committee. PPI members, or 'experts by experience', can bring diversity and coalition of perspectives which in turn can add value to REC reviews.[2] It is also important to acknowledge how PPI members can differ from broader lay membership which has long been recognised as an integral component of RECs.[3]

The definition of a lay member varies, one being "independence from the institution/organisation under whose authority the REC is established and their non-involvement in scientific, clinical practice and legal work"[4], while others may just specify the person

must not be employed or have a primary professional interest in health or care-related research.[5] While recognising that members are no 'one-thing' and as such reflect many points of interest it is not enough to say that an academic member or healthcare professional brings the 'lived experience' to the REC if their primary role on the REC relates to their professional (even if prior) expertise. PPI membership should primarily reflect diverse viewpoints focussed very clearly on the 'lived experience' which may be more in tune with study participants in human studies, or the local community/ societal impact of the research. Membership should be broad and bring a balanced societal perspective.[6]

Preparation

Review of Existing Structures

Critically evaluate the structure and functions to the committee to review what needs to be addressed to support incoming and existing members of the REC.

MEMBERSHIP

All REC members should be treated equally within the committee to create a favourable environment for dialogue (public contributors, academics, professional staff, etc.) Each member of the REC is responsible for ensuring parity and equity during proceedings.

- What is the composition of the committee and who makes up the quorum?
 - Is the number of proposed PPI contributors conducive to open communication? One or two PPI members among a group of up to 15 requires certain strengths of character to contribute openly and productively. Aside from addressing membership imbalance, focussing on group dynamics in training and induction can also support more active input from new members.[7] (see also *Training and On-going Support*)
- What methods are used to find new committee members?
 - Are you reaching potential new members from outside of the institutional network?
 - Can you communicate what constitutes a realistic commitment of time and effort?
 - Who is involved in this process of finding new members and are resources in place to facilitate effective engagement with interested applicants? It is important to take time to support potential new members, understand their motivation and ensure their agenda aligns with that of the committee.
- Do members receive any type of reimbursement or recognition? PPI

members are unlikely to gain the same benefits as institutional staff committee members e.g. alignment with professional goals / career development. RECs should explore funding options to ensure potential PPI members are not discouraged or prohibited from joining/contributing.

MEETINGS

- **How often does the committee meet, when and for how long?**

The REC is likely to be operationally set up for staff of the institution and may not cater well to external members. Liaise with existing lay members to understand challenges or barriers for external members and how to improve meeting accessibility e.g. hybrid-flexible meetings.
- **How many applications /amendments to applications are usually reviewed per meeting?**

Who are the primary / secondary reviewers? How much time is provided to carry out these application reviews and is this sufficient? Consider how frequently members request additional time or the backlog of applications. Looking at the committee activity breakdown is essential to clearly inform new members of the expected workload and to ensure adequate time for sharing contributions in meetings.
- **What accommodations are available to support new members at and in-between meetings?**

Identifying what changes can be made in advance of requests from individual members can proactively support inclusion of interested applicants, and may also support other members of the team e.g. disability access, companion to accompany to meetings, pairing with experienced member to learn etc.

RESOURCES

- How do members access, review and comment on applications and is support for these tools readily available?

- What resources are required for basic function of the committee e.g. institutional account, email; access to document management system?
 - Be aware of what logistical requirements are, recognising what appears 'standard' for existing members may not be the case for PPI members.
- Is a guidance pack provided on joining the committee and is the content suitable for non-research/academic members? Consider additional supports which may be required e.g. a glossary of commonly used terms. Leverage the experience of existing lay members when reviewing this.
- Do external members have access to institutional benefits that could support their ability to contribute, for example, e.g. library access. Are there processes that can make these benefits readily available to external members?
- Is the conflict management process or pathway to raise and resolve potential issues transparent?
- What safeguarding measures are in place for committee members e.g. distress protocol or debriefing if covering sensitive topics – are the same measures available for internal and external members?
- Are there steps in place to manage potential conflict of interest in REC application review?

Action

Taking institutional steps

A clear and shared understanding of the role of all members, including PPI members, in the committee will support effective incorporation of new members and aid transition to a wider membership model. Where intent to adapt a REC to accommodate new PPI members exists, and potential barriers have been identified, the next step is to explore ways of reducing or preferably eliminating these barriers altogether.

TRAINING AND ON-GOING SUPPORT

- What training is offered for induction of new members?
 - A comprehensive introduction into the work of the REC should be available to members in an accessible format. Induction should allow for research-naïve members to become familiar with research integrity, the mandate of the REC, conflicts of interest, key regulatory and legislative documents etc.
- How often do the members receive ongoing training to support the running of the committee?
 - Do members receive training on their roles/responsibilities and group dynamics? To support parity and opportunities for team-building, all members should receive the same training, with a process in place to request additional support or training.
- Does the committee have a peer-support / mentorship model for new members? This is an effective way to support new members and encourage their active participation.
- Who needs to be involved i.e. who are the stakeholders within the institution, and the agents of change?
- It is likely that collaboration with multiple departments will be required to remove barriers e.g. finance, human resources, IT departments. Start planning early and identify where existing institutional procedures can be optimised.
- Do changes need to be made to your existing committee policies and membership structure before any changes can occur?
- What resources are required to sufficiently support REC staff in making these adaptations, in particular the administrative aspect e.g. finding members; facilitating training etc.?

Maintenance Evaluation

Evaluating the experience of REC members is an important step in ensuring effectiveness of the REC. Any adjustments made to the committee to accommodate new PPI members should also be reflected on, to assess if they have had the intended effect, and the REC has been able to efficiently carry out the duties according to the REC mandate.

The committee should review the mechanisms for evaluation to deduce if any amendments need to be made as new PPI members join the REC. It is also pertinent to measure/ evaluate the impact of PPI members on REC applications and the approval process.

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