

STU-SOP-POL-001 – Public and Patient Involvement in Research

Version No:	3	Effective Date:	10-Apr-2026
Description of changes:	SOP reviewed in light of clinical trial regulations 2025 and GCP updates.		

List of Abbreviations	
GCP	Good Clinical Practice
PPI	Patient and Public Involvement
SOP	Standard Operating Procedure
STU	Swansea Trials Unit

1. BACKGROUND

Swansea Trials Unit (STU) aims to work with members of the public to ensure their contribution to developing and delivering research that contributes to the health and wellbeing of the wider population. In this sense, the ‘public’ means individuals and groups including patients, their carers and/or families, as well as users of health and social care services. In STU, the people who undertake this role in the planning and delivery of research are referred to as Public and Patient Involvement (PPI) representatives. It is important to note that involvement in research is different to participation in or engagement with a research project. The differences are set out on the Health and Care Research Wales Website.

2. SCOPE

STU manages a varied portfolio of trials and studies, which are undertaken across a range of disease or health and social care areas as well as in different locations and settings. This policy provides the operating framework for PPI input to all trials and studies where possible and is intended to ensure that public involvement is genuine, achievable, adequately resourced, transparent and effective. This policy does not describe how to recruit PPI representatives. This information can be found at:

- <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/>
- <https://www.nihr.ac.uk/career-development/health-and-care-research-introduction/involve-patients>
- <https://healthandcareresearchwales.org/support-and-guidance-researchers-develop-research-idea/involving-public-your-research>

3. PRINCIPLES OF PPI

Evidence of good PPI is expected by everyone involved in research delivery because:

- Public involvement leads to research that is more relevant to users of public services and is more likely to be implemented in practice.

- Public involvement leads to more effective public engagement, which may increase the reach and impact of our findings.

For STU this means that:

- All stages of the research process should be open to public involvement from when ideas for research are first generated through to when results are shared and used to inform practice.
- Members of the public should be involved in strategic and operational aspects of research.

4. RESPONSIBLE PERSONNEL

STU staff should make themselves familiar with the Policy, understand how it applies to their work and support its implementation. This may include becoming familiar with the latest codes of conduct in the area. In addition:

- Each study or trial should identify a study team member who is responsible for leading on PPI for that project (designated the “PPI lead”). This should happen as early as possible and should be kept under review.
- The PPI lead (in consultation with the relevant parties e.g sponsor) will be expected to ensure that there is adequate PPI representation on study management and oversight committees.

Ideally there would not be overlap of PPI representation on more than one committee e.g. trial committee PPI representatives should not be PPI on oversight committees

5. PLANNING PPI

Where PPI representatives are recruited to a study or trial, the roles and desired outcomes of their involvement should be clarified and appropriately supported throughout the lifetime of the study. Advice may be sought from the STU PPI lead on this matter. Consideration of public involvement will be a criterion for STU involvement in the project.

STU expects appropriate PPI representation to have been planned and implemented for any study or trial that they adopt as part of their project portfolio. STU also recognises that the inclusion of PPI representatives on studies or trials may not always be practical or possible. Adequacy of PPI planning will form part of the adoption discussion by the STU Executive group. The PPI lead for each project team should use the UK Standards for Public Involvement when developing the PPI plan a that study (<https://sites.google.com/nih.ac.uk/pi-standards/home>).