STANDARD OPERATING PROCEDURE FOR PLANNING PATIENT AND PUBLIC INVOLVEMENT (PPI) IN CLINICAL RESEARCH

SOP NUMBER:	TASC SOP066 v2
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the process for including Patient and Public Involvement (PPI) in clinical research and is based on the UK Standards for Public Involvement in Research.

2. SCOPE

This document applies to all clinical research studies sponsored or co-sponsored by the University of Dundee and/or NHS Tayside.

3. RESPONSIBILITIES

Chief Investigator (CI) or delegate:

- Ensure PPI is planned prior to the submission for study funding
- Ensure PPI has been budgeted for in study funding
- Include PPI plan details in study protocol
- Ensure PPI is carried out as planned.

PPI Manager:

- Support researchers in planning PPI.

4. PROCEDURE

4.1 Planning PPI

4.1.1 If required, support can be obtained from the TASC PPI Manager for facilitating pre-award PPI, developing a PPI plan and including PPI into the research application.

4.1.2 TASC have a PPI group available to provide pre-award support but support can also be given to form a new PPI group or link to existing groups.

4.1.3 Researchers across the University of Dundee or NHS Tayside can request support for planning PPI in clinical and health research by emailing: public-involvement@dundee.ac.uk.

4.1.4 Contact the PPI Manager at the earliest opportunity, to ensure there is sufficient time to plan and host a PPI meeting.

4.1.5 The TASC PPI Plan Template for Researchers (Doc Ref 128) can be used by researchers to help plan and budget the PPI activities.

4.1.6 Researchers who are planning to form a new PPI group should develop a role description & responsibilities before recruitment begins.

4.2 Funding application

4.2.1 Any specific funder requirements for PPI should be identified.

4.2.2 Ensure that PPI input is included in the development of the funding application.

4.2.3 Ensure that the PPI activities described in the application have been budgeted appropriately. Budget requirements should follow the NIHR Payment guidance for researchers and professionals.

4.2.4 PPI plans should be documented in the research application. Please refer to the guidelines in the PPI section on the TASC website for questions to consider.

4.3 Design of the research:

Consider if PPI can be included in designing the research. Examples:

- Identify research priorities for patient population
- Input into the research question to be studied
- Assist with recruitment strategy
- Identify patient centred outcomes
- Advise on appropriateness of research methods.

4.4 Management of the research:

Identify what PPI activities are appropriate in the management of the research. Examples:

- Inclusion in Trial Steering Committee
- Review of protocol
- Assist with writing participant documents e.g. Participant Information Sheets, invite letters, newsletters.

4.5 Undertaking the research

Identify if there are any activities which PPI representatives can assist with such as conducting interviews, surveys or focus groups.

4.6 Analysis of the results

Identify any areas where the PPI may give input. Examples:

- PPI input into developing data priorities
- PPI members involved in data analysis and interpretation.

4.7 Dissemination of the findings

4.7.1 Identify areas where PPI may be appropriate: Examples:

- Advise on different ways of reaching patient population
- Jointly present findings
- Produce plain language summaries of findings

4.8 Remuneration for PPI

Ensure that PPI members are appropriately reimbursed for their time and direct expenses, such as travel and subsistence. Please refer to the guidelines in the PPI section on the TASC website for information on payment rates.

4.9 Data protection

4.9.1 Ensure that the PPI group members understand what personal information they will be required to share, where this data will be held and who can access their data.

4.9.2 Ensure personal information such as contact details are securely stored and only appropriate staff members can access.

4.9.3 Electronic personal information should be stored in a password protected file on a secure University of Dundee or NHS drive.

4.10 Recording and evaluating PPI

4.10.1 Details of PPI should be included in all study protocols.

4.10.2 Researchers should have methods in place to document PPI that is carried out throughout the project and the impact this has had on the project. For example, meeting minutes, blogs documenting patient experiences and keeping tracked changes as evidence of how PPI input has changed documentation.

4.10.3 There should be ongoing evaluation of the PPI plan throughout the project. This is the responsibility of the research team, to ensure the PPI plans are following what is detailed in the protocol and meet and funder milestones or reporting requirements.

4.10.4 The PPI group should be involved during the evaluation process.

4.10.5 It is important that the research team provide continuous feedback to those involved in PPI activities. This should include documenting the PPI feedback that was provided and how this has been implemented into the project, as well as a justification of why any suggestions were not possible to implement.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
PPI	Patient and Public Involvement
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 128: TASC PPI Plan Template for Researchers

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
1	Gillian Craig (TASC PPI Manager)	13/12/2021	New.
2	Billal Elahi (TASC PPI Manager)	13/12/2023	Scheduled review, no changes required.

8. APPROVALS

Approved by:	**Date:**
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	11 Dec 2023