

## SELPHI Patient and Public Involvement Strategy

### 1. Background

The MRC CTU patient and public involvement (PPI) policy recognises the central role of patients and the public in its research. The MRC CTU is committed to ensuring active PPI within individual clinical studies, across programmes of clinical research and at strategic level. The policy aims to ensure that CTU researchers build partnerships with patients and the public to shape decisions about research ([http://www.ctu.mrc.ac.uk/our\\_research/patient\\_and\\_public\\_involvement/](http://www.ctu.mrc.ac.uk/our_research/patient_and_public_involvement/)).

The MRC CTU uses the National Institute for Health Research's (NIHR) INVOLVE definition of PPI as "research being carried out **'with'** or **'by'** members of the public rather than **'to'**, **'about'** or **'for'** them" (<http://www.invo.org.uk/>). 'Involvement' is where members of the public are actively involved in research projects and in research organisations. This is distinguished from 'participation' where people take part in a research study, and 'engagement' where information and knowledge about research is provided and disseminated.

At the MRC CTU the term 'patients and public' includes study participants, current, former and potential patients, carers, people who use health and social care services, and people from organisations that represent people who use these services.

The goal of PPI is to seek a broad and varied range of *perspectives* rather than trying to gain 'representativeness' of specific population groups.

#### 1.1 SELPHI

SELPHI is a randomised clinical trial within the PANTHEON programme. The overall PANTHEON programme consists of three distinct workstreams: 1. Feasibility 2. The SELPHI randomised control trial and 3. Modelling and economic evaluation. There is also a dissemination, engagement and translation working group chaired by Kevin Fenton which will include independent PPI representation. Simon Collins and Gus Cairns were named as the PPI members in the grant application and Simon Collins is a co-applicant. PANTHEON oversight is provided by an independent Programme Steering Committee, chaired by Professor Mike Adler. Paul Fisher is the PPI member of the Programme Steering Committee.

### 2. Purpose

The purpose of this strategy is to describe the process of PPI throughout the lifecycle of the SELPHI clinical trial.

This document describes

- the procedures for implementing and actioning input from PPI,
- the framework for assessing PPI and
- the roles and responsibilities of those managing PPI.

### 3. Procedures

#### 3.1 PPI in SELPHI advisory groups

**PANTHEON Core Group (Core):** These meetings will be held approximately quarterly. Roy Trelivon and/or Roger Pebody will attend these meetings to represent input from PPI and identify opportunities for PPI. There will be a standing agenda item on PPI.

**Community Advisory Group (CAG):** Simon Collins formed a community advisory group for the SELPHI trial in July 2016 of 28 people who were either linked to organisations working in the field of HIV, affiliated to the UK CAB, or individual participants in the PROUD PrEP trial. A list of members and their affiliations is at appendix 1. The CAG will review their membership regularly to ensure that the study population is represented. Roger Pebody and Roy Trelivon co-chair this group. The CAG will convene at least annually, ideally face to face, to discuss progress with the study team and identify any issues that would benefit from **ad hoc PPI activities**. Notes will be taken (either by CAG co-chairs or MRC CTU at UCL team member) and shared with the TMG and Paul Fisher.

**Trial Management Group (TMG):** the SELPHI study team will meet at least monthly to review progress and notes of these meetings will be taken and shared with the CAG co-chairs. On review of the notes, the CAG co-chairs may identify a topic or issue that would benefit from an **ad hoc PPI activity**.

#### 3.2 Participant involvement in PPI

Once the trial has started, we will invite participants enrolled in the SELPHI trial who have agreed to join the **participant mailing list** to contribute to PPI. Participant involvement in PPI will usually be ad hoc and topic (issue) specific. For example, participant involvement will be sought during the review of study procedures at the end of the 'soft start' recruitment phase.

The SELPHI TMG or CAG can initiate a request for participant involvement on a specific topic, which may also be discussed by CAG. Once agreed and defined by the TMG and CAG, the **ad hoc PPI activity** will be advertised via the participant mailing list and potentially other sources such as via surveys, the study website, and via stakeholder organisations. PPI activities could include in-person meetings (nationally or regionally), remote telephone or web-based meetings, or email discussions (for example to review a document). A member of the public, for example a CAG member, will usually facilitate participant involvement activities. A member of the MRC CTU at UCL SELPHI team will usually administer activities, including arranging the meeting or involvement activity, coordinating the documentation including writing minutes or reports, following up on action points and reporting outcomes back to participants involved in the activity.

#### 3.3 PPI of other stakeholders

The recruitment plan lists a range of community based organisations such as THT, Yorkshire MESMAC, NAZ, cliniQ, etc, who will be approached to assist with advertising the study and be listed as support services on the SELPHI website. We will communicate with these stakeholders through the **other stakeholder eGroup** and may seek their assistance with **ad hoc PPI activities** to support recruitment, retention and trial conduct, particularly with harder to reach populations. A list of members and their affiliations is at appendix 2.

As in section 3.2, the SELPHI TMG or CAG can initiate a request for PPI of other stakeholders to address a specific topic which will be agreed and defined. PPI activities will be facilitated by a member of the public and administered by a member of the MRC CTU at UCL team.

### 3.4 Engagement activities

Engagement activities include providing information and knowledge about the study to stakeholders. It is beneficial to engage with PPI members (CAG, participant mailing list, other stakeholder eGroup) regularly through the course of a trial, so as they are well informed of trial progress when asked to review or advise on an aspect of the study. PPI members will be provided with regular updates through newsletters produced by the MRC CTU at UCL team.

### 3.5 Training and support

PPI members training needs will be assessed, especially members of the CAG. Training will be offered to PPI members via the London Community Resource Network (LCRN) and in-house training as budget allows. UCL run an annual four-day course on study design, interpretation and statistics, and two free places on this course are offered every year to community members through the UKCAB. SELPHI TMG members routinely conduct research workshops at UK-CAB meetings and PPI members involved in SELPHI will be informed about these and will be able to attend free of charge.

### 3.6 Payment and recognition of involvement

The PANTHEON grant includes a budget of up to £30,000 for PPI activities to support the SELPHI trial.

Individuals engaging in PPI activities that are face to face will be offered £20 per hour for their time as well as reimbursement of travel costs. Prior to a PPI activity, it will be made clear to those invited what they can claim payment for and how they will be paid.

In recognition of the contribution that PPI members make to the study, and in the interest of transparency, a list of CAG members will be maintained on the SELPHI website. CAG members can choose whether to be named, identified solely by affiliation, or anonymised. Other members of the public will be similarly recognised for the contribution and again can choose whether to remain anonymous.

The contribution of PPI to our research will be acknowledged in reports, publications, posters and presentations.

## 4. Assessment of PPI

We will assess the impact of all PPI activities throughout the course of the trial. The impact assessment template (appendix 3) will be used to record the planning and implementation of PPI activities, and analysis and reporting of the PPI impact. The template draws on the 'Engagement for Impact' logic model ([www.engagementforimpact.org/toolkit/Documents/CSE%20Manual.pdf](http://www.engagementforimpact.org/toolkit/Documents/CSE%20Manual.pdf)).

To ensure transparency, details of all PPI activities and outcomes will be documented, distributed to the PPI members involved in the activity, and posted on the **SELPHI PPI website** page.

#### 4.1 PPI input and activity

Anyone can initiate a request for PPI on a specific topic, for example, members of the TMG or CAG. The MRC CTU study team lead for PPI will raise a request on the PPI template defining the **input** (who requested PPI on the topic/issue, and who is responsible for actioning the request) and **activity** (the aims of the PPI activity and questions to be addressed, the expected impact of the activity and the PPI model to be used). All PPI requests will be discussed on the TMG.

#### 4.2 PPI outputs and outcomes

The facilitator of each PPI activity will document the details of the activity in a report, including numbers of people who contributed, issues discussed, and recommendations. The CAG chairs and PPI activity facilitator will review the recommendations, discuss any discrepant recommendations, and summarise the main **outputs** (agreed recommendations) of the activity. In consultation with the CAG chairs, the MRC CTU study team lead for PPI, will document the main outputs on the PPI template and submit it with related reports to the TMG for discussion.

After TMG review, the MRC CTU study team lead for PPI will document the **outcome** (which recommendations will be actioned) and related action points on the PPI template.

#### 4.3 PPI impact

When appropriate, the MRC CTU study team lead for PPI will document the **impact** (resulting impact of actioned recommendations) of the implemented recommendations. The impact may be recordable immediately or after a significant period depending on the expected outcome. If recommendations from PPI activities are not actioned, the reasons should be documented on the PPI template. The completed PPI template should be discussed by the TMG, and notes regarding the impact of the activity recorded on the template.

Where possible, it would be beneficial to summarise the impact of the PPI activities either annually or after key milestones in the trial. It would also be beneficial to conduct a survey of TMG members to illicit their thoughts on the impact of patient and public involvement generally, including PPI membership on the TMG, the CAG and other PPI activities. The MRC CTU at UCL advisory group (chair [claire.vale@ucl.ac.uk](mailto:claire.vale@ucl.ac.uk)) are available to assist with the annual report, based on the PPI templates, and the TMG survey. Ideally, the process for assessing PPI activities and their impact on the study should be written up for publication, inviting PPI members as authors on the publication. The MRC CTU at UCL PPI advisory group may be able to support the analysis and write up of the findings.

## 5. Roles and responsibilities

The table below lists the PPI activities described in the procedures and assessment sections and notes the person(s) or group responsible for the activity.

<b>Doc point no.</b>	<b>Activity</b>	<b>Role and responsibility</b>
1.1	PPI input to grant application	Simon Collins read and commented on the grant and drafted text.
1.1	PPI input to Programme Steering Committee meeting.	Paul Fisher provides PPI oversight to the programme that is independent of the study team.
3.1	PPI input to PANTHEON core group meeting.	Roger Pebody and Roy Trelvelion provide PPI views and help to shape decisions which will be taken by this group.
3.1	Manage CAG membership.	Roger Pebody and Roy Trelvelion to invite new members and review existing membership (in consultation with Simon Collins).
3.1	Manage CAG involvement and meetings.	Roger Pebody and Roy Trelvelion to draft agenda, co-chair the meetings and review the notes. MRC CTU at UCL study team to administer meetings.
3.2	Manage participant mailing list.	MRC CTU at UCL study team to liaise with IT staff to create secure mailing list and to maintain this with regular newsletters.
3.3	Manage other stakeholder list.	MRC CTU at UCL study team to create an email list and to maintain this with regular newsletters.
3.1-3	Define topic and format for ad hoc PPI according to available budget.	SELPHI TMG and CAG to review and agree document that defines PPI activity. Alison Rodger to approve budget.
3.1-3	Manage ad hoc PPI activities.	MRC CTU at UCL study team, with a PPI member as facilitator to issue the documentation for ad hoc PPI, prepare the report and ensure that action is taken and participants are informed.
3.4	Prepare and distribute updates.	MRC CTU at UCL
3.5	Training and support for PPI members.	MRC CTU at UCL to notify PPI members of workshops. Applications for training to go to CAG co-chairs, and to attend 4 day UCL in-house training to go to CAG and UK CAB.
3.6	Reimburse PPI activities	Invoices to be raised by individuals and submitted to UCL (to be confirmed).
4	Updating of PPI website page	MRC CTU at UCL
4	Assessment of PPI	MRC CTU at UCL study team to manage the PPI impact assessment template.

**Appendix 1: CAG members and their affiliations**

<b>Name</b>	<b>Organisation</b>
Aedan Wolton	cliniQ
Andrew Gill	Personal capacity
Ben Cromarty	North Yorkshire AIDS Action
Harry Dodd	Personal capacity
Kat Smithson	Policy and Campaigns Manager, NAT
Marc Thompson	National Coordinator, Project 100. Positively UK
Michelle Ross	Co-Founder cliniQ
Roger Pebody (co-chair)	NAM
Roy Trevelion (co-chair)	HIV i-Base
Simon Collins	HIV i-Base

Plus 18 other members, some of whom have elected to remain anonymous

**Appendix 2: eGroup members and their affiliations**

<b>Name</b>	<b>Organisation</b>
Aedan Wolton	cliniQ
Cary James	THT
Jamie Pallas	Gender Intelligence
Kate Nambiar	Clinic T
Louie Stafford	LGBT Foundation Trans programme
Mark Santos	Positive East
Michelle Ross	cliniQ
Monty Moncrieff	London Friend
Paul Steinberg	Do-it London
Rob Cookson	LGBT Foundation
Roger Pebody	NAM
Roy Trevelion	i-base
Simon Collins	i-base
Stephan Gampenrieder	THT Direct
Zahra Jamal	NAZ Project

**Appendix 1: PPI impact assessment template**

There is a standing PPI agenda item on the SELPHI TMG. The CAG co-chairs should discuss potential PPI activities at each TMG and the co-chairs or MRC CTU study team lead for PPI should complete the template from the start to the end of the PPI activity.

	<b>PPI process steps</b>	<b>Report</b>
1	<b>Input:</b> who initiated the PPI activity, and who is responsible for it	
2	<b>Activity:</b> aims of PPI activity, expected impact, and PPI model.	
3	<b>Outputs:</b> PPI recommendations	
4	<b>Outcome:</b> outcome of recommendations	
5	<b>Impact:</b> impact of PPI recommendations	
6	If recommendations not actioned, give reasons	
7	Notes from final TMG review as relevant	



**Instructions to completion of PPI template**

	<b>PPI process steps</b>	<b>Report</b>
1	<b>Input:</b> who initiated the PPI activity, and who is responsible for it	Detail who initiated the PPI activity and when, and who is responsible for implementing the PPI activity: <i>i.e. at a TMG on 1<sup>st</sup> January 2017 Sheena suggested we seek PPI on this topic. This was supported by the TMG. Roy will lead on this.</i>
2	<b>Activity:</b> aims of PPI activity, expected impact, and PPI model	Detail the aims of the PPI activity (what question or issue are you seeking PPI on), the expected impact, and the PPI model that you plan to use: <i>i.e. we want PPI into the re-design of the website in order to improve the comprehension of the information on the website and incorporate information about PPI in the trial. Roy will email the CAG and ask them to review the website by 20<sup>th</sup> January 2017. We will ask them to address 2 key questions 1) how can we simplify the language on the website (based on feedback from participants that the website language is too technical) and 2) how should we add information about PPI to the website.</i>
3	<b>Outputs:</b> PPI recommendations	Detail recommendations from the PPI activity. This may be a summary of the key recommendations, supported by a full report. Make note of any conflicting recommendations and how these were reconciled: <i>i.e. the CAG recommended simplified language for the home page and recommended that we add a new PPI page to the website and drafted a sample page. The peer support network also recommended that we add photographs of people to the website.</i>
4	<b>Outcome:</b> outcome of recommendations	Detail the review process, the outcome of the review, and related actions. <i>i.e. the TMG reviewed the recommendations on 27<sup>th</sup> January 2017. The TMG supported the recommended home page language and the idea for a new PPI page. However, the TMG felt that it would be difficult to include photographs to reflect all population groups so recommended that we seek further input on this idea from trial participants. The website will be updated with the new language and PPI page by 12<sup>th</sup> February by the trial manager.</i>
5	<b>Impact:</b> impact of PPI recommendations	Provide as much detail as possible on the impact of the PPI recommendations including any plans for evaluation of the impact: <i>i.e. the website was updated in February 2017 (see attached print out of website language before and after the changes). The CAG members reviewed the website in March and felt that the language was more comprehensible and the role of PPI was clear.</i>
6	If recommendations not actioned, give reasons	Detail recommendations from the PPI that were not actioned and give reasons: <i>i.e. the recommendation to add photographs to the website was not actioned as the TMG was concerned that these could not be representative of the study population. We have initiated a PPI activity with trial participants to seek their input on this topic.</i>
7	Notes from final TMG review as relevant	Detail TMG members thoughts on the impact of the PPI activity. <i>i.e. most TMG members thought the new language improved the website, but one thought the changes did not make a difference.</i>