Patient and Public Involvement Handbook

Essential information for members of the public working in partnership with the Southampton Clinical Trial Unit

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1 Introduction

This handbook is designed to assist patient and public contributors who are supporting the delivery trials managed and run by the Southampton Clinical Trials Unit (SCTU). We have tested the links in this document - they do load but can take time!

1.1 Who are patient and public contributors?

When we use this phrase, we mean it to include:

- Patients and potential patients
- Informal (unpaid) carers
- Parents and guardians
- People who use health and social care services

In fact, it includes anyone who is not employed as a health professional or academic, involved in research or research management.

1.2 Why am I doing this?

In 2014, an independent panel conducted a review of public involvement in the National Institute for Health and Care Research (NIHR), called 'Breaking Boundaries', which led to a report entitled 'Going the Extra Mile'. The report offered a new vision and called for a set of principles to support public involvement in research, and for public involvement to be focused on six common goals.

Three of these goals show why patient and public involvement (PPI) is important and why we need you to join in:

- It is standard practice for the public and professionals to work together.
- The experience of patients, service users and carers is valued.
- Public involvement is a required part of high-quality research.

If you are interested in the full report or its summary, it can be found here: https://www.nihr.ac.uk/documents/about-us/our-contribution-to-research/how-we-involve-patients-carers-and-the-public/Going-the-Extra-Mile.pdf

1.3 How can I support research?

You can support research by sharing the knowledge, experiences and insight you have gained through being a patient and/or carer (this is sometimes called being an 'expert by experience'). Researchers want to learn from the

knowledge you have gained as a result of living with a condition, or through caring for someone with a condition. Your lived experiences of being on the receiving end of health and social care can help to shape how future research is undertaken, and that, in the longer-term, can help to shape and improve how care is provided.

The links below offer two people's views on how and why sharing a person's 'lived experience' is important. May Griffiths: A Carer's Journey of Involvement in Research: www.youtube.com/watch?v=rYwIq2fq-EU&feature=youtu.be

Or how a young man's health condition enabled him to be involved in research. Tom Grew, February 2015: https://www.invo.org.uk/thisismystory/

1.4 Being a critical friend

A critical friend can be defined as: "a person who asks the 'difficult' questions" (or sometimes they ask the obvious questions that nobody else has asked), but in a friendly way. Many researchers have never been a patient, carer or seen a family member go through an illness, and so they may miss things from their research plans that seem obvious to you. As a critical friend you can help to make them aware of what they may have missed. In addition, as an independent member of the public, you have the freedom to ask the awkward question (sometimes known as 'pointing out the elephant in the room') - in a friendly, supportive way.

In research there is no such thing as a stupid question, so keep asking questions – get the researchers thinking!

Your role as a critical friend is to look at the research from your perspective, and to offer thoughts, advice and guidance to researchers on whether you feel that this research appropriately reflects the needs and values of the people who use health and social care services.

You do not need to have specialist / academic / research, knowledge that the others in the room may have that!

2 Getting Started

2.1 What should I know before I start?

The following is a list of key information that you should be provided with once you have agreed to be a public contributor with the SCTU. The amount of information available will differ from project to project and is often dependent on the amount of public involvement in the project so far. If you aren't provided with any of this information, you are fully entitled to ask for it.

1. **Who is my main contact?** Make sure you have a name and contact email of the person who you will liaise with at SCTU. This may be the PPI lead, a trial manager or trial coordinator. They will help you establish your role description, provide any useful resources (such as a lay summary of the research project), arrange meetings, facilitate reimbursement/expenses, and help if you have any questions along the way.

2. **Who else is involved?** Who else is on the project team, Steering Committee or similar group? Who might you need to contact during your involvement? This can include photographs, job titles and details of the role(s) and responsibilities of the people you are working with. This will help you to get to know who to ask for what advice. In the rare event of problems arising, you should also know who you can talk to. There should be someone whose job it is to support you, this is normally the trial manager working on the trial.

3. **Organisational details and structure**. What does the organisation you are involved with do? What do the various researchers and other people involved do? Having this information will help you to understand where you and your work, or the research project, fits in the big picture. For example, is the research project part of a bigger research programme?

4. **A Glossary or Jargon Buster.** Who are NIHR, CCF, RDS, CRN, NETSCC, CLAHRCs, HRA? What is GCP, progression free survival, loss to follow-up?
All these groups, names and abbreviations may seem very complicated until they are fully explained. Make sure you are provided with a Glossary which explains what the full names are. A Glossary might also explain any 'technical jargon', so that words or

terms, such as 'randomised control trial', are explained. So, take a deep breath…and be prepared for getting used to dealing with some technical words, jargon, acronyms and abbreviations.
It is almost impossible to understand all these at the start – and each one you come across should be fully explained, either in the footnotes or Glossary of a document. The NIHR has a useful glossary on their website:

https://www.nihr.ac.uk/glossary

The SCTU have a specific glossary which is later on in this handbook.
Never feel nervous getting people to explain acronyms, abbreviations or jargon, as often others in the room are also confused by the language too!

2.2 Role description

What is your role? What might you be expected to 'do'? What are the time commitments? How are meetings held?
The role description should offer a clear idea of what your roles and responsibilities are. This could be negotiated between you and the SCTU. It may depend upon how much time you have to commit, or what parts of the research you might be involved in.

Some of the common roles at the Southampton Clinical Trials Unit include:

- **Trial Management Group (TMG).** This group is responsible for the set-up, running and analysis of a clinical trial. It is generally made up of the research team and chaired by the Chief Investigator (lead researcher). It meets regularly to oversee the progress of the trial and discuss any issues. TMGs typically meet monthly for 60-90 minutes, but this may vary depending on the size and complexity of a trial. As a public member on the group, you may also be asked to review patient-facing documents such as information sheets and consent forms to check they are understandable.

- **Trial Steering Committee (TSC).** This group has overall oversight for a trial and provides advice to the TMG, funder and sponsor of the research. It is made up of independent members but will be attended by the research team who will provide updates on the progress of the trial and any issues. The TSC can make recommendations to the TMG and even stop a trial if they need to. TSC meetings are less frequent (every 4-6 months) but can last for 1-3 hours depending on the number of trials being reviewed.

• **Trial Review Group (TRG).** This group reviews applications from researchers who would like the trials unit to run their trial. They look at things like the proposed trial procedures, the relevance of the research question to patients, the capacity with the unit and decide whether to take the trial on. It's a bit like Dragon's Den for clinical trials! The TRG meets every month for between 1-3 hours, depending on the number of applications.

• **Independent Data Monitoring Committee (IDMC).** This group is also sometimes called a Data Monitoring and Ethics Committee (DMEC) or just Data Monitoring Committee (DMC). It is completely independent of the TMG and looks at the clinical data coming in during a trial to assess the safety of the people taking part, and whether any side effects or adverse reactions to trial treatments/ procedures are acceptable or not. The group can make recommendations to the TSC about any changes that may be needed to the trial protocol or even if a trial should be stopped. The frequency of IDMCs can vary depending on the size and type of trial. Involvement in IDMCs may require some introductory training and refresher meetings with the statistics team.

• **Safety Review Committee (SRC).** This group is similar to the IDMC in that it looks at safety data. SRCs are part of very early-phase trials which are looking at the safety of a brand -new treatment, rather than whether it is better than standard care. SRCs tend to happen approximately once a month, depending on the individual trial. Involvement in SRCs may require some introductory training and refresher meetings with the statistics team.

• **One-off focus group.** Sometimes researchers need some feedback on a trial proposal or specific idea from a focus group. This generally requires a little pre-reading and then attending a meeting where the ideas are discussed.

• **Reviewing documents or taking a survey.** Sometimes we may ask for a few people to look over patient-facing documents to check they are understandable or ask people to take part in a survey about research or public involvement. These opportunities are often circulated via newsletters or mailing lists, and anyone can get involved.

These are just some of the main ways public members may get involved in trials at SCTU, but

before you get involved in any role you should make sure you are given an idea of what the role will involve, the time commitments and have any questions answered.

2.3 Policies and Procedures relevant to your role and the organisation

What is the policy for payments and expenses for your involvement? Will you need to sign a charter or confidentiality agreement? Is there any training or pre-reading you will need to do before starting?

You should be provided with all of this kind of information at the start of your involvement. If you are not, ask your main SCTU contact to provide it as soon as possible.

There are more details on reimbursement and expenses in section 5 of this handbook (pg 12).

3 Support

There is lots of support available to anyone taking part in public involvement at SCTU.

3.1 Administrative support

Can a member of the research team or organisation help you with paperwork (for example, printing meeting papers) and things like travel arrangements to help you carry out your role?

Before meetings, you should be provided with electronic (e-mailed) copies of papers in good time for you to be able to read and comment on them. You may also request hard/paper copies are sent to you in the post.

Specific support requirements, such as wheelchair-accessible rooms and special dietary needs, can be provided to enable your involvement, but please remember to give the research team plenty of notice of any requirements. The research team or organisation should ask you at the start of your involvement about any support you might need. Research teams and organisations often value a diverse group of people being involved, so any reasonable support you might need should be provided, as long as you raise it with the team with enough notice.

3.2 Relevant training and learning opportunities

Are there any training courses that you can attend? Are there any easy-to-follow guides on the research process that will help you in your role?

If you think that you would benefit from any specific training related to the activity you are involved in, ask for it. Training might be available in both as formal training, or through observation and discussion sessions, and / or through simply spending a few hours with a relevant member of the Research Team.
The SCTU does have access to ad-hoc training opportunities or can direct you to on-line training courses.
We also have a list of helpful resources on the PPI pages of our website:

https://www.southampton.ac.uk/ctu/ppi/patient-and-public-involvement-at-sctu.page#helpful_resources

It may help to have pre-meetings with your key contact so you can ask questions or be brought up to date with things in advance of the meeting.

In time, you might like to create a 'CV' of the skills you have, and those you have gained while involved.
Start this as soon as you start your involvement, as it may be useful to remember what you have done and what skills you have gained when applying for other involvement activities.

3.3 Having a mentor or a buddy

Is there anyone else who has been involved in research who you can turn to for help? The SCTU will try to find a buddy or mentor if you would like to have one. This will usually be an 'independent' person like you (often a patient or carer) who has been involved with the organisation or research projects before and who will be able to support and guide you. Ask your key contact if someone might be available to support you.

3.4 Feedback

You should be able to find out how you are doing, whether your comments and feedback useful, and how they are being used. Being kept 'in the loop' is an essential part of being involved in research. The research team or organisation should keep you regularly updated with information, such as:

- What has happened since the last meeting?
- How is the research going?
- How have your comments and suggestions been used?

Sometimes there may be long gaps between information updates: when this is the case, the research team should explain this to you, so that you do not feel 'left out'.

3.5 Emotional support

What happens if you start to feel distressed or upset when you are participating in activities? Researchers should understand that sometimes it might be difficult or upsetting for you to share your experiences and thoughts with them. When that happens, there should be a supportive person available for you to talk to, or to seek support from. Remember to ask for the contact details of that person right at the start, if they are not already provided.

3.6 What if you feel unfairly treated, or something goes wrong?

You should raise any concerns with your key contact in the research team or organisation. However, if you feel uncomfortable about discussing it with them, please contact Peta Durrant, Head of Operations at the SCTU in the first instance (P-A.S.Durrant@soton.ac.uk).

If this does not resolve your issue, then you can contact the SCTU host organisation (University of Southampton). They have a formal complaints procedure. You can access this service by contacting a member of legal services at legalservices@soton.ac.uk.

4 SCTU Jargon Buster

Acronym	Definition
ARSAC	Administration of Radioactive Substances Advisory Committee
CAPA	Corrective and Preventative Actions
CBS	Central Booking System
CI	Chief Investigator
CPAS	Chemotherapy and Pharmacy Advisory Service
CR	Clinical Reviewer
CRE	Clinical Radiation Expert
CRF	Case Report Form
CTA	Clinical Trial Authorisation
CTAAC	Clinical Trials Awards and Advisory Committee
CTCAE	Common Toxicity Criteria for Adverse Event
DM	Data Manager
CTIMP	Clinical Trial of an Investigational Medicinal Product
DB	Database
DLP	Data lock Point
DLT	Dose Limiting Toxicity
DMEC	Data Management and Ethics Committee
DMP	Data Management Plan
DSUR	Development Safety Update Report
ECMC	Experimental Cancer Medicine Centre
GCP	Good Clinical Practice
GTAC	Gene Therapy Advisory Committee
HoDM	Head of Data Management
HoTM	Head of Trial Management
HRA	Health Research Authority
HTA	Health Technology Assessment
IB	Investigator's Brochure
ICD	International Classification of Disease
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
IRAS	Integrated Research Application System
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
mNCA	Model Non-Commercial Agreement
MPE	Medical Physics Expert
nIMP/ Non-IMP	Non Investigational Medicinal Product
PI	Principle Investigator
PIS	Patient/Participant Information Sheet
PPI	Patient and Public Involvement
PVQM	Pharmacovigilance and Quality Manager
QC	Quality Check
QRT	Quality and Regulatory Team
PVCO	Pharmacovigilance and Coding Officer
RA	Risk Assessment
REC	Research Ethics committee
RSI	Reference Safety Information
SAE	Serious Adverse Events
SAR	Serious Adverse Reactions
SCTU	Southampton Clinical Trials Unit
SMF	Site Master File
SmPC/SPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
SQAM	Senior Quality Assurance Manager
SRC	Safety Review Committee
STM	Senior Trials Manager
StMF	Statistical Master File
STS	Senior Trials Statistician
SUSAR	Suspected Unexpected Serious Adverse Reaction
TA	Trial Assistant
TC	Trial Coordinator
TM	Trial Manager
TMF	Trial Master File
TMG	Trial Management Group
TO	Trial Officer
TRG	Trial Review Group
TS	Trials Statistician
TSC	Trial Steering Committee
UADR	Unexpected Adverse Drug Reaction

5 Reimbursement and Expenses Policy

Please refer to the document "SCTU Payment Policy for PPI" for our full policy.

5.1 Why is reimbursement offered?

Reimbursement for public involvement acknowledges the experience, knowledge, views and time expended by public contributors in support of health research. This also includes reimbursement for any expenses incurred through involvement activities (for example, travel, carer costs).

5.2 Who can be offered reimbursement?

The people who can claim reimbursement for public involvement include:

- People who use health and social care services, patients, the public, carers and people from organisations which represent those who use such services.
- People who are asked to provide a patient or public view about aspects of health research.
- People who are not in receipt of a full-time salary from public funds. Those who work full time in the public sector may still be entitled to reimbursement, provided that the involvement activity is not related to their employment, and that the activity is not undertaken during normal working time.

5.3 What is reimbursement offered for?

Reimbursement is usually offered for public involvement activities such as the following:

- Face-to-face meetings with clinicians and/or researchers
- Writing or drafting information relating to health research (for example information for research participants, sections of research applications, Plain English summaries, training and education plans and materials)
- Reviews (for example of research protocols, proposals, applications, Plain English summaries, Patient or Participant Information Sheets)

Generally, we do not offer reimbursement to public contributors for:

- Time spent on training and education (unless this is essential in order for public contributors to undertake a specific task required by their organisation). However, we do meet the cost of some training and education for public contributors, and also cover travel and other expenses in order to attend such opportunities.

5.4 Should I accept reimbursement?

Public contributors will make a decision about whether to accept reimbursement for their involvement. Such payments are treated as part of a person's overall income for tax purposes and National Insurance contributions, and so need to be declared. Additionally, some organisations require proof of identity (e.g. sight of a passport) in order to process payments.

Legislation was changed in 2009, and again in 2013, 2014, 2015 and 2017 to make it easier for public contributors who are in receipt of benefits to receive payment for their involvement activities, and expenses such as travel costs. A more detailed explanation about payment whilst on benefits is available from the Social Care Institute for Excellence here: https://www.scie.org.uk/co-production/supporting/paying-people-who-receive-benefits.

A confidential Benefits Advice Service was launched in 2015 by NIHR to provide personal advice and support about how payment for public involvement might impact on state benefits. This service is offered free of charge to members of the public involved with NIHR organisations (including the SCTU) or NIHR funded research. More information about this service is available on the NIHR website: https://sphr.nihr.ac.uk/news-and-events/nihr-benefits-advice-service-for-public-involvement-in-research/

5.5 What is the process for claiming reimbursement?

Before you agree to take part in public involvement, you should understand what the opportunity/ role is, how long it is likely to take, and what reimbursement will be

offered (including any expenses). This information should be provided by your main contact at SCTU before the activity starts so that you can make an informed decision about whether to accept the involvement opportunity.

Your main contact should clearly explain how claims for payment and expenses are to be made. This should include giving support and guidance for completing any claim forms, and clarifying to whom the form should be returned, plus any additional supporting information (for example, whether receipts need to be sent with the form).

As with other staff within the organisation, there is usually a cut-off date for processing such claims, in order for people to be repaid promptly (usually the following month). Organisations often ask that claims are submitted promptly, and sometimes are not able to guarantee that claims will be reimbursed if submitted many months after the involvement activity takes place.

The University of Southampton, for example, asks that people submitting claims do so within three months of the activity occurring.

5.6 How much will I be reimbursed?

£12.50 -£25	For involvement in a short one-off task or activity which requires little or no preparation • Reviewing a short document • a short telephone/online interview with a researcher. (the exact amount will depend on time taken for the activity)
£25/hr	For involvement in a longer task or activity or recurring meetings, e.g. • A 1-hour teleconference, with related papers to read in advance • Reviewing and commenting on a longer document via email.
£75	For involvement in a task or activity which equates to approximately half a day's activity, for example: • A half-day meeting or teleconference,

	with related papers to read in advance
£150	For involvement in a task or activity which equates to approximately a day's activity

Some involvement opportunities will not be eligible for reimbursement, such as voluntarily taking part in an online survey or reviewing a short document.

It should be made clear before you begin an involvement opportunity whether reimbursement is available.

You can see more about which kinds of activities qualify for reimbursement in the document ***"SCTU Payment Policy for PPI" for our full policy.***

5.7 Expenses

Southampton Clinical Trials Unit will also cover reasonable expenses including:

- Travel (e.g. public transport, use of own car, car parking, taxi)
- Subsistence/meals if activity lasts for large parts of the day and no food is provided.
- Accommodation (if activity lasts for more than one day, or travel for the activity in one day is unfeasible)
- Alternative carer or child-care costs (maximum rate of £25/hr up to a maximum of £100)

If expenses are likely to exceed £100, please discuss this in advance with the Southampton Clinical Trials Unit before the expenses are incurred. As we are often covering expenses through limited budgets, we are generally unable to cover large expense claims.

PLEASE NOTE ALL EXPENSES MUST BE ACCOMPANIED BY THE RELEVANT RECEIPT.

5.8 What if there is a problem?

If there is a problem, for example, a delay in receiving payment please get in touch with your main contact at SCTU. But please be aware that payments can take several weeks and we cannot chase payments for at least four weeks after a claim is submitted.

5.9 Further information about reimbursement for involvement?

The following resources will provide further information about payment and recognition for public involvement:

SCTU Payment Policy for PPI
All Public contributors should be provided with this document by SCTU alongside this handbook. Please get in touch with your main SCTU contact if you don't have it.

Benefits Advice Service is run by the Bedford Citizens Advice Bureau to offer free, confidential and personalised support to those who receive state benefits while involved in NIHR paid activities.
https://sphr.nihr.ac.uk/news-and-events/nihr-benefits-advice-service-for-public-involvement-in-research/

Department for Work and Pensions' guidance is available on their website: www.gov.uk/dwp

HM Revenue and Customs information about the need to complete a tax return is available from: https://www.gov.uk/check-if-you-need-tax-return

The NIHR has a comprehensive set of online resources (many also available in hard copy):
https://www.nihr.ac.uk/documents/payment-guidance-for-members-of-the-public-considering-involvement-in-research/27372

The **Social Care Institute for Excellence** provides information about payment for co-production work for people who receive benefits here:
http://www.scie.org.uk/files/co-production/supporting/aag50/atglance50.pdf