



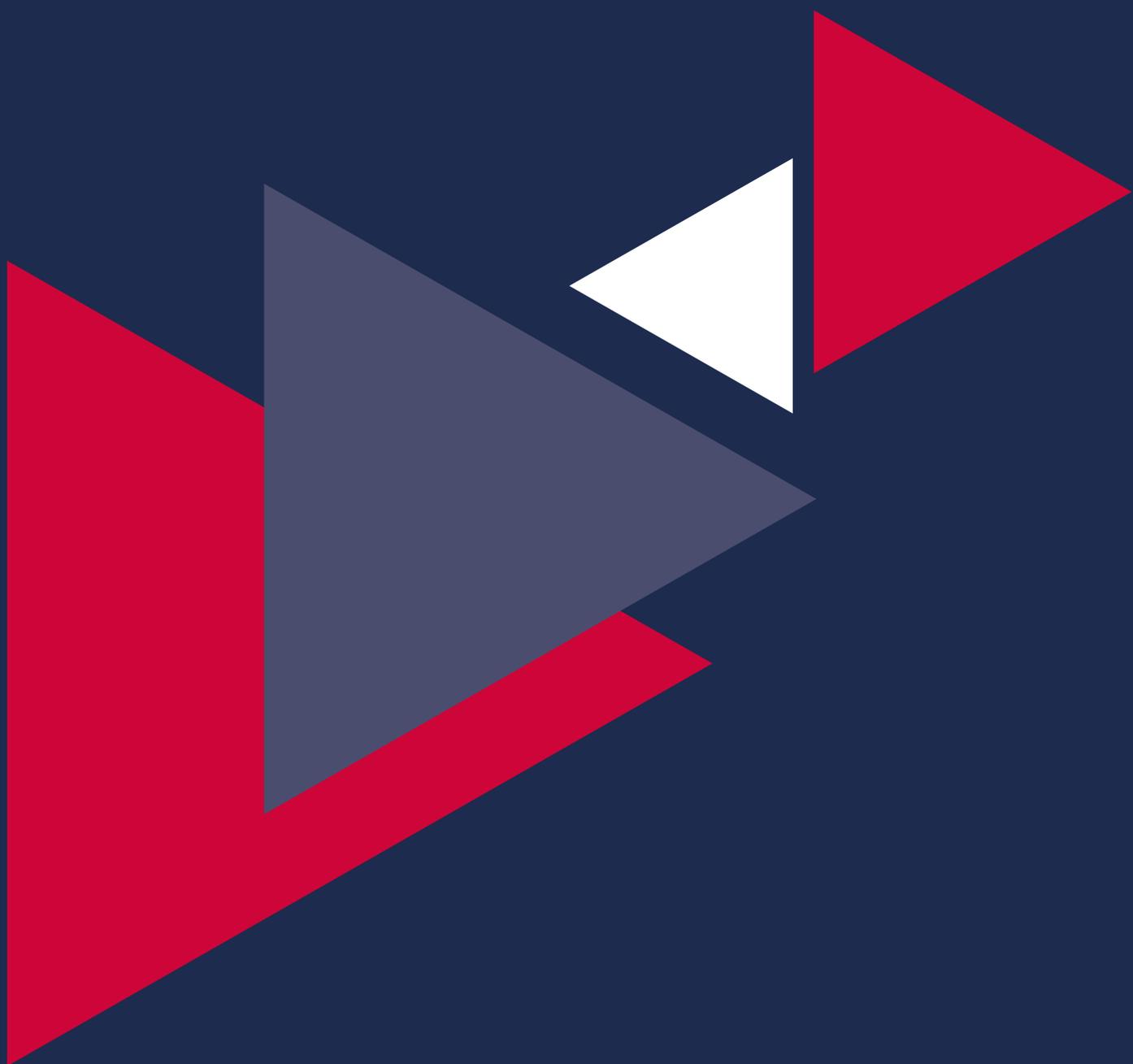
Centre for
Trials Research
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Ymchwil Treialon



Working with the Centre for Trials Research

A Guide for Research Partners





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Welcome to the Centre for Trials Research

We would like to welcome you to Centre for Trials Research (CTR). This guide is aimed at Research Partners (members of the public like yourself) working with the CTR in their role.

We hope you will find it useful and that it can help answer any questions you may have. You can use it as a prompt to guide discussions about your role with your named researcher – this is a member of staff in the CTR who you will be introduced to and who is your main point of contact.

Public Involvement (PI) is a vital part of all study procedures, and health and care research more widely, and you will play a very important role in providing a public perspective. Always feel free to ask for any additional information you may need, or if there is anything you do not understand. You can contact the CTR Public Involvement & Engagement (PI&E) Hub for general enquiries, or your named researcher for specific queries*.



With best wishes, Sarah Peddle & Sue Campbell
(CTR Research Partners & Hub Members)

Contacting CTR Hub

Email: ctr-hub@cardiff.ac.uk

Website: www.cardiff.ac.uk/centre-for-trials-research/public-and-patient-involvement

*You will be introduced to your named researcher who will be your main contact for your study or particular role.

Understanding the CTR and Our Mission

The CTR at Cardiff University is a registered clinical trials unit. We are the largest group of academic clinical trials staff in Wales.

The Centre is home to a range of researchers and professional services staff, including trial managers, computer systems experts, data managers, qualitative researchers, administrators, quality assurance managers and statisticians. Our mission is to improve the health and wellbeing of society through clinical trials and other well-designed studies, for example, research which examines people's experiences of healthcare.

We tackle the big diseases and health concerns of our time, including growing resistance to antibiotics, early cancer diagnosis and how to eliminate health inequalities. We achieve this by building lasting relationships with the public, whose participation is essential for the success of our studies.

We are publicly funded by Welsh Government through Health and Care Research Wales and by Cancer Research UK to carry out research that informs policy in health and social care. We are currently running studies across Wales, the UK and internationally.

The Centre runs randomised controlled trials of new medications, treatments or services. An example of a trial would be comparing a new cancer drug with the best existing treatment, to see if it performs better. However, the Centre also conducts many other types of high-quality research. If you are working with us, you may be involved in a trial or another type of research study.

You can find examples of our research in our latest annual report at:
www.cardiff.ac.uk/centre-for-trials-research/about-us



The Importance of Public Involvement and Engagement

When we talk about Public Involvement (PI), we are referring to research that we carry out ‘with’ members of the public (rather than ‘to’, ‘about’ or ‘for’ them). Members of the public can include patients, service users, survivors, carers and family members. We refer to members of the public in this guide as our Research Partners, as they help us carry out the research.

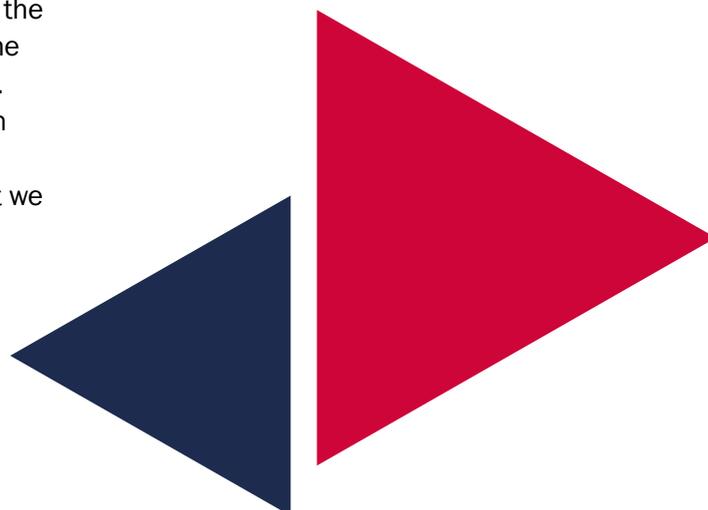
Public Involvement is crucial to us as it means that patients or other people with relevant experience contribute to how our research is designed, carried out and shared with the right people. This makes our research more relevant, efficient and useful. Research Partners fulfil many different roles within the Centre, from helping us decide what to research, to advising on how to invite participants into a study. Examples of these roles can be found in the Research Partner Roles section of this guide.

There are ‘UK Standards for Public Involvement’. The Standards are a framework which can be used to guide good public involvement and encourage reflection and learning. You can read about them here: healthandcareresearchwales.org/public-help-research/uk-standards-public-involvement

You might also hear us talk about Public Engagement (PE), which is when we share information and knowledge about research with the public. This might include, for example, letting the public know about the findings from our studies. Research Partners can advise us on how we can share what we’ve learnt in an engaging way. It is important to us that the public understand what we do and have access to our research.

In becoming a Research Partner, members of the public can gain new skills such as using new computer programmes or learning to present confidently, and can gain a lot of satisfaction from engaging with the role.

Crucially, Research Partners provide a lay perspective on our work. They are not there to be representative of all patients or all members of the public. That is neither feasible nor necessary. What they can provide is a different view point from which to consider a problem and to help find a solution.





Our CTR Hub

As **Public Involvement & Engagement (PI&E)** are integral to our work, we established the CTR Public Involvement & Engagement Hub, which we refer to simply as **‘the Hub’**.

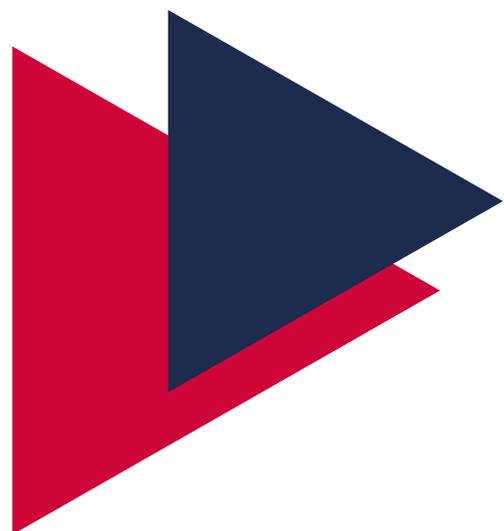
It is a team of researchers (members of staff) and Research Partners (members of the public). The Hub aims to promote and co-ordinate PI&E activities across the Centre.

We meet every two months and any member of staff or Research Partner in the Centre can attend or submit queries. We work closely with the Health and Care Research Wales Public Involvement and Engagement team and voluntary organisations which support PI&E. Our work is in line with the UK Standards.

Examples of our activities include:

- Developing the Centre’s policy and five-year targets for PI&E
- Providing advice to staff & Research Partners
- Gathering resources and sharing best practice
- Advising on relevant training for CTR staff & Research Partners
- Monitoring PI&E activities across the Centre
- Working with study teams to ensure that study findings are shared widely, in an engaging way
- Supporting the inclusion of diverse groups in Public Involvement

The Hub is on a journey rather than at its destination. One of our aims is to develop our community of Research Partners, so that you can come together for support, mentoring and training. Our overall ambition is the same as that of the Centre; to support high quality publicly informed research that will produce real benefits for patients and the public in Wales and beyond.





CTR Public Involvement and Engagement Policy

The Hub helped to develop the Centre's **PI&E policy**. The policy sets out the framework for Research Partner input into our studies. It is based on the **UK Standards**. All CTR staff should be familiar with the Policy, understand how it applies to their work and support its use.

The key principles of the policy are that:

- Public involvement leads to research that is more relevant to the public and is more likely to be used by professionals
- Public involvement leads to more effective public engagement which then may improve awareness of our findings and the impact they have
- All stages of the research process should be open to public involvement, from when ideas for research are first created, through to when results are shared and used to guide health care or social care
- Members of the public should be involved in strategic aspects of the research. By this we mean how we develop our bigger goals for research in the CTR, as well as the practical day-to-day arrangements for our work.

Part of the policy is that the Centre will have a Directorial Lead for PI&E (currently Prof Mike Robling) and an Academic Lead for PI&E (presently Dr Claire Nollett). Both are members of the Hub. It also states membership of the CTR Strategic Board, which meets once a year, will include Research Partners. Their role will be to update the Board on PI&E activities in the Centre and provide a public perspective on all other issues.

Research Partner Roles within CTR

What is the role in general?

You can influence what research takes place and how it is done. You can bring a different perspective and provide a public voice to the research.

What roles are available?

There are many opportunities available, some of the most common are described here. All help to shape and deliver health and social care research in Wales and beyond.

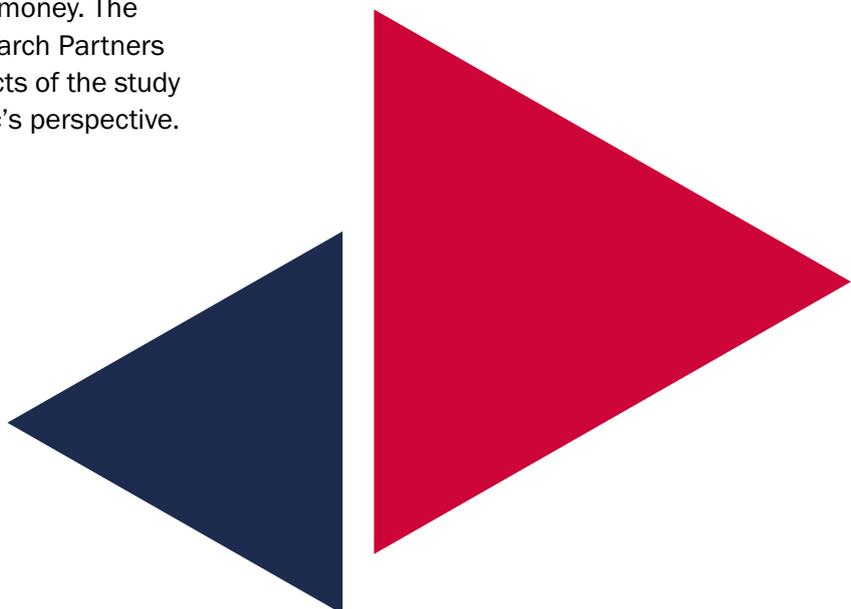
Contribute to applications for grant funding

There are around 10 members of the public in our **Research Ready Review Group (RRRG)**, which was set up to help researchers with their grant applications. Researchers need money to carry out their studies, e.g. from charity or government funds. To apply for the funds, they have to write a grant application. Research Partners may be asked to read over a grant application to check that it can be understood by members of the public. This is important because there will be public members on the panel that decides if the researcher should be given the money. The researcher might also ask the Research Partners for their opinion on important aspects of the study design from a member of the public's perspective.

Henry Yeoman's is a member of our RRRG. He explains: *"As a lay reviewer I notice jargon, whether it is the terminology or acronyms commonplace in any discipline, or clichéd turns of phrase so often irritating in ministerial broadcasts. Simple, clear language is key. There are many online readability guides to help with this. In my experience, clinicians and scientists greatly welcome the input of a lay person who is prepared to share their research vision, but is also keen to communicate it clearly to as many people as possible."*

Carry out research or engagement activities

Sometimes Research Partners help us to do the research or to connect with the public. For example, in one study, members of the public provided their communities with information on cancer symptoms to ensure early diagnosis. In another study, called HealthWise Wales, they attended events for members of the public, to talk to them about the study and to encourage them to join up.



Be part of an advisory group

We run a large number of studies and clinical trials. For example, we have studies looking at people's experiences of breastfeeding, and trials testing new treatments for cancer. Every study has a group of people, known as the **Management Group**, who are responsible for managing the day-to-day running of the research. They meet between once per month and every 6 months, and will have at least one Research Partner who can provide a public perspective. Their role is to help the researchers provide the best experience for the people in the study and ensure that good quality data is collected. They can do this in many ways. For example, by contributing their opinion at meetings, reviewing information given to participants and giving advice on how we should invite people into the study.

Most studies will also have a **Steering Committee**. They ensure the rights and safety of the participants. They meet less frequently, about once every six months or once per year. Again the Research Partner's role is to give a public perspective and they will be encouraged to contribute their opinion at meetings.

Sometimes we work with **existing charities or organisations**, such as Our Place, which is a group of young mums in Pontypridd. We visited their meetings and asked for their opinion on different aspects of one study called Building Blocks 2. There may be an opportunity for you to become involved via an organisation you are connected with.

Help to share our research

Research Partners can help to write the study findings in a way that is accessible to members of the public. They can also suggest where we should share our results so that people who need to see them can do so. Some are also keen to link with key agencies and policy makers to ensure the findings are put into practice.

Each role has different requirements and time commitments and it is likely that we can find a role to suit you. For more detailed information about each role, please contact the Hub or your named researcher.



Here two of our Research Partners share their experiences of working with CTR study teams.

Multiple sclerosis (MS) is a disease that affects the central nervous system and can cause difficulty with mobility amongst other things. Many people with progressive MS need help to remain physically active, but they do not always receive this support. Researchers in the CTR worked alongside people with progressive MS to develop a suitable Lifestyle, Exercise and Activity package (LEAP-MS) for them to use.

Ceri Roden is a nurse by background and joined the LEAP-MS steering group as a Research Partner with husband Simon early in project. Ceri and Simon helped with an array of tasks from reviewing the information given to patients in the study to testing the LEAP support package. They have now agreed to be Research Partners for their onward grant LEAP-MS 2.

Joining the study

Ceri recalls: I was contacted by my GP, who mentioned the LEAP-MS study. He knew my history, that I have had MS for 24 years, although it was originally not diagnosed properly at the start. I trusted him enough to find out more. Although I am a nurse by profession, I had never been involved with a research study before, so this was all new to me. I didn't know what to expect, but I knew that I would not have been recommended by the practice doctor unless he knew he could be worthwhile.

Sharing my experiences

We gave our ideas about what it was like to live with MS. We didn't know at the start what form the final support package would take: a leaflet, a pamphlet, a video. We only knew we needed to develop a tool to encourage people to exercise in their own way.

Because I can't drive anymore and walking can be a challenge, my partner would bring me. Julie, the study lead, was totally understanding and welcomed him to stay and be part of the experience. We were asked about our own journey with MS. I like to go swimming and the team were very interested in how I got involved. When you have MS you can feel very isolated. Because

my initial role was to contribute my personal experience, I enjoyed the freedom to say anything I liked.

Developing a support package

Myself and the other Research Partners wanted to reach out to people who were isolated, alone and don't like going out. We wanted to encourage people to do that. In the end we produced some activity videos that people could pick and choose from, and go at their own rate. When you can actually see someone doing exercise and doing it in a light-hearted way, you can see yourself doing it. This study really helped inspire us, and we were involved at every step in developing the materials.

What stood out for me was the kindness of people throughout the study, we had the opportunities to speak to fantastic physios who interviewed us. I enjoyed the camaraderie of being with like-minded people who really understand the condition and wanted to make things better for other people.

It's wonderful, it's made a big impact on lots of people outside the study already – and me and my husband. Being a Research Partner on a study was the best thing I ever did because it gave me something to focus on.

Ceri Roden
Research Partner, LEAP-MS

LEAP-MS is
funded by the
MS Society



The THESEUS study is about Hidradenitis Suppurativa (HS) which is a long term, painful skin condition that affects approximately 1% of adults. It involves boils in areas such as the armpits and groins and has a big effect on quality of life. THESEUS will provide important information to answer questions that were identified as priority areas for research by patients with the condition and the doctors and nurses who treat them.

Angela has suffered with the skin condition for over 30 years and is passionate about advocacy. She was keen to be involved in shaping the study and tells us about her experience.

My motivation to be involved

Angela recounts: I was contacted about the study through the HS Trust, who said a researcher had been in touch and would I be interested in becoming involved. The nature of HS means it something many people don't talk about, it's a hidden condition and people feel a sense of embarrassment or shame. I felt I had both the time and confidence to contribute now I've had the condition for 30 years plus. So I agreed to get involved to help other people who are struggling with the condition. In the HS community there's often a lack of hope and sometimes people disengage with health care professionals. I feel as though by contributing a patient voice it goes some way to building that trust and hope.

Working with the study team

I hadn't heard about the Centre for Trials Research at Cardiff University before, but I was invited to a conference where I was introduced to the rest of the study team. I met two or three other Research Partners and we broke away to have our first meeting as a THESEUS study team. The nicest thing was that it felt that patients were being brought on board at the beginning of the study and that our opinion genuinely mattered.

My main role is as a patient advocate on the study's management group. During the pandemic we have met virtually on a regular basis to see the study through. Because the Research Partners have busy day jobs, we don't attend every meeting – only those where our input is really required. For example, to advise on how we might invite patients into the study and checking information that the researchers put together is relevant and makes

sense. It is easier to attend virtual meetings as there is no travel time. Between meetings we keep in touch by email and are sometimes asked for input into reports.

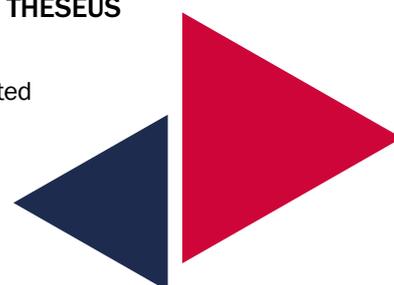
My contribution

In my day job I feel I need to understand everything. When you're a Research Partner, you have to accept you won't understand everything that the researchers are talking about but that's ok! We come from all walks of life, with varied experience, but it is our lived experience of the condition that is helpful. You might not have the same qualifications and experience as the researchers but you are just as valued in terms of what you can contribute.

One of the things we have been able to provide advice on is the language used in the information given to participants. People with HS prefer certain terms for their symptoms, which make them more comfortable to talk about. We guided the researchers on the best terms to use. Just knowing our input will make the study more accessible is rewarding. Hopefully, at the end of this we will find out what is most effective in terms of treating HS. I would encourage those who are thinking about getting involved to do so. It can make you feel empowered knowing you are making a difference to other people who have suffered. You can empathise and connect with them in a way that others cannot. For all the frustrations you've had with your condition, this is a chance to shape the lives of other people in a similar situation.

Angela Gibbons
Research Partner, THESEUS

THESEUS is supported
by the HS Trust



Making a Difference

The contributions of Research Partners vary widely, but you all make a difference to shaping the research undertaken.

For example, you may know what issues matter most to someone with arthritis. You may belong to a community group who would benefit from taking part in mental health research. You could have a creative idea for how to tell the public about our latest findings. Research Partners add a perspective that strengthens the work we do together. Our research teams are encouraged to document how including members of the public has an impact on our research. Examples of how Research Partners have shaped the **Building Blocks 2 Study** and **Proxy Consent Project** are illustrated below.

Building Blocks 2 Study

Building Blocks 2 was a follow up to the Building Blocks research, which looked at the impact of visits from specially trained nurses to support young pregnant women

Members of the public were involved in various ways.
The main involvement came from 3 groups:

1

CASCADE Voices

Group of care-experienced young people

2

'Our Place' Group

Network of young parents with young children

3

ALPHA

Group of young people who advise researchers organised by Cardiff University

Input

Gave a broad range of advice on topics from study design to dissemination of results.

Their advice had a key influence on:

- The letters that were sent out to participants about this study
- Creating the animation to explain what routine data is and how it can be used

Public Involvement in the Proxy Consent Project

The Proxy Consent project explored family members and friends' experiences of being involved in decisions about research made on behalf of an adult who lacks decision making capabilities.

Summary



Developing research questions

Before the project was funded, the PPI group helped shape the research questions to ensure that the right and most important questions were being asked.

1



Project planning

During the planning stage, the group provided invaluable insights into their experiences of caring for and advocating for, people with impaired capacity. This meant that the project was designed to reflect the integration of decisions about research in the complex reality of caring relationships.



Phrasing interview questions

The members of the group helped to ensure that the questions were sensitively worded when interviewing families, and that they could be clearly understood.

4



Reporting back to participants

It is important to provide information back to participants to let them know what the study found. The PPI group helped to create the summary for participants.

6



Refining content and format

The content and format changed considerably over time, with the group reviewing each version along the way until the final version was agreed.

9



Making sense of the findings

Using their own experiences, the group connected the research findings to the wider context of caring for others, and so helped 'make sense' of the data and interpretation.

5



Developing information sheets

The group helped to make sure that the information given to families considering taking part in the project was accessible and they had enough information to make an informed decision.

3



Developing the decision support tool

The final part of the project was to create a decision-support tool for families making decisions about research. The group were vital in understanding what form the tool should take.

7



Accessibility and acceptability

It was important that the tool was accessible for families, and acceptable. The group played a big part in helping to shape the language, use of colour, and layout.

8

Reimbursement for Time and Expenses

Will I receive payment for my involvement?

We greatly value your input and hope you enjoy the experience of working with us. We appreciate your involvement may incur some costs. You will be reimbursed for 'out-of-pocket' reasonable expenses such as mileage or transport costs. You must agree these with your named researcher in advance. Where appropriate and possible, you may also be offered a payment (honorarium) for your time. We generally follow the guidance of Health and Care Research Wales in this regard. They have outlined three levels of involvement. Further information about the categories can be found on the Health and Care Research Wales web site (healthandcarenresearchwales.org/public-help-research/current-opportunities) or by contacting the Hub. In some instances, where you are providing input before a study has been awarded money, reimbursement is provided by a fund held by Health and Care Research Wales that researchers can access.

What is the process of reimbursement?

Your named researcher is the best person to contact about reimbursement. The process will be slightly different depending on the stage of the research. If you are assisting with a study which has already received funding, your researcher will ask you to complete an expenses form for your out-of-pocket expenses, or where possible will book any transport or accommodation for you in advance. If you are also receiving an honorarium, they will complete a CTR Memo Form on your behalf. They may ask you for information such as your bank account details so the money can be paid directly into your account. The form will then be forwarded to our finance department and you will be paid directly.

If you are providing input before the study has received funding, it may be that your payment will be made by Health and Care Research Wales. Your researcher will let the team there know that you have completed some work for us and you will be sent a payment directly. You must be registered with Health and Care Research Wales to receive this payment – your researcher can let you know this process.

As reimbursement methods can vary between studies, please do check the exact process with your named researcher.

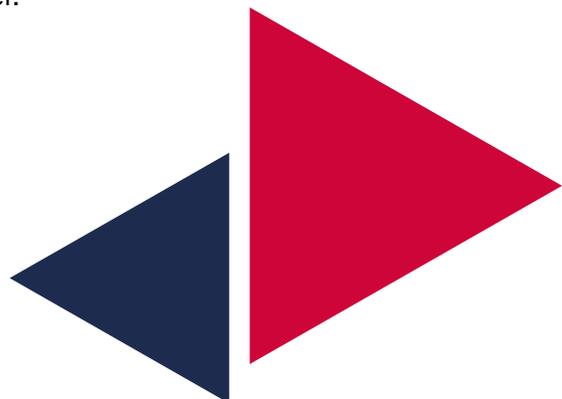
Will the payment affect my benefits?

Any payment may affect the benefits you receive. It is your responsibility to check this. You can find further advice on this on the Health and Care Research Wales web site at healthandcarenresearchwales.org/public-help-research/frequently-asked-questions-faqs. If necessary, we can provide a letter to the Job Centre explaining your role with us.

Will I need to pay tax?

Payments made to you may be liable for tax and National Insurance. You can learn more by referring to the 'Payment guidance for members of the public considering involvement in research' document at www.nihr.ac.uk/documents/payment-guidance-for-members-of-the-public-considering-involvement-in-research/27372.

You can choose not to accept a payment if you prefer.



Training and Support Available

Will I receive an introduction to my role?

When you join us as a Research Partner, your named researcher will invite you to an induction meeting. They will go through the checklist in Appendix 1 at the end of this guide with you. They will explain the study or board you will be working on with us (if relevant) and what is expected from your role. Please feel free to ask them any questions. You can also ask them for guidance around particular tasks or meetings. We have provided a list of acronyms in Appendix 3 to help you understand the terms commonly used in research. For more general advice on involvement in research, you can get in touch with the CTR Hub. We are planning to expand our community of Research Partners and provide networking and training events through the Hub in the near future.

Where else can I receive support & training?

Health and Care Research Wales have an active Public Involvement Community which you are encouraged to join if you live in Wales. You are invited to complete their free training which provides an introduction to Public Involvement (healthandcareresearchwales.org/training/introduction-to-public-involvement-in-research/) and the UK Standards for Public Involvement (healthandcareresearchwales.org/uk-standards-public-involvement-training).

You can sign up to the community and training on their web site or speak to your named researcher for further information (healthandcareresearchwales.org/public/help-research).

Other training opportunities and resources are available at: learningforinvolvement.org.uk

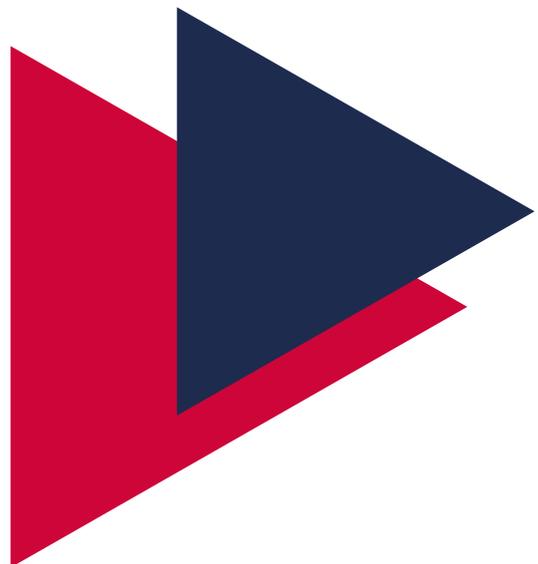




Equality, Diversity and Inclusivity

The **UK Standards** recommend that public involvement opportunities are easy to access. As a Centre, we are committed to providing equal access to opportunities and developing a diverse and inclusive community of Research Partners in line with what the UK standards recommend.

We understand that you may have specific requirements which will need to be considered, these include mobility limitations, sensory impairments or child-care needs. Please let your named researcher know how they can best support you in fulfilling your role.





Mutual Expectations of Researchers and Research Partners

We expect that researchers and Research Partners will treat each other with respect at all times and show common courtesies such as being punctual at meetings.

Being part of a research team means that we will want to share with you information that may be sensitive and usually confidential. As for all team members, it will be important to not share such information with people outside of the research team. We will discuss this as part of the induction or at any time after that if you still have any queries.

We have created a Public Involvement Agreement which you will be asked to sign at your induction meeting (see Appendix 2).



Next Steps

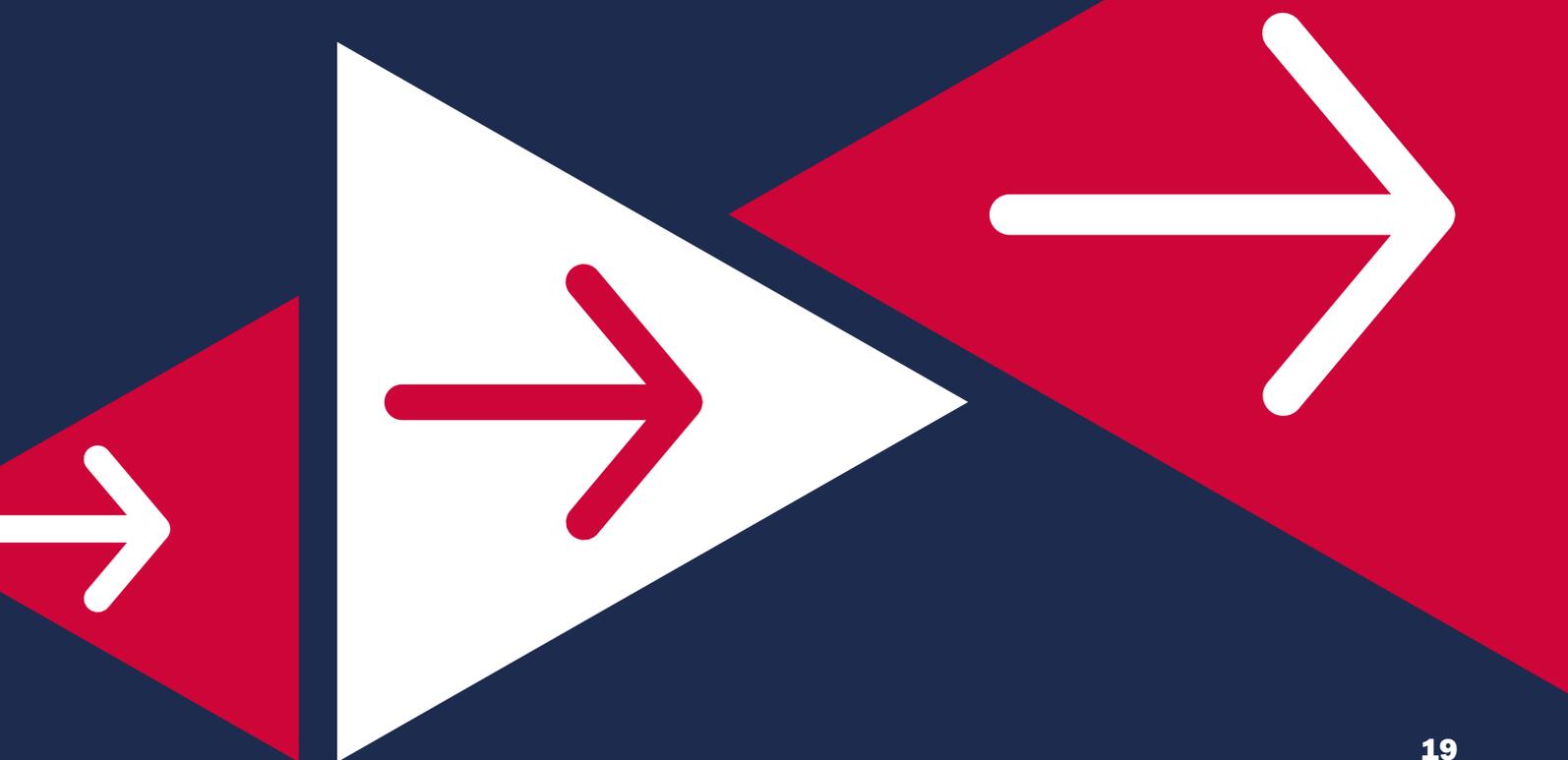
If you have joined us as a Research Partner then welcome, we look forward to working with you.

Please contact your named researcher to arrange an induction meeting. You can use the checklist in Appendix 1 to help you think about what to ask in that meeting.

If you are not yet a Research Partner but are interested in the role, please contact either the CTR Hub (CTR-Hub@cardiff.ac.uk) or Health and Care Research Wales to find out about available opportunities (research-involvement@wales.nhs.uk).

Health and Care Research Wales can also provide more information on training and joining the involvement community. Their web site is healthandcareresearchwales.org/public/help-research. Information about how the public can help with research can be found on the public tab.

We hope you enjoy shaping the future of research in Wales and beyond and thank you for working with us.



APPENDIX 1:

Checklist for Induction Meeting

When you join the CTR for the first time, start on a new project or take on a new role, you should be invited to an induction meeting with a member of the research team.

The checklist below can act as a prompt for items to discuss at that meeting. It is not an exhaustive list and there may be other important things to cover. You can use the list as a guide and make notes about your particular role.

- Introduction to the CTR, Our Mission and website (www.cardiff.ac.uk/centre-for-trials-research)
- The importance of public involvement in research
- Your named researcher (this is your main contact) and their contact details
- Details of administrator if applicable
- Background to the study/project/board (copy of/link to lay summary)
- Names and roles of the study/project team
- Expectations of your role (including time requirements) and how you can make a difference
- Skills and knowledge needed to achieve this and identification of training needs
- Your preferred methods of contact and access to IT
- Procedures for payment for expenses and time
- Public Involvement Agreement (complete Appendix 2)
- How you can contact the Hub
- Opportunity to join Health and Care Research Wales Public Involvement Community
- Next steps – next meeting, first steps for involvement, annual review
- Your questions



APPENDIX 2:

Public Involvement Agreement

Thank you for your interest in becoming a Research Partner with the Centre for Trials Research. Your research team and the Centre's Hub are here to support you, to make your experience positive and rewarding.

Our public involvement agreement tells you what you can expect from us to make your involvement experience a beneficial and worthwhile one, as well as what is expected of you while you are involved. By signing below, you, and we, are confirming our commitment to this agreement. This is entirely voluntary and not a contract of employment. It can be cancelled at any time by us or you.

As Research Partner you can expect the following from the CTR:

- An induction and information about your role
- Training to support you and adjustments so that you can carry out your role
- Payment of reasonable 'out of pocket' expenses
- Review of your role on an annual basis
- Recognition and thanks for the work undertaken
- Respectful and confidential treatment
- Response to your concerns or complaints as quickly as possible
- We will hold your personal data in line with GDPR

In return we ask that Research Partners:

- Attend an induction meeting
- Consider joining the Health and Care Research Wales Public Involvement Community
- Commit to understanding the role being undertaken
- Maintain confidentiality of study documents & discussions (please do not discuss outside CTR). You may be asked to sign an additional document or charter in regards to confidentiality.
- Give as much notice as possible if you are unable to attend a meeting or to continue with your involvement
- Let us know if you have any concerns for your safety/wellbeing or that of others

Research Partner

Signature: _____

Name: _____

Date: _____

CTR Staff

Signature: _____

Name: _____

Date: _____

APPENDIX 3:

Commonly-Used Research Acronyms

In research, we often use acronyms as a short-hand. We recognise this is confusing and may exclude people from participating fully in research. It would be unwieldy to include all the acronyms so we have included some of the most common ones used in the Centre.

A full list can be found at: www.invo.org.uk/resource-centre/jargon-buster and www.ct-toolkit.ac.uk/glossary/

AE	Adverse Event	An unwanted outcome that occurs during or after the use of a medicine or other intervention, but is not necessarily caused by it.
CI	Chief Investigator	The person who takes overall responsibility for the design, doing and reporting of a study.
CRF	Case Report Form	A paper or electronic document which records the data or information collected for the study.
CT	Clinical Trials	Clinical trials are research studies which compare one type of medication with something else, for example the best medication currently available or no treatment.
CTR	Centre for Trials Research	Our place of work – a clinical trials unit based at Cardiff University
CTIMP	Clinical Trial of an Investigational Medicinal Product	A trial of an unlicensed new medicine, or an existing medicine tested outside its licence, or existing medicines tested against each other for their safety or effectiveness.
GCP	Good Clinical Practice	A set of internationally recognised ethical and scientific standards which must be followed when studies involves humans.
HCRW	Health and Care Research Wales	A Welsh government organisation which promotes, funds and supports research into health and social care in Wales.

HRA	Health Research Authority	An organisation which regulates different aspects of health and social care research. Mostly deals with research undertaken in England, but also works closely with the other countries in the UK to provide a UK-wide system.
HTA	Health Technology Assessment	A type of funding researchers can apply for when there is some evidence that an intervention can work, and this needs to be compared to the current standard intervention to see which works best.
IDMC	Independent Data Monitoring Committee	The committee ensures that the interests of the patients in a study are being well-served (i.e. that the potential benefits and harms of participating are fully considered) and that the scientific integrity of the study is maintained.
IMP	Investigational Medicinal Product	An unlicensed new medicine, or an existing medicine tested outside its licence, or existing medicines tested against each other for their safety or effectiveness.
MHRA	Medicines and Healthcare products Regulatory Agency	The agency regulates medicines, medical devices and blood components for transfusion in the UK
NIHR	National Institute for Health Research	The UK's largest funder of health and care research and provides the people, facilities, and technology to enable research.
PI	Principal Investigator	The person responsible for a study at a particular site (studies often recruit participants from more than one site). A site can be a hospital, school, clinic etc
PI	Public Involvement	Often defined as doing research 'with' or 'by' people who use services rather than 'to', 'about' or 'for' them. This would include, involvement in the choice of research topics, assisting in the design, advising on the research project or in carrying out the research. Sometimes referred to as PPI (Public & Patient Involvement).
RDCS	Research Design and Conduct Service	The service is part of the Centre and supports staff working within the National Health Service and social care to develop high quality research funding proposals.
RCT	Randomised Controlled Trial	<p>A controlled trial compares two or more groups of people: an experimental group who typically receive a new treatment and a control group, who receive the usual treatment or a placebo. The control group allows the researchers to see whether the treatment they are testing works better than the usual or standard treatment.</p> <p>In a randomised controlled trial, the decision about which group a person joins is random (that is, based on chance). A computer will decide rather than the researcher or the participant.</p>
REC	Research Ethics Committee	Reviews studies taking place in the NHS or social care, to check they are safe and ethical for people to take part in.

SAE	Serious Adverse Event	Any adverse event (see AE) that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.
SAR	Serious Adverse Reaction	A serious adverse event (see SAE) that occurs during research with a medicine is considered a serious adverse reaction if there is a chance that the event is a harmful and unwanted reaction to the trial medicine.
SUSAR	Suspected Unexpected Serious Adverse Reaction	If a serious adverse reaction is unexpected it is called a SUSAR. In this case 'unexpected' means that the nature and severity of the adverse reaction do not match with the safety information that we have about the trial medicine.
SOP	Standard Operating Procedure	Detailed written instructions designed to achieve consistency in the way a task is carried out.
TMF	Trial Master File	A file containing all essential documents which permits the evaluation of the conduct of a trial and the quality of the data produced. Also called a Study Master File.
TMG	Trial Management Group	The group normally includes those individuals responsible for the day-to-day management of the trial. The role of the group is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is followed and take appropriate action to safeguard participants and the quality of the trial itself. Also called a Study Management Group.
TSC	Trial Steering Committee	The committee's role is to provide the overall supervision of the trial. It should include members who are independent of the researchers, their employing organisations, funders and sponsors. The TSC should monitor trial progress and advise on scientific credibility. Also called a Study Steering Committee.

You might also hear reference to a license. A clinical trials provide the evidence used by government regulators about new or existing medicines. If there is sufficient evidence about the medicine's effectiveness and safety the regulator will grant a licence which describes how a medicine can then be used in practice.

